



**United Nations  
Environment Programme**

**Food and Agriculture Organization  
of the United Nations**

Distr.: General  
2 December 2008

English only

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**Rotterdam Convention on the Prior Informed  
Consent Procedure for Certain Hazardous  
Chemicals and Pesticides in International Trade  
Chemical Review Committee**

**Fifth meeting**

Rome, 23–27 March 2009

Item 4 (b) (ii) of the provisional agenda\*

**Listing of chemicals in Annex III to the Rotterdam Convention:  
review of notifications of final regulatory actions to ban  
or severely restrict a chemical: endosulfan**

## **Endosulfan**

### **Note by the Secretariat**

#### **Addendum**

#### **Supporting documentation provided by Burkina Faso, Cape Verde, Gambia, Mali, Mauritania, Niger and Senegal**

The Secretariat has the honour to provide, in the annex to the present note, documentation received from Burkina Faso, Cape Verde, Gambia, Mali, Mauritania, Niger and Senegal to support their notification of final regulatory action on endosulfan as a pesticide.

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\* UNEP/FAO/RC/CRC.5/1.

## Annex

1. Decision to ban endosulfan by the Permanent Interstate Committee for Drought Control in the Sahel (13/11/2007);
2. Assessment of the risks for surface and ground waters pollution by pesticides used in cotton production in Burkina Faso (Adama TOÉ1, Ray CORRELL, Rai KOOKANA ,Ros MILLER)
3. Examination of pesticides for conversion from provisional sale authorization to registration (Mission Report 2007, Permanent Interstates Committee For Drought Control in the Sahel)
4. The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels - Final Review Report and Regulatory Decision-Review Series 2 June 2005, Australian Pesticides & Veterinary Medicines Authority (APVMA)
5. Re-registration Eligibility Decision for Endosulfan (US Environmental Protection Agency, Prevention Pesticides Toxic Substances (7508C), EPA 738-R-02-013, November 2002)
6. Review of Endosulfan, August 1998, Volume 2, National Registration Authority for Agriculture and Veterinary chemicals (NRA, Australia)

The following information is not annexed to the present document and will be made available at the meeting:

7. At the URL <http://www.inchem.org/documents/ehc/ehc/ehc40.htm> you can download the Environmental Health Criteria 40: Endosulfan (IPCS)
8. At the URL [www.inchem.org/documents/pds/pdsother/class.pdf](http://www.inchem.org/documents/pds/pdsother/class.pdf) you can download the: The WHO Recommended Classification of Pesticides by Hazard

## BAN ON ENDOSULFAN

Having regard to the revised version of the Common Regulation for Pesticide Registration of the CILSS (Permanent Inter-State Committee on Drought Control) Member States, resulting from Resolution N° 08/34/CM/99 adopted in 1999 in N'Djamena, Chad, by the CILSS Council of Ministers;

Concerned with the protection of human and animal health as well as with the environment;

On the proposal of the Sahelian Pesticide Committee submitted at its working session on the 8th May 2007 in Bamako,

The use of Endosulfan in agriculture is prohibited in CILSS Member States for the reasons stated in the enclosed document.

Taking into account agricultural specificities and the time needed to use up all existing stocks, the decision taken by the coordinating minister on the recommendation of the Sahelian Committee to ban this pesticide enters into force on the date of the signature as for its distribution and on 31<sup>st</sup> December 2008 as for its use.

The present decision will be communicated wherever necessary.

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Minister Coordinator of CILSS  
Minister of agriculture and breeding  
Islamic Republic of Mauritania  
Ampliations  
- Executive Secretary of CILSS (Original)  
- Institut du Sahel (CSP)  
- Regional center Agrhvmet

### **Annex to the decision to ban Endosulfan**

Endosulfan is an organochlorine insecticide/acaricide. It is composed of isomers a and b whose main metabolite, Endosulfan sulfate, is more toxic and persistent than Endosulfan itself. Endosulfan is highly, acutely toxic (class Ib, i.e. highly toxic) and the risk of intoxication under Sahelian conditions is unacceptable.

Endosulfan is used to control pests and cotton mites following the high recrudescence of *Elicoverpa armigera* in 1996 and its resistance to pyrethroids. Huge quantities of the product have been used ignoring good agricultural practices and with serious risks for human health and the environment. It is applied twice during the farming season in the Sahel at doses between 300 and 750 gr. of active ingredient per hectare. It is applied with a terrestrial sprayer (rotating disc sprayer or engine-driven portable sprayer). The application is carried out by farmers without adequate protection.

Comparing the product applications in Australia and in the United States of America and the decisions taken in Europe and France, the following can be observed:

- The use of Endosulfan is severely restricted in Australia. The product is only used by authorized people. The use of complete protective clothing is required during sprayer filling and terrestrial application (waterproof protective clothing, long sleeve PVC gloves, waterproof boots and complete respiratory mask (full- face mask) or safety goggles with half-mask respirator.
- In the United States, Endosulfan has been registered for cotton trees. Having been assessed that the risk of worker exposure was high, a whole range of measures to reduce the risk has been adopted. These included a suit over a long-sleeve shirt and trousers, chemical resistant shoes and boots, waterproof gloves, waterproof overall for sprayer filling and a respiratory mask against organic vapor.

Endosulfan is not authorized in France in chemical formulations approved for marketing. The opinion published on the Official Gazette of 22nd February 2006 withdrew marketing authorizations for plant protection products containing Endosulfan for all agricultural and non-agricultural uses, with the following time period during which existing stock had to be used up:

- until 31st December 2006 for its distribution,
- until 30th May 2007 for its use.

Endosulfan is prohibited in the European Union following the review concerning the entry in Annex I (positive list) of Directive 9L/414/EEC pursuant to Community ruling 2005/864/EC of 2<sup>nd</sup> December 2005.

The European Union refused to enter Endosulfan in Annex I because it did not meet minimal safety requirements, particularly with regards to its impact on the environment and its toxicological profile.

Although application doses are similar to those used in the Sahel, required protection clothing is neither available nor is it adequate for local conditions (heat). The training level of farmers in the Sahel is far below that of American and Australian farmers. Furthermore, it should not be forgotten that many dwellings in the Sahel are surrounded by cotton fields.

In the Sub-Saharan region, cases of intoxication have been reported in Benin and in Senegal. Endosulfan residues have been found in peanut oil in Senegal. Endosulfan is highly toxic for fish and some aquatic invertebrates. The adverse impact on aquatic ecosystems due to the contamination of surface water in cotton-tree areas in the Sahel is considered to be unacceptable.

A Risk-assessment study of pesticides used on cotton-trees has been carried out in Burkina Faso in 2003 to evaluate their impact on surface waters. According to the Pesticide Impact Rating Index, Endosulfan was the only one among all pesticides used for foliar application having been reported as having a high risk of contaminating surface waters.

Similar studies have been carried out in the United States of America where buffer zones are required. The use of Endosulfan is prohibited in areas where surface waters are abundant and potentially vulnerable.

In cotton-trees areas in the Sahel, surface waters are environmentally important. The buffer zones required in the United States are not respected in the Sahel.

The use of Endosulfan in the CILSS Member States is no longer justified since other valid alternatives to effectively control *Helicoverpa armigera* exist and are authorized by the Sahelian Pesticide Committee.

**Assessment of the risks for surface and ground waters pollution by  
pesticides used in cotton production in Burkina Faso:**

**Evaluation des risques de pollution des eaux de surface et des eaux  
souterraines par les pesticides utilisés en culture cotonnière au  
Burkina Faso**

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## Summary

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. But the cotton production uses a huge amount of pesticides. Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers. The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

In spite of this potential threat on water resources related to the pesticides used in such conditions, few studies have been undertaken to assess it. This work describes the first assessment of the risks both on surface and ground water related to the pesticides used in cotton production in Burkina Faso. The primary tool used is a software package “Pesticide Impact Ranking Index”(PIRI) which has been developed by CSIRO. PIRI is used to quantify the pollution and toxicological impact by pesticides on the environment by ,:

- Ranking pesticides in terms of their relative pollution to ground water and/or surface water;
- Comparing different land uses in a catchment or at a regional scale in terms of their relative impact on water quality.

The application of PIRI to pesticides used in Burkina Faso on cotton production shows the following results:

- The pesticides used for weed control and for seed protection are ranked of low risk impact. They don't represent a prominent threat either for surface water or for ground water for the conditions of their use in Burkina Faso;
- The pesticides used as insecticides in foliar spraying. For the impact of all the insecticides on the surface water, only the use of endosulfan is the greatest potential threat to the surface water. The other products don't represent a big threat except in the situation of soils of low organic matter content and of crops near surface water. For the impact of all the insecticides on the ground water, all the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact in situations of soils of very low organic matter content. The overall risk remains non-significant for ground water.

Based on these case studies, the authors propose an Environmental System Management that has the potential to reduce or minimize these risks and to protect the important asset of natural water resources in Burkina Faso.

## Résumé

Le coton est le plus important produit d'exportation du Burkina Faso et la principale source de croissance économique. Mais la production cotonnière utilise une grande quantité de pesticides. Plusieurs études et rapports ont montré qu'il n'y a pas un respect des Bonnes Pratiques Agricoles (BPA) par les agriculteurs. Les sols sont fragiles contenant une faible matière organique et sont sujets à l'érosion. Cela se traduit par un potentiel de contamination des eaux de surface à la fois à travers le ruissellement et l'érosion. De plus, la situation est compliquée par les fortes intensités de pluies durant la saison humide.

Malgré cette menace potentielle sur les ressources en eau liée à l'utilisation des pesticides dans de telles conditions, peu d'études ont été entreprises pour l'évaluer. Ce travail décrit la première évaluation des risques à la fois pour les eaux de surface et les eaux souterraines liés à l'utilisation des pesticides en production cotonnière au Burkina Faso.

L'outil primaire utilisé est un logiciel appelé "Pesticide Impact Ranking Index"(PIRI) ou "Index de classement des pesticides selon leur impact" lequel outil a été développé par le CSIRO. PIRI a été employé pour mesurer la pollution et l'impact toxicologique sur l'environnement par des pesticides :

- En classant les pesticides en termes de leur potentiel de pollution relative à l' eau souterraine et/ou à l'eau de surface ; et
- En comparant différentes utilisations de la terre dans une captation ou à une échelle régionale en termes de leur impact relatif sur la qualité de l'eau.

L'application de PIRI aux pesticides utilisés au Burkina Faso le coton montre les tendances globales suivantes :

- Les pesticides utilisés pour le contrôle des mauvaises herbes, et pour la protection des semences sont classés en impact faible. Ils ne représentent une menace prééminente ni pour les eaux de surface ni les eaux souterraines dans leurs conditions d'utilisation au Burkina.



- Les pesticides utilisés comme insecticides en application foliaire. Pour l'impact de tous les insecticides sur les eaux de surface, l'utilisation de l'endosulfan constitue la plus grande menace pour les eaux de surface. Les autres produits ne représentent pas une grande menace excepté les situations de sols à faible taux de matière organique avec des cultures proches des cours d'eau. Pour l'impact de tous les insecticides sur les eaux souterraines, tous les produits sont classés en très faible risque d'impact excepté benfuracarb qui est classé en risque d'impact excessivement élevé seulement pour les situations de sols à très faible taux de matière organique . Le risque global reste non significatif pour les eaux souterraines.

En se basant sur ces études de cas, les auteurs proposent un System de Gestion Environnemental qui a le potentiel de réduire ou de minimiser ces risques et de protéger les valeureuses ressources en eaux du Burkina Faso..

## Introduction

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. In 2004-2005, the national production was 632 355 tones of cotton grain on 566 278 ha by more than 325 000 farmers [1] .

Cotton has on average contributed 66.5% of Burkina Faso's exports over the last five years. (Source: ONAC Stat. Customs – INSD (2002) quoted by TOE and KINANE[2] .

Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers [3] ; [4] ;[5] .The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

On the whole, pesticides represent real dangers at three (3) levels:

1. Toxicity of the pesticides for the users in agricultural sector and the professionals of plant health industry [6]; [7] ;
2. Toxicity for the consumer related to the presence of toxic residues[8] ;
3. Pollution and Toxicology of the Environment [9] .

To quantify the pollution and toxicology to the environment by pesticides, a software package “Pesticide Impact Ranking Index” (PIRI) has been developed by CSIRO [10] .This package:

- Ranks pesticides in term of their relative pollution to ground and/or surface water; and
- Compares different landuses in a catchment or at a regional scale in teirms of their relative impact on water quality .

The present study is an application of PIRI to pesticides used on cotton in Burkina Faso. The main purpose of the study is:

- To evaluate the potential risks of contamination of both surface water and ground water;
- To evaluate the indirect risks to humans and animals using the natural resource in water; and
- To work out a ranking index of the pesticides used in the production of cotton.

## **Materials and methods**

The following resources were used in this study:

- ❑ The software package PIRI [10] (Appendix 1)
- ❑ Data on cotton cultivation (including data on pesticides used and their characteristics (**Table I**))
- ❑ Land Use information

We had distinguished 3 groups of pesticides:

Group 1: herbicides

Group 2: fungicides and insecticides for seed protection

Group 3: insecticides in foliar spraying

The land use information for the pesticides of group 1 and 2 (herbicides and seed protection pesticides) differs from that of group 3 in that the ground is bare with no buffer zone and they are applied once a year.

For the pesticides of group 3 (insecticides in foliar spraying) applied many times a year, for the land use information we have had defined 5 scenarios taking into account 4 factors:

- The distance between the field and the water body,
- The width of the buffer zone,
- The number of days between the application and the rainfall;

- The percentage of soil organic matter.

Scenario 1 (**Table II**) is most like the current situation for the pesticides of group 3 (foliar sprayed). Even though there is no special buffer zone managed by the farmers, on the whole the fields of cotton are separated from the sources of water by bush or by other crops not treated with pesticides which can to some extent be considered as a buffer zone. Scenarios 2, 3, 4 and 5 may be considered as rare situations (**Table III**).

**Table I Characteristics of insecticides used on cotton**

Pesticide	Classification	Spray type	Dosage (kg or litres product/ha)	Fraction active ingredient	Frequency of application (times/period of interest)	Percentage of farm	Toxicity (LC50, Rainbow Trout)	Sorption	Persistence in environment (days)
Endosulfan	insecticide	Foliar sprayed 240+-20 microns	2	0.35	1	35	0.002	12400	50
Esfenvalerate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.015	1	35	0.00007	5300	35
lambda-cyhalothrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.012	1	35	0.00024	180000	30
Cypermethrin	insecticide	Foliar sprayed 240+-20 microns +	0.5	0.03	1	35	0.00069	100000	30
Chlorpyrifos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.2	1	35	0.003	6070	30
Cyfluthrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.018	1	35	0.006	100000	185
Deltamethrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.01	1	35	0.0009	100000	25
Benfuracarb	insecticide	Foliar sprayed 240+-20 microns	0.5	0.1	1	35	0.037	316	30
alpha-cypermethrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.015	1	35	0.0028	100000	30
Profenofos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.2	1	35	0.08	2000	8
Dimethoate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.4	1	35	6.2	20	7
Omethoate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.3	1	35	9.1	50	7
Methamidophos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.3	1	35	25	5	6
Pyriproxyfen	insecticide	Foliar sprayed 240+-20 microns	0.5	0.01	1	35	0.325	20142.9	8

**Table II Land Use information for Cotton**

**PIRI Pesticide Ranking Index: cotton\_pattern1**

**PIRI Land Use information: cotton\_pattern1**

<b>Land use</b>	cotton_pattern1	▼
Soil type of land use	Sand	▼
Start month for period of interest (inclusive)	May	▼
End month for period of interest (inclusive)	October	▼
Toxicity, target species	LC50, Rainbow Trout	▼
Field cover	Covered Ground	▼
Usual moisture condition of soil during period of interest	Wet	▼
Soil organic matter (%)	1	
Total rainfall during period of interest (mm)	1000	
Total irrigation during period of interest (mm)	0	
Recharge rate during period of interest (mm)	<input type="radio"/> estimate <input checked="" type="radio"/> actual	150
Average minimum air temperature during period of interest (degrees C)	25	
Average maximum air temperature during period of interest (degrees C)	35	
Depth to water table (metres)	10	
Diameter of nearest water body (metres)	100	
Distance from edge of crop to water body (metres)	1000	
Slope of land to water body (degrees)	<input checked="" type="radio"/> degrees <input type="radio"/> %	1.14576283803
Width of buffer zone (metres)	100	
Estimated average soil loss (tonnes/ha) during period of interest	10	
Minimum number of days from application of pesticide to first rainfall/irrigation	3	

**Table III Scenarios considered for the study of pesticides used in foliar application for cotton**

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Distance between field /water body (m)	1000	100	100	10	10
Width of buffer zone (m)	100	10	10	0	0
Delay between spray and rainfall in days	3	3	0	0	0
soil organic matter(%)	1	1	1	1	0.1

## Results and discussion

On the whole, the pesticides used for seed protection (endosulfan, thiram, imidacloprid, metalaxyl, carbendazin and for weed control as herbicides (pendimethalin, paraquat, terbutryn, diuron, prometryn, fluometuron, clomazone) don't represent a major threat either for surface water or for ground water. This is likely related to their conditions of use in Burkina Faso where they are applied once a year [11]. In a study based on a probabilistic risk assessment method similar low risk of impact for surface water was found for atrazine [12].

On the other hand, there is some concern about a few of the pesticides used as insecticides in foliar spraying. According to the scenarios, the results are as follows:

### - **Surface water toxicity impact, insecticides.**

On the whole, on taking into account all 5 scenarios (Table IV), we can distinguish according to the results of each individual rating, 5 situations in progressing from the lower risk to the higher risk group:

- A group of 8 pesticides namely, cyfluthrin, deltamethrin, Alpha-cypermethrin, profenofos, dimethoate, omethoate, methamidophos, pyriproxyfen present a very low risk impact irrespective of the scenario considered;
- A second group of 2 pesticides Lambda-cyhalothrin and cypermethrin present a low risk impact whatever the scenario considered;
- Benfuracarb is rated with a low or very low risk impact for the first four scenarios but is rated in the medium risk category for the last scenario.
- A second group of 2 pesticides chlorpyrifos and esfenvalerate move from a very low risk impact with the first scenario to a very high and Exc. High risk (respectively) with the last scenario;
- Endosulfan presents a potential threat whatever the scenario considered. It is always ranked from a high risk impact to an Exceedingly High risk impact (Fig.1). The reasons of the threat to the environment (for surface water) of this organochlorine insecticide that is being used on cotton is due to its dose, and its persistence time. The

amount of endosulfan used on cotton to control insects is normally 700g /ha of a.i., its toxicity (LC50) to rainbow trout is 0.002 mg L<sup>-1</sup> and it has a persistence in the environment of 50 days. This threat on surface water by endosulfan revealed by PIRI has also been confirmed by the presence of endosulfan residues carried out by GPC-ECD in water samples in the cotton region where this chemical is used [13].

**Table IV Insecticides rating for surface water on different scenarios of agricultural practice**

Pesticides	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
endosulfan	High	High	High	Very high	Ex. high
esfenvalerate	Very low	Low	medium	High	Ex. high
chlorpyrifos	Very low	Very low	Very low	medium	Very high
Lambda-cyhalothrin	Low	Low	Low	Low	Low
cypermethrin	Low	Low	Low	Low	Low
benfuracarb	Very low	Very low	Very low	Low	medium
cyfluthrin	Very low	Very low	Very low	Very low	Very low
deltamethrin	Very low	Very low	Very low	Very low	Very low
Alpha-cypermethrin	Very low	Very low	Very low	Very low	Very low
profenofos	Very low	Very low	Very low	Very low	Very low
dimethoate	Very low	Very low	Very low	Very low	Very low
omethoate	Very low	Very low	Very low	Very low	Very low
methamidophos	Very low	Very low	Very low	Very low	Very low
pyriproxyfen	Very low	Very low	Very low	Very low	Very low

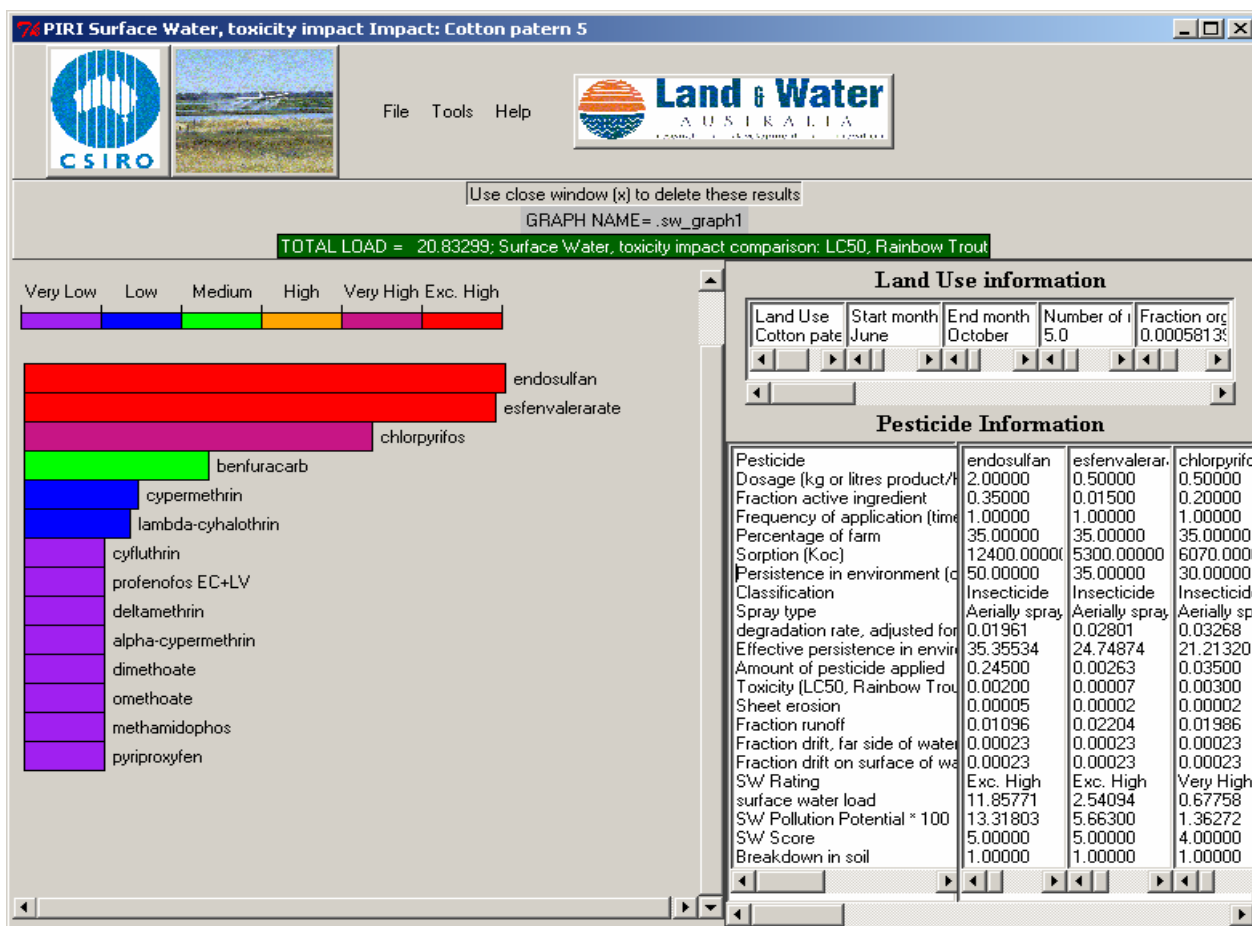


Figure 1 Insecticides used on cotton rated for surface water impact (scenario 5)

#### - Ground water toxicity impact insecticides (Table V)

For the impact of all the insecticides on the ground water, whatever the scenario considered, there is no significant change. All the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact scenario 5 only (Fig.2). The overall risk remains non-significant for ground water.

The threat on the environment related to the use of pesticides to some extent depends on some factors underlined in our studies. They are:

- the low organic matter content in soil the soil;
- the short distance between the field and the water body;
- the absence of any managed buffer zones;
- the short space of time between the any rainfall and the application of pesticides.



The characteristic of the pesticides is obviously a determining factor.

The low impact of the pesticides as given by PIRI may be distorted depending on the value accorded to the water, because of the mosaic of the crops and of the array of pesticides being used. Pesticides with similar active ingredients are being used, and a more realistic measure of their impact would be the sum of their impacts.

In summary, the key factor susceptible to reducing or increasing the threat of the products to both the surface water and ground water seem to be the soil organic carbon content. For surface water only the buffer zone could reduce the threat. An environmental system management with a buffer zone on a soil with a good level of organic matter combined with the choice of pesticides that present less threat, is desirable.

Tools like PIRI will play a key role in the future in the assessment of pesticides risks on waters. CHEN *et al.*; [14] on analyzing a surface water mobility index ( SWMI) based mainly on degradation half life and  $K_{oc}$  (also taken into account in PIRI) to the concentrations of pesticides in agricultural drainage watersheds found that there were statistically correlated.

**Table V Insecticides ranking for ground water on considering different Scenarios**

Pesticides	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
endosulfan	Very low	Very low	Very low	Very low	Very low
esfenvalerate	Very low	Very low	Very low	Very low	Very low
chlorpyrifos	Very low	Very low	Very low	Very low	Very low
Lambda-cyhalothrin	Very low	Very low	Very low	Very low	Very low
cypermethrin	Very low	Very low	Very low	Very low	Very low
benfuracarb	Very low	Very low	Very low	Very low	Exceedingly. high
cyfluthrin	Very low	Very low	Very low	Very low	Very low
deltamethrin	Very low	Very low	Very low	Very low	Very low
Alpha-cypermethrin	Very low	Very low	Very low	Very low	Very low
profenofos	Very low	Very low	Very low	Very low	Very low
dimethoate	Very low	Very low	Very low	Very low	Very low
omethoate	Very low	Very low	Very low	Very low	Very low
methamidophos	Very low	Very low	Very low	Very low	Very low
pyriproxyfen	Very low	Very low	Very low	Very low	Very low

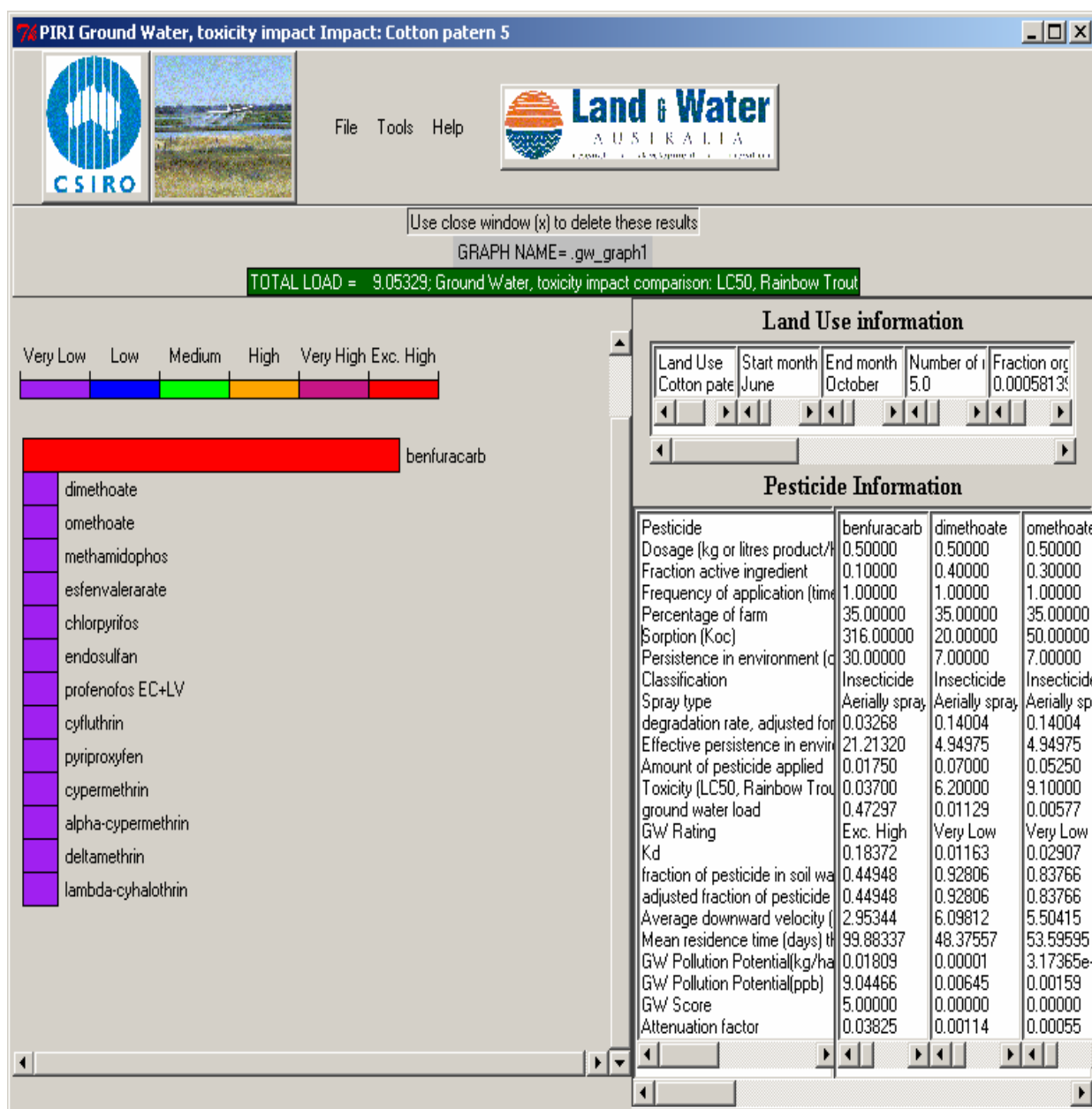


Figure 2 Insecticides ranked for ground water (scenario 5 )

## Conclusion

The overall trends related to the risks of using pesticides in Burkina Faso shows that for cotton production:

- the use of endosulfan as a foliar application for insecticides could lead to the greatest potential threat to the surface water .

- The other pesticides don't represent a large threat except with soils of low organic matter content and fields near the surface water;

It is noteworthy that these results are obtained in considering specific situations of land use. Other results with bad conditions of land use and bad Agricultural Practices could lead to severe impact of pesticides on the water resources.

In the context of Burkina Faso, water resources are very important. In the context of Burkina Faso, the surface water represents an important asset because it is drunk by humans and also by both domestic and wild animals. In addition fish from this water are consumed and sometimes the water is used for irrigation. Consequently, the protection of this natural resource is very important. In considering the major factors responsible for the threat such as: the soil organic matter content, the distance between the field and the water body, the width of the buffer zone, the number of days between the application and the rainfall, the three first factors might be monitored because they could be controlled. Another controlling factor is that the choice of pesticides can be modified by the growers.

In short, the threat of pesticides to natural water resources is evident in some extent. It must be alleviated and monitored. Up to now there is no Environmental Management System for cotton culture in Burkina Faso. This lack must be corrected. Our work sets up the basis of such upcoming programs based on relevant selections of pesticides, the setting up of appropriate buffer zones and the distance between the field and the water body.

This assessment of the risks related to the pesticides used in Burkina Faso is one of the firsts in the history of Burkina Faso and probably in many Sahelian countries. We hope that it will be regarded as a good step in the right direction. In anticipation, we thank all those Government, Companies, International Institutions, and Non Governmental Organizations for their awareness of the importance of conservation of natural water resources, who will help us to continue to examine and improve this work.

***PIRI seems to be very adapted for the developing countries like Burkina Faso with poor resources and where the setting up and maintenance of laboratories are very difficult. PIRI could be a handy tool for help in decision taking .***

## Acknowledgements

The authors gratefully acknowledge:

- Government of Burkina Faso and his companies responsible for the production and trade of cotton (SOFITEX) and his company of formulation of pesticides (SAPHYTO).
- CSIRO for the supply of facilities for this project.
- IAEA who funded this project (Nº: RAF/0/018) and Fellowship BKF/01001

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## **APPENDIX A The software package PIRI**

(Developed by Dr. R. Kookana, Dr. R. Correll and Mrs R. Miller, 2003)

- provides ratings for each pesticide's pollution potential to surface **and** ground water;
- assesses relative impacts of different land uses in a catchment;
- serves as an education tool and enhances awareness of the potential risk of pesticides;
- is user-friendly, being simple and easy to use;
- is scientifically sound and semi-quantitative;
- considers pesticide toxicity to fish, flea, algae and humans
- integrates pesticide properties (toxicity, persistence in the environment, sorption to soil), their use scenario and specific soil and site conditions (permeability, depth of water table and water input).
- utilises built-in data bases and requires minimum input parameters. Where possible, sensible default values are provided to assist the users.
- contains a data base which includes information on a large number of pesticides – their fate data (sorption, degradation), toxicity data (LC50 for fish, daphnia, algae), drinking water Health Advisory Levels, and recommended rates for pesticide use for selected land uses.
- has been compared with the results of pesticide residue monitoring in two intensive agricultural areas and found to be correct in more than 80% of cases.



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INSTITUT DU SAHEL

# Consultation Mission Report

## Examination of pesticides for conversion from provisional sale authorization to registration

**Sahelian Pesticide Committee (CSP)**

**Dr Adama M. TOÉ (Toxicologist - Ecotoxicologist)**  
**CSP Expert**

## **Acknowledgements**

This consultation mission was made possible by the coordinated efforts of officials from the Institut du Sahel (INSAH) and the Sahelian Pesticide Committee (CSP). We received scientific and technical support from the CSP Permanent Secretary throughout our stay in Bamako. We also received contributions from expert colleagues and members of the CSP in examining and assessing the pesticide files. We wish to extend our thanks to everyone in INSAH and CSP for their contributions and assistance during our mission.

We are most appreciative of the trust placed in us by CSP senior officials and hope that we have lived up to their expectations.



## 1. Introduction

At the extraordinary session of the CSP that was held from 19 to 30 December 2005 in Bamako, it was recommended that two CSP experts, namely Mr Macoumba M'BODJ and Mr Adama M. TOÉ, support the Institut du Sahel (INSAH) in enhancing the CSP work procedures for the "Study of Pesticides for Conversion from Provisional Sale Authorization (PSA) to Registration". This support was to be provided in the form of a consultation mission with the following specific objectives:

- To evaluate requirements and criteria for the conversion of 66 products from PSA to registration;
- To propose to the CSP products qualified for conversion without additional information;
- To propose products for which additional information was required and to determine the nature of such information;
- To propose a methodology for the future.

The mission was carried out from 17 to 23 July 2007 in Bamako by Mr Adama Toé in the absence of Mr Macoumba M'Bodj. This is a synthesis report on the work undertaken.

## 2. Methods of work

Identification of products having received two PSAs which expired before 2006;

Classification of products into 3 groups:

- Pesticides used in desert locust control (DLC);
- Products under toxicosurveillance;
- Other products.

Identification of the active substances concerned;

Identification of data needed for the evaluation of active substances (7. Annex):

- Name of active substances
- Evaluation of risks to humans
  - LD<sub>50</sub> (mg/kg) (see Annex 7.2 for definition)
  - ADI (mg/kg/d)
  - ARfD (mg/kg/d)
  - AOEL (mg/kg/d)
- Evaluation of risks to non-target organisms
  - PNEC (µg/L)
- Evaluation of (physical) risks to the environment
  - K<sub>OC</sub>
  - DT<sub>50</sub>

*NB : see Annex 7.2 for meaning and definition of acronyms and abbreviations*

- Classification
  - Consultation of databases on AGRITOX, EXTOXNET, EPA, PIP and other sites.
  - Analysis of toxicological and ecotoxicological profiles of active substances concerned;

- Use of decision grids;
- Information on registration status of individual active substances in other regions;
- Personal experience.

### 3. Work constraints and limits:

- Absence of Sahelian data;
- Contrasting and dispersed data;
- Frequency of binary, even tertiary, products for which there is no environmental data;
- Reliability of databases (possible errors, out-of-date);
- Absence of agreed decision grid;
- Very limited time available.

## 4. Results

### 4.1. Results of evaluation of pesticides used in desert locust control

#### 4.1.1. Identification of main pesticides used and evaluation of their potential risks to humans and the environment

The pesticides used are mainly 18 formulations (**Table 1**) derived from 11 active substances (**Table 2**): 3 synthetic pyrethrinoids, 4 organophosphors and 1 phenylpyrazole (fipronil), 1 carbamate, 1 benzoylurea, 1 mycopesticide.

#### ➤ Evaluation of potential hazards to humans

Examination of the toxicological profiles (DL<sub>50</sub>) indicates that only the formulations based on chlorpyrifos-methyl and those based on phenitrothion at under 200 g/l belong to the non-hazardous U class under normal conditions of use. The other products are in classes III (slightly hazardous) and II (highly hazardous).

Fipronil carries serious health risks from prolonged exposure through ingestion.

#### ➤ Evaluation of potential hazards to the environment (except cyanophos)

##### Risk for aquatic organisms (fish and arthropods):

Chlorpyrifos-ethyl and fipronil are high-risk for aquatic arthropods. Fipronil can cause long-term harm to the aquatic environment. The other products used are low-risk for fish in general.

##### Risk for terrestrial vertebrates:

No product seems to present a major hazard.

##### Risk for non-target terrestrial arthropods (wasps, natural predators, earth insects):

Fipronil, phenitrothion and chlorpyrifos-ethyl are high-risk.

##### Risk of persistence in the soil (by DT<sub>50</sub> classification):

None of the products belongs to the “very slightly degradable” class. They do not therefore include any persistent products.

*Risk of mobility and contamination of surface waters through runoff ( $K_{OC}$  index)*

Mobility of the products used is very low, reducing the risk of contamination of surface waters from runoff. On the other hand, use of the carbosulfan-based product can incur high risk of pollution of groundwaters. The main product of degradation of carbosulfan is carbofuran. It is worth noting that in its current decision on eligibility for registration, the EPA prescribes the immediate cancellation of all uses of carbofuran, except for 6 minor crops that account for 2% of sales.

***4.1.2. Recommendation for the registration of pesticides used in desert locust control***

Considering that 6 pesticides are already registered by the CSP for desert locust control, including 5 based on chlorpyrifos-methyl (class II) and 1 based on diflubenzuron (class II);

Taking into account the wide availability in the Sahel countries of data on the effects of desert locust control on health and the environment:

Considering the findings of study of the toxicological and ecotoxicological profiles;

Considering the registration status of these products in other regions (European Union, USA);

With the reservation that the outcome of the 2004 assessment of the impact of desert locust control in the countries of the Sahel does not reveal serious impacts of these products on health and the environment;

We recommend the conversion to registration of 14 pesticides (**Table 1**) with the following restrictions:

- That farmer groups only use products in the U class;
- That specialized operators only use products in classes III and U;
- That pilots only use those in classes III , II and U.

In addition, in order to reduce risk, preference should be given to the least concentrated formulations. All these products should be used in accordance with FAO guidelines on desert locust control, in particular the observance of buffer strips during ground and aerial application.

Because of its inadequate database, the product based on cyanophos requires supplementary information on its use in other regions. Before it can be used in the Sahel, the manufacturing company should provide the results of environmental impact studies. We therefore keep it under study.

We are against the registration of the product based on fipronil because of the above-mentioned toxicological and ecotoxicological risks.

**Table 1 : Pesticides used in desert locust control and opinion for registration**

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion
ALSYSTIN 050 UL	III	Bayer Crop Science	triflumuron (50 g/l)	0109/I/12-00/APV-SAHEL 0109/I/12-03/APV-SAHEL	Favourable
ADONIS 4 UL	III	Rhône Poulenc	fipronil (4 g/l)	0065/I/11-99/APV-SAHEL 0065/I/06-02/APV-SAHEL	Unfavourable
CONFIDOR 010 UL	III	Bayer	imidacloprid (10 g/l)	0165/I/11-01/APV-SAHEL	Favourable for renewal PSA
CYANOX L-50	II	Sumitomo Corporation	cyanophos (500 g/l)	0107/I/12-00/APV-SAHEL 0107/I/12-03/APV-SAHEL	RS
MARSHAL 2% DP	III	FMC Europe	carbosulfan (20 g/kg)	0047/I/06-99/APV-SAHEL 0047/I/06-02/APV-SAHEL	Unfavourable
CYHALON 4 ULV	II	Syngenta	cyhalothrine (40 g/l)	0175/I/06-02/APV-SAHEL	Favourable for renewal PSA
GREEN MUSCLE	III	Calliope	metarhizium flavovirid ( $5.10^{10}$ spores/g)	0152/I/06-01/APV-SAHEL	Favourable for renewal PSA
OFUNACK 40 EC	II	Africa Agro Service	pyridaphenthion (400 g/l)	0092/I/05-00/APV-SAHEL	Favourable for renewal PSA
OFUNACK 25 ULV	II	Africa Agro Service	pyridaphenthion (250 g/l)	0093/I/05-00/APV-SAHEL	Favourable for renewal PSA
RELDAN 50 EC	U	Dow AgroSciences	chlorpyrifos-methyl (500 g/l)	0016/I/06-95/APV-SAHEL 0016/I/11-01/APV-SAHEL	Favourable
RELDAN 500 ULV	U	Dow AgroSciences	chlorpyrifos-methyl (500 g/l)	0017/I/06-95/APV-SAHEL 0017/I/11-01/APV-SAHEL	Favourable
RELDAN 170 ULV	U	Dow AgroSciences	chlorpyrifos-methyl (170 g/l)	0018/I/06-95/APV-SAHEL 0018/I/11-01/APV-SAHEL	Favourable
SUMICOMBI 30 EC	II	Sumitomo Corporation	phenitrothion (250 g/l) phenvalerate (50 g/l)	0099/I/12-00/APV-SAHEL	Favourable

				0099/I/12-03/APV-SAHEL	
SUMICOMBI- ALPHA 25 ULV	II	Sumitomo Corporation	phenitrothion (245 g/l) esphenvalerate (5 g/l)	0100/I/12-00/APV-SAHEL 0100/I/12-03/APV-SAHEL	Favourable
SUMITHION 3 D	U	Sumitomo Corporation	phenitrothion (30 g/kg)	0101/I/12-00/APV-SAHEL 0101/I/12-03/APV-SAHEL	Favourable
SUMITHION 5 D	U	Sumitomo Corporation	phenitrothion (50 g/kg)	0102/I/12-00/APV-SAHEL 0102/I/12-03/APV-SAHEL	Favourable
SUMITHION 50 EC	II	Sumitomo Corporation	phenitrothion (500 g/l)	0103/I/12-00/APV-SAHEL 0103/I/12-03/APV-SAHEL	Favourable
SUMITHION L-20	U	Sumitomo Corporation	phenitrothion (200 g/l)	0104/I/12-00/APV-SAHEL 0104/I/12-03/APV-SAHEL	Favourable
SUMITHION L-50	II	Sumitomo Corporation	phenitrothion (500 g/l)	0105/I/12-00/APV-SAHEL 0105/I/12-03/APV-SAHEL	Favourable
SUMITHION L-100	II	Sumitomo Corporation	phenitrothion (1000 g/l)	0106/I/12-00/APV-SAHEL 0106/I/12-03/APV-SAHEL	Favourable
TRACKER 16,5ULV	III	Du Pont de Nemours	tralomethrin (66 g/l)	0022/I/12-95/APV-SAHEL 0022/I/05-00/APV-SAHEL	Favourable
UNDEN 2 DP	III	Bayer CropScience	propoxur (20 g/kg)	0108/I/12-00/APV-SAHEL 0108/I/12-03/APV-SAHEL	Favourable

**Table 2. Active substances in desert locust control products**

Active substance	EU status	USA status	Database situation	Opinion on registration
fipronil	Authorization in process	Authorized	XXX	no
triflumuron	Authorization in process	-	-	yes
metarhizium flavovirid	-	-	-	yes
phenitrothion	-	Authorized	XXX	yes
propoxur	Expired	Authorized	XXX	yes
cyanophos	-	-	-	RS
phenvalerate			X	yes
esphenvalerate	Authorized	Authorized	XXX	yes
tralomethrin	-	-	-	
carbosulfan	Authorization in process		XXX	no
chlorpyrifos-methyl			XXX	yes

EU : European Union

X : little available data

XX : moderate available data

XXX : abundant available data

## **4.2. Results of evaluation of pesticides under toxicosurveillance**

The pesticides under toxicosurveillance are all products of toxicological class Ib used against cotton pests. There are 14 commercial products (**Table 3**) derived from 9 active substances (**Table 4**). Eight are based on endosulfan and eight on other active substances (**Table 2**). Nine of the 14 products have already received 2 PSAs while 3 present serious problems and cause concern (endosulfan, methamidophos and monocrotophos).

### **4.2.1. Endosulfan**

Endosulfan is an organochloride insecticide with two isomers:  $\alpha$  and  $\beta$  which metabolize into endosulfan sulphate and endosulfan diol. Endosulfan sulphate, the main product of degradation is more toxic and persistent than endosulfan.

The neurotoxic effects of endosulfan on humans and animals are well documented. Exposure can cause liver and kidney toxicity, haematological effects and alterations to the immunity system and reproductive organs.

Endosulfan is in the environment, more specifically in air, soil and sediments. Its persistence in the environment is as follows:

- The DT<sub>50</sub> of endosulfan  $\alpha$  is 60 days
- La DT<sub>50</sub> of endosulfan  $\beta$  is 900 days

Because of its potential displacement over long distances, its persistence in the environment, its bioaccumulation in various aquatic organisms and its ecotoxicity, there is agreement that endosulfan and its metabolite endosulfan sulphate meet the criteria for inclusion in the list of Persistent Organic Pollutants (POP).

As regards the Rotterdam Convention, endosulfan is one of those products for which a Decision Guidance Document (DGD) is being prepared.

As regards the European Union, endosulfan is banned following its examination for inclusion in Annex I (positive list) of Directive 91/414/EEC, in application of community decision 2005/864/EC of 2 December 2005.

This refusal of the European Union to include endosulfan in its positive list is due to the fact that it does not meet minimum safety requirements, particularly its impact on the environment and its ecotoxicological profile. It was authorized for use in 7 countries of the Union. That authorization should have been withdrawn from the 1 February 2006 (EFSA Journal (2005) 234,1-31).

In France, endosulfan is not authorized in the composition of formulations granted market sale authorization. The determination published in the Official Gazette of 22 February 2006 withdraws market sale authorizations of phytopharmaceutical products containing endosulfan for all agricultural and non-agricultural uses, with a time limit set on stock throughput:

- until 31 December 2006 for distribution,
- until 30 May 2007 for use.

In the USA, agricultural uses and MRLs of certain usages are cancelled.

For the countries of the CILSS, endosulfan is used for the cotton crop at a dose of 500 to 700 g/ha following a major outbreak of *Helicoverpa armigera* in 1996 and its resistance to pyrethrinoids. For the cotton producing countries of the CILSS, large quantities of this hazardous product have been heavily used without respecting good agricultural practices, resulting in serious risks to human health and the environment for some ten years. In a classification of pesticides according to their impact on surface waters in Burkina Faso, of all the pesticides applied as foliar spray to the cotton crop, endosulfan is the only one classified as having an excessively high risk of contamination of surface waters (TOE *et al*, 2003). This threat to surface waters from endosulfan identified by the Pesticide Impact Rating Index (PIRI) has been confirmed by the presence of endosulfan residues after GPC-ECD analysis of water samples taken from the area in which this product was used (TOE *et al*, 2004).

Because of its very high toxicity (class Ib) and the serious danger it poses for human and animal health, the environment and non-target organisms, and in view of the provisions of international conventions on organochlorides, endosulfan cannot remain authorized in CILSS countries with particularly fragile ecological conditions.

Use of this product is no longer justified in the CILSS countries, because there are now many other products capable of effectively controlling *H. armigera*. In application of article 13.5(iii) of the common regulation of the CILSS Member States on the registration of pesticides, we

recommend that no current PSA be renewed for endosulfan-based products and that no registration be granted. We also strongly recommend that a time limit be set on stock throughput, taking into consideration the period of cotton pesticide use and the lead time from ordering by the cotton producing companies:

- until 30 October 2007 for distribution,
- until 30 October 2008 for utilization.

We also recommend that the CILSS launches an information campaign on behavioural change aimed at all operators using endosulfan.

#### **4.2.2. *Methamidophos and monocrotophos***

Methamidophos (concentration above 600 g/ha) and monocrotophos are included in the PIC list (Annexe III).

Because of its toxicity, monocrotophos is banned in the European Union countries and in the USA. Methamidophos is not authorized in the European Union countries. For the Rotterdam Convention, two countries in two different regions (Nigeria and Bulgaria) have already provided the information needed for a revision of the status of this molecule in the PIC list. Our own research revealed that all incidences of toxicity in cotton production in Burkina Faso in 1996-1997 were due to methamidophos-based products (TOE *et al*, 2000; TOE *et al*, 2002). In further application of article 13.5, we propose withdrawing current PSAs for all products based on methamidophos and monocrotophos, and propose setting a time limit for stock throughput, as for endosulfan.

#### **4.2.3. *Other class Ib products.***

##### ***Products based on carbosulfan***

We are strongly against the registration of these products because of associated risks of groundwater pollution.

##### **Conquest plus 388 EC (ternary)**

Insecticide/herbicide ternary products used on a large scale are generally very broad spectrum, making it difficult to avoid non-target organisms. In addition, their physico-chemical qualities deteriorate rapidly in storage and use. We are strongly against their registration.

##### ***Dursban B 18/150 EC and B 18/200 (based on cyfluthrin and chlorpyrifos).***

Because of their toxicity, we suggest that these products should not be registered once their PSAs expire.



#### ***4.2.4. Conclusion for class Ib products***

These products are used by small farmers who are poorly trained in the safe use of pesticides. They do not observe recommended hygienic practices and do not wear appropriate protective equipment. We therefore propose that class Ib products meant for use by small farmers no longer be authorized by the CSP because of the restrictions placed on their use which cannot be observed by poorly trained and often illiterate small operators. In the case of cotton, there is a wide range of class II, III and IV products that are equally effective. There is absolutely no justification in using class Ib products. Similarly, we propose that ternary products should no longer be authorized, given their very broad spectrum of activity in Sahel countries with fragile ecological conditions.

**Table 3: Pesticides under toxicosurveillance and opinion for registration**

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion on registration
CAÏMAN 500 EC	Ib	STPC	endosulfan (500 g/l)	0214/I,A/06-03/APV-SAHEL	Unfavourable
CONQUEST PLUS 388 EC	Ib	Aventis	acetamiprid (16g/l), cypermethrin (72 g/l) and triazophos (300 g/l)	0086/I/05-00/APV-SAHEL 0086/I/05-03/APV-SAHEL	Unfavourable
CYPERFOS 336 EC	Ib	Senchim AG	cypermethrin (36 g/l) and methamidophos (300 g/l)	0217/I,A/06-03/APV-SAHEL	Unfavourable
CYTOFOS 286 EC	Ib	Senchim AG	cypermethrine (36 g/l) monocrotophos (250 g/l)	0218/I/06-03/APV-SAHEL	Unfavourable
DURSBAN - B 18/150 EC	Ib	Dow AgroSciences	cyfluthrin (18 g/l) and chlorpyrifos (150 g/l)	0128/I/06-01/APV-SAHEL 0128/I/06-04/APV-SAHEL	Unfavourable
DURSBAN - B 18/200 EC	Ib	Dow AgroSciences	cyfluthrin (18 g/l) and chlorpyrifos (200 g/l)	0129/I/06-01/APV-SAHEL 0129/I/06-04/APV-SAHEL	Unfavourable
ENDOCOTON 350 EC	Ib	Hydrochem CI	endosulfan (350 g/l)	0119/I/12-00/APV-SAHEL 0119/I/12-03/APV-SAHEL	Unfavourable
ENDOCOTON 500 EC	Ib	Hydrochem CI	endosulfan (500 g/l)	0120/I/12-00/APV-SAHEL 0120/I/12-03/APV-SAHEL	Unfavourable
MARSHAL 25 EC	Ib	FMC Europe	carbosulfan (250 g/l)	0046/I/06-99/APV-SAHEL 0046/I/06-02/APV-SAHEL	Unfavourable
PHASER 350 EC	Ib	Bayer CropScience	endosulfan (350 g/l)	0082/I/05-00/APV-SAHEL 0082/I/05-03/APV-SAHEL	Unfavourable
PHASER 500 EC	Ib	Bayer CropScience	endosulfan (500 g/l)	0113/I/12-00/APV-SAHEL 0113/I/12-03/APV-SAHEL	Unfavourable
ROCKY 500 EC	Ib	Calliope	endosulfan (500 g/l)	0200/I/06-02/APV-SAHEL	Unfavourable
ROCKY 500 EC	Ib	Calliope	endosulfan (500 g/l)	0200/In,Ac/06-02/APV-SAHEL 0200/In,Ac/06-05/APV-SAHEL	Unfavourable
ROCKY 330 CS	Ib	Calliope	endosulfan (330 g/l)	0244/In,Ac/07-05/APV-SAHEL	Unfavourable

**Table 4. Active substance of the pesticides under toxicosurveillance**

Active substance	European Union status	USA status	Database situation	Opinion on registration
triazophos	expired	-	-	yes and no
endosulfan	expired	authorized	XXX	no
methamidophos	-	authorized	XXX	no
monocrotophos	banned	Banned 01 91	XXX	no
carbosulfan	authorization in process		XXX	no
acetamiprid	-	-	XXX	yes
chlorpyrifos-ethyl	-	authorized	XXX	yes
cyfluthrin	-		XXX	yes
cypermethrin			XXX	yes

### 4.3. Results of evaluation of other pesticides

Products for which there would not appear to be any obvious objection to registration would be those based on the following active substances:

cyfluthrin  
indoxacarb  
ioxynil  
acetamiprid  
zeta-cypermethrin  
buprofezin  
cypermethrin  
bensulfuron-methyl  
profenofos  
permethrin  
malathion  
oxadiargyl  
fluometuron  
prometryn

#### **Products to remain under study:**

pyrimiphos-methyl  
triazophos  
phenthoate  
isoprothiolane

We have kept these products under study at the present stage of our investigations, as we do not have enough information from the databases consulted and do not know their EU or USA status.

We recommend that the CSP continue more in-depth investigations into these active substances.

***Product to be banned: paraquat***

Paraquat is a highly toxic non-selective herbicide when ingested. Any paraquat-based formulation is obliged to contain a stenching agent and an emetic agent. This product has also proved to be mutagenic in tests with microorganisms. Paraquat is among those pesticides that alter immunitary functions and significantly reduce the resistance of organisms to infection (immunosuppressants). They alter organism defences against microbial or toxic aggression. Paraquat and diquat in particular reduce the formation of antibodies and disturb white blood cell phagocytosis. Paraquat is very persistent in the environment with half-life times in excess of 1000 days and in certain areas 13 years. Under such conditions, the risks are significant to both the environment and non-target organisms.

Because of these toxicological and ecotoxicological risks, tight restrictions have been placed on use of this product. We therefore recommend that this product should not be registered for use by small farmers in CILSS countries with fragile ecological conditions.

**Table 5 : Other pesticides and opinion for registration**

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion on registration
ACTALM SUPER	U	ALM International	pyrimiphos-methyl (17 g/l) and cyfluthrine (3 g/l)	0097/I/05-00/APV-SAHEL 0097/I/05-03/APV-SAHEL	RS
ACTRIL DS	U	Bayer CropScience	ioxynil (100 g/l) and 2,4-D (577 g/l)	0067/H/11-99/APV-SAHEL 0067/H/11-02/APV-SAHEL	Favourable
APPLAUD 40 SC	III	Nihon Nohyaku	buprofezin (400 g/l)	0110/I/12-00/APV-SAHEL 0110/I/12-03/APV-SAHEL	Favourable
AVAUNT 150 SC	III	Asteria	indoxacarb (150 g/l)	0039/I/06-99/APV-SAHEL 0039/I/06-02/APV-SAHEL	Favourable
CONQUEST 88 EC	II	Bayer CropScience	acetamiprid (16 g/l) and cypermethrin (72 g/l)	0114/I/12-00/APV-SAHEL 0114/I/12-03/APV-SAHEL	Favourable
COTOGARD 500 SC	III	Agan Chemical	fluometuron (250 g/l) and prometryn (250 g/l)	0089/H/05-00/APV-SAHEL 0089/H/05-03/APV-SAHEL	Favourable
CYPERCAL 50 EC	III	Calliope	cypermethrin (50 g/l)	0037/I/11-98-APV-SAHEL 0037/I/11-02/APV-SAHEL	Favourable
CYPERCAL P 186 EC	II	Calliope	cypermethrin (36 g/l) and profenofos (150 g/l)	0124/I,A/12-00/APV-SAHEL 0124/I,A/12-03/APV-SAHEL	Favourable
CYPERCAL P 230 EC	II	Calliope	cypermethrin (30 g/l) and profenofos (200 g/l)	0125/I,A/12-00/APV-SAHEL 0125/I,A/12-03/APV-SAHEL	Favourable
CYPERCAL P 286 EC	II	Calliope	cypermethrin (36 g/l) and profenofos (200 g/l)	0126/In,Ac/12-00/APV-SAHEL 0126/In,Ac/12-03/APV-SAHEL	Favourable
ELSAN 50 EC	II	Tomen	phenthoate (500 g/l)	0052/I/06-99/APV-SAHEL 0052/I/06-02/APV-SAHEL	RS
FUJI-ONE 40 EC	III	Nihon Nohyako	isoprothiolane (400 g/l)	0034/F/11-98/APV-SAHEL	RS

				0034/F/06-02/APV-SAHEL	
FURY P 162 EC	II	FMC	zeta-cypermethrin (12 g/l) and profenfos (150 g/l)	0117/I,A/12-00/APV-SAHEL 0117/I,A/12-03/APV-SAHEL	Favourable
GRAMOXONE SUPER	II	Syngenta	paraquat (200 g/l)	0096/H/05-00/APV-SAHEL 0096/H/05-03/APV-SAHEL	Unfavourable
KALACH 360 SL	III	Calliope	glyphosate (360 g/l)	0049/H/06-99/APV-SAHEL 0049/H/06-02/APV-SAHEL	Favourable
LONDAX 60 DF	III	Dupont de Nemours	bensulfuron-methyl (600 g/l)	0053/H/06-99/APV-SAHEL 0053/I/06-02/APV-SAHEL	Favourable
PERCAL M DP	III	Calliope	permethrin (4 g/kg) and malathion (16 g/kg)	0050/I/06-99/APV-SAHEL 0050/I/06-02/APV-SAHEL	Favourable
TOPSTAR 400 SC	III	Bayer CropScience	oxadiargyl (400 g/l)	0084/H/05-00/APV-SAHEL 0084/H/05-03/APV-SAHEL	Favourable
TRIAZOPHOS HOSTATHION 40 EC	II	Bayer CropScience	triazophos (420 g/l)	0112/I/12-00/APV-SAHEL 0112/I/12-03/APV-SAHEL	RS

**RS : Remain under study**

**Table 6: Active substances of other pesticides**

Active Substance	European Union Status	USA Status
pyrimiphos-methyl (17 g/l) et l)	-	-
cyfluthrin (3 g/	-	-
ioxynil (100 g/l) et	-	-
2,4-D	-	-
buprofezine (400 g/l)	-	-
indoxacarb	authorized	authorized
acetamiprid (16 g/l)	-	-
cypermethrin		-
fluometuron		
prometryn	-	-
profenofos (150 g/l) (3)	expired	-
phenthoate (500 g/l)	expired	-
isoprothiolane (400 g/l)	expired	-
zeta-cypermethrin (12 g/l)	-	-
paraquat (200 g/l)	authorized	authorized
glyphosate (360 g/l)	-	authorized
bensulfuron-methyl (600 g/l)	-	-
permethrin (4 g/kg)	-	-
malathion (16 g/kg)	authorization in process	authorized
oxadiargyl (400 g/l)	authorized	-
triazophos (420 g/l)	expired	-

## 5. Conclusions and outlook

Our determination based on expert analysis and available data is as follows:

- a favourable opinion for the registration of all pesticides used in desert locust control that have already been granted 2 PSAs, with the exception of fipronil and cyanophos. Fipronil should be banned and cyanophos should remain under study;
- a very unfavourable opinion for the registration of all pesticides under toxicosurveillance (pesticides in toxicological class 1b) with a time limit set on stock throughput;
- a favourable opinion for the registration of all the other pesticides that do not belong to the two above classes and all products except those based on: paraquat, pyrimiphos-methyl, triazophos, phenthoate and isoprothiolane. We strongly recommend that paraquat be banned and that the other four products remain under study.

We have constantly borne in mind that risks associated with phytopharmaceutical products can only be considered in relation to the usage of those products. A decision on registration should be taken on the basis of individual usage and not only individual product. We therefore strongly recommend that any decision on conversion from PSA to registration should be made on the basis of more in-depth examination of each case with the involvement of stakeholders (distributors, users, certification services, civil society...). Supplementary information should be provided for all cases with details on:

- the use and distribution of the products (companies) ;
- the effectiveness and phytotoxicity of the products (users) ;
- the observed impacts on health and the environment (.....).

For conversion of binary products from PSA to registration, we must insist that companies provide data on the effects of those binary products on the environment and on non-target organisms.

Regarding future work of the CSP in general and Sub-Committee II (Toxicology – Ecotoxicology) in particular, we reiterate all the suggestions and recommendations we made in our mission report to the INRA Joint Research Unit in Versailles last December.



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**Databases consulted:** CSP, AGRITOX, Pesticide Manual, EXTOWNET, EPA., PIP...

## 7. Annex

### 7.1. Essential data for evaluation of active substances:

<b>Substance</b>	<b><u>ADI</u> (mg/kg/d)</b>	<b><u>ARfD</u> (mg/kg/d)</b>	<b><u>AOEL</u> (mg/kg/d)</b>	<b><u>PNEC</u> (µg/L)</b>	<b><u>Classification</u></b>
<u>2,4-D</u>	0.05	not applicable	0.15	58	N Xn R22 R37 R41 R43 R52/53
<u>acetamiprid</u>	0.07	0.1	0.124	0.5	Xn R22 R52/53 S2 S46 S61
<u>bensulfuron-methyl</u>	0.2				N Xi R43 R51/53
<u>bifenthrin</u>	0.015	0.074	0.0125	0.0012	N T R20 R25 R40 R43 R50/53 S36/37 S45 S60 S61
<u>buprofezin</u>	0.01				EC
<u>carbofuran</u>	0.001	0.001	0.001		N T+ R26/28 R50/53
<u>carbosulfan</u>	0.01	0.01	0.02		N T R23/25 R43 R50/53 S1/2 S36/37 S45 S60 S61
<u>chlorpyrifos-ethyl</u>	0.01	0.1	0.01	0.1	N T R25 R50/53 S1/2 S45 S60 S61
<u>chlorpyrifos-methyl</u>	0.01	0.1	0.01		N Xi R43 R50/53 S2 S36/37 S60 S61
<u>cyfluthrin</u>	0.003	0.02	0.02	0.0068	N T+ R23 R28 R50/53
<u>cypermethrin</u>	0.05	0.2	0.06	0.001	N Xn R20/22 R37 R50/53 S2 S24 S36/37/39 S60 S61
<u>cypermethrin high cis</u>					N Xn R22 R37/38 R43 R50/53 S2 S36/37/39 S60 S61
<u>deltamethrin</u>	0.01	0.01	0.0075	0.0032	N T R23/25 R50/53 S1/2 S24 S28 S36/37/39 S38 S45 S60 S61
<u>diflubenzuron</u>	0.02				EC
<u>esphenvalerate</u>	0.02	0.05	0.018	0.08	N T R23 R25 R43 R50/53 S1/2 S24 S36/37/39 S45 S60 S61
<u>fenitrothion</u>	0.005	0.013	0.013		N Xn R22 R50/53
<u>fipronil</u>	0.0002	0.009	0.0035	0.00077	N T R23/24/25 R48/25 R50/53 S2 S36/37 S45 S60 S61
<u>glyphosate</u>	0.3	not applicable	0.2	60	N Xi R41 R51/53 S2 S26 S39 S61

<u>indoxacarb</u>	0.006	0.125	0.004		Xn R22 R43 R50
<u>ioxynil</u>	0.005	0.04	0.01	2.7	N T R21 R23/25 R36 R48/22 R50/53 R63 S1/2 S36/37 S45 S60 S61 S63
<u>lambda cyhalothrin</u>	0.005	0.0075	0.0025	0.00016	N T+ R21 R25 R26 R50/53
<u>malathion</u>	0.03	0.3	0.03	0.5	N Xn R22 R50/53 S2 S24 S60 S61
<u>methamidophos</u>	0.001	0.003	0.001		N T+ R24 R26/28 R50 S1/2 S28 S36/37 S60 S61
<u>oxadiargyl</u>	0.008	not applicable	0.006	0.23	N Xn R48/22 R50/53 R63 S2 S36/37 S46 S60 S61
<u>prometryne</u>					EC
<u>spinosad</u>	0.024	not applicable	0.024 0.012	0.17	N Xn R48/22 R50/53 S2 S46 S60 S61
<u>triflumuron</u>	0.005				Xn R48/22
<u>zetacypermethrin</u>	0.02		0.05	2.6e-05	N T R23 R25 R43 R50/53
<u>ziram</u>	0.006	0.08	0.015	18.9	N T+ R22 R26 R37 R41 R43 R48/22 R50/53 S1/2 S22 S26 S28 S36/37/39 S45 S60 S61
<u>zoxamide</u>	0.5	not applicable	0.3	0.348	N Xi R43 R50/53

## 7.2. Acronyms, abbreviations and definition of essential data for toxicological and ecotoxicological evaluation of active substances (see Chapter 2. Methods of work)

**AOEL:** Acceptable Operator Exposure Level

This is the maximum quantity of active substance to which operators can be exposed daily without harmful effects on their health.

**ARfd:** Acute Reference Dose

This is the maximum quantity of active substance that can be ingested by consumers during a short period (i.e. during a meal or a day, in food or water) without harm to their health.

**ADI:** *Acceptable Daily Intake*

This is the quantity of the substance that can be ingested daily by consumers, throughout their lifetime, without effect on their health.

**DL<sub>50</sub>:** Lethal Dose<sub>50</sub> (fatal) of active substance for 50 percent of experimental animals after a single administration of the active substance.

**DT<sub>50</sub>:** Dissipation time (Half-life)

This is the time needed for the degradation (in the laboratory) or the dissipation (in the field) of 50 percent of the initial quantity of the active substance in the soil.

*K<sub>oc</sub>*: Adsorption coefficients

This characterizes the mobility of an active substance and indicates the risks of contamination of surface waters.

*PNEC*: Predicted No Effect Concentration

This is the concentration below which exposure is not expected to cause an effect on aquatic organisms.



**Australian Pesticides &  
Veterinary Medicines Authority**

**The reconsideration of approval of the active constituent Endosulfan, registrations of  
products containing Endosulfan and their associated labels.**

**FINAL REVIEW REPORT  
AND  
REGULATORY DECISION**

**Review Series 2**

**June 2005**

**Australian Pesticides &  
Veterinary Medicines Authority**

**Canberra  
Australia**

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**ISSN 1448-1553**

This final review report for the active constituent Endosulfan, products containing Endosulfan and associated labels is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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## **FOREWORD**

The APVMA is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the *Agricultural and Veterinary Chemicals Code Act, 1994* (Agvet Codes).

The APVMA can reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers of chemical products at any time. This is specified in Part 2, Division 4 of the Agvet Codes.

The basis for the reconsideration is whether the APVMA is satisfied that continued use of the active constituent endosulfan and products containing endosulfan in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and/or
- would not be likely to have an effect that is harmful to human beings; and /or
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment; and/or
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product or its label.

The process for reconsideration includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

In undertaking reviews, the APVMA works in close cooperation with advisory agencies including the Department of Health and Ageing, the Department of the Environment and Heritage, the National Occupational Health and Safety Commission, and State Departments of Agriculture as well as other expert advisors, as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This document is '*The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels*' and relates to all products containing endosulfan. The review's findings and regulatory decision are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The final review report and regulatory decision containing the APVMA assessments (Volume I, June 2005) and the technical reports from its advisory agencies (Volume II) are available from the APVMA website: <http://www.apvma.gov.au/chemrev/chemrev.shtml>.

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## GLOSSARY OF TERMS AND ABBREVIATIONS

AAAA	Australian Aerial Agricultural Association
ACAHS	Australian Centre for Agricultural Health & Safety
ADI	Acceptable Daily Intake
a.i.	Active Ingredient
ai/100L	active ingredient per 100 Litres
aPAD	Acute Population Adjusted Dose
ARfD	Acute Reference Dose
ATV	All Terrain Vehicles
BCF	Bioconcentration Factor
bw	Body weight
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CP	Pressure control nozzles
cPAD	Chronic Population Adjusted Dose
C-PAS	Centre for Pesticide Application Safety
CRDC	Cotton Research & Development Corporation
CRP	Chemical Review Program
CXL	Codex Maximum Residue Level
d	Days
DFR	Dislodgeable Foliar Residue
EC	Emulsifiable concentrate
ECRP	Existing Chemical Review Program (APVMA)
EPA	US Environmental Protection Agency
ER	Oestrogen Receptor
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
g	Gram
g ai/ha	grams of active ingredient per hectare
GAP	Good Agricultural Practice
HPA	Hypothalamic-pituitary-adrenal
HPG	Hypothalamic-pituitary-gonadal
HPT	Hypothalamic-pituitary-thyroid
HRs	Highest Residues
IPM	Integrated Pest Management
kg	Kilogram
L	Litre
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOEL	Lowest Observable Effect Level
MFL	Maximum Feed Level
mg	Milligram
mg/kg	milligrams per kilogram
mL	Millilitre
M/L	Mixing/loading
M/L/A/C	Mixing/loading/application/cleaning

**Australian Pesticides and Veterinary Medicines Authority (APVMA)**

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MOE	Margins of Exposure
MRL	Maximum Residue Limits
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NOEL	No Observable Effect Level
NOHSC	National Occupational Health & Safety commission
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
OP	Organophosphorus compound
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PF	Processing Factor
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	parts per million
PVC	Polyvinyl chloride
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RLEM	Red Legged Earth Mite
SHBG	Sex hormone-binding globulin
STMRS	Supervised Trial Median Residues
SUSDP	Standards for the Uniform Scheduling of Drugs and Poisons
TC	Transfer Coefficient
TGA	Therapeutic Goods Administration
TGAC	Technical Grade Active Constituent
ULV	Ultra-low Volume
US EPA	United States Environment Protection Authority
WHP	With Holding Period

## EXECUTIVE SUMMARY

### Introduction

Endosulfan is a broad-spectrum insecticide/acaricide, which has been registered in Australia for over 35 years. It is used widely for the control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. Endosulfan products are not registered for home garden use.

There are five product registrations for endosulfan, all of which are emulsifiable concentrates. All of these product registrations are currently under suspension (since 2002), with new instructions issued for use under specified conditions.

Alternative products are available for all use patterns, although endosulfan has a number of important advantages in that it is inexpensive, soft on beneficial insects, and provides a different chemistry useful in resistance management. It is expected that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan.

### ***Previous Reconsideration Action***

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan. The review was initiated because of concerns regarding possible health and environmental effects, residues in commodities and possible trade implications.

An interim report of this review was released in 1998 and recommended a number of changes to the registered uses for endosulfan. Amongst other things, the interim report required additional Occupational Health & Safety (OH&S) and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. Subsequently, the endocrine disruption potential for endosulfan was also reassessed. This Final Review Report and Regulatory Decision, *The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels*, June 2005, considers the assessment of this additional information.

During the period 1998 to 2001, the APVMA implemented a range of changes to the registrations and label approvals of endosulfan products to address risks associated with protection of the environment, worker safety and residues in commodities. Some of the principal changes included:

- declaring endosulfan products to be restricted chemical products;
- requiring users of endosulfan to undertake specified training;
- restricting the number of applications for endosulfan per season.

Following this action, the APVMA received new reports of endosulfan residues in beef as a result of spray drift. The APVMA took action to impose mandatory buffer zones, neighbourhood notification requirements before application to cotton, and ultimately cancelled the registration of ultra-low volume endosulfan products.

In 2002 the APVMA, following assessment of additional residue data, further restricted the use of endosulfan on the basis of trade and human health (dietary intake) concerns. These additional restrictions were given effect by suspending product registrations and label approvals, and issuing new instructions for the supply and use of the suspended products. These new instructions included prohibited crop uses (pears, Brussels sprouts and leafy vegetables), some new withholding periods and livestock feeding restraints. The suspensions were in place until 21 December 2005, unless revoked.

## **Public Consultation**

The draft review report was released for a 2 month public consultation period in May 2004. This attracted a total of 85 submissions from the general public, community groups, individual growers, grower organisations, registrants of endosulfan products, and Commonwealth and State agencies. A detailed discussion of the main issues raised during public consultation on the draft review report, including the APVMA responses, is presented in Appendix 2.

Submissions received from the public consultation have resulted in some changes to the findings that were presented in the draft review report.

## **Occupational Health and Safety Assessment**

As an outcome of the interim report of the endosulfan review, additional worker exposure data was required. New data generated under Australian conditions for workers conducting a range of tasks was provided. These involved operations for treating nursery, orchard and broadacre crops by ground and aerial applications and re-entry of workers to broadacre crops. During the public consultation on the draft review report, further crop specific data was provided to allow refinement of worker exposure and re-entry evaluations.

Evaluation of all the available information found that acceptable occupational exposure safety margins could be achieved for all registered nursery, orchard and broadacre uses, with re-entry allowed once the spray deposit has dried. New requirements for personal protective equipment (PPE) and re-entry periods for various tasks have been determined.

## **Residues Assessment**

In response to the requirements of the interim report, additional residues studies were submitted to assess dietary exposure and trade risks from endosulfan use. The initial findings from these studies led to interim action in 2002 to suspend existing endosulfan products, with new instructions for supply and use of the suspended products.

A full assessment of the residues data has resulted in the recommendation to delete certain uses of endosulfan on the basis either of no data being submitted, dietary exposure risk, or trade risk. This includes the late spray for many broadacre crops, and some uses for horticulture crops.

The draft report noted that a key issue was the potential for by-products of cotton and legume vegetables that have been treated with endosulfan to be fed to livestock and cause residue violations in the meat.

As part of the public comment period, the APVMA sought assurances that, should uses on cotton and legume vegetables be retained, appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

During the public consultation period the APVMA received numerous submissions from key stakeholders on this issue. A commitment was received from the Australian cotton industry and the livestock industry regarding continued use of endosulfan in cotton. Specifically Cotton Australia and the Cotton Ginners Association have agreed upon a memorandum of understanding (MOU) with the Cattle Council of Australia and the Australian Feedlotters Association that specifies the management practises to be adopted by cotton growers and livestock producers to allow the continued use of endosulfan in cotton.

As no similar assurances could be provided for legume vegetables, these uses have been deleted.

Other issues raised in the public submissions included requests for changes to withholding periods, and inclusion of export slaughter intervals.

### **Water quality monitoring**

The 1998 interim report noted relatively high levels of endosulfan contamination in surface waters in cotton growing areas, with targets set to reduce levels of contamination. Results of river monitoring by the NSW Department of Land and Water Conservation, have shown a significant reduction for both endosulfan detections and concentrations since 1999. these results demonstrate that measures put in place by the APVMA and the cotton industry have been effective in reducing endosulfan contamination in surface waters. Therefore the continued use of endosulfan would not be likely to have an unintended effect that is harmful to the environment.

### **Endocrine disruption**

The 1999 interim report found no evidence of endocrine disruption caused by endosulfan. A US EPA RED (Reregistration Eligibility Decision) report in 2002 identified endosulfan as “a potential endocrine disruptor”. The APVMA reassessed their original conclusions in light of this information. This reassessment again concluded that the endocrine disrupting potential of endosulfan is not a significant risk to public health under the existing management controls and health standards.

### **Summary of review outcomes**

The recommendations of the review are that:

- the suspension of registration and label approvals for endosulfan can be revoked;
- product labels will be varied by deleting certain uses, adding new label instructions, amending withholding periods, safety directions and re-entry statements for retained product uses;
- all product registrations for endosulfan can be affirmed; and
- label approvals considered not to contain adequate instructions will be cancelled.

## 1. INTRODUCTION

The APVMA has completed its review of the active constituent endosulfan, products containing endosulfan and the associated labels. The purpose of this document is to provide a summary of the most recent data evaluated, subsequent to the interim report released in 1998, and of the regulatory decisions reached as a result of the review of endosulfan.

### 1.1 REGULATORY STATUS OF ENDOSULFAN IN AUSTRALIA

Endosulfan is a broad-spectrum insecticide/acaricide that has been registered in Australia for over 35 years. It is used widely for the control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. Endosulfan products are not registered for home garden use.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it has relatively low persistence in the soil and in animal and human tissue. It also has the benefit of relatively low toxicity to many species of beneficial insects, which prevent population explosions of damaging pests, which in turn would require higher levels of harsher pesticides to control.

Prior to the APVMA review of endosulfan, approximately 900 tonnes of technical grade endosulfan was imported annually into Australia. The greatest use was in cotton (approximately 70%), followed by vegetables (approximately 20%). Since commencement of the review in 1995, endosulfan usage has decreased significantly as a result of interim measures put in place by the APVMA and industry. The introduction of transgenic Bt cotton (genetically altered) is also likely to have a continuing impact on the amount of endosulfan used by the cotton industry.

#### *Current Active Constituent and Product information*

There are four active constituent approvals for endosulfan whose approvals were affirmed at the interim report stage. One active constituent has been approved since this time and was subject to outcome of the review.

Approval Number	Active Name	Approval holder
44093*	Endosulfan	MAKHTESHIM-AGAN (AUSTRALIA) PTY LIMITED
44288*	Endosulfan	FARMOZ PTY LTD
44305*	Endosulfan	BAYER CROPS SCIENCE PTY LTD
57040 <sup>#</sup>	Endosulfan	BECOT PTY LTD T/AS IMTRADE COMMODITIES

\* included in the review      # approved subsequently, but subject to outcome of the review.

There are five endosulfan product registrations, all of which are emulsifiable concentrate formulations. All of these registrations are currently under suspension, and instructions for use have been issued for use under specified conditions.

Three of the products (32799, 45570, 45838) are included in the review. Two products (50004, 52163) were registered subsequent to announcement of the review, but are subject to the outcomes as a condition of registration:

Product Number	Name of Product	Label Number(s)
32799 *	Nufarm Endosulfan 350 EC Insecticide	32799/0899 32799/0400 32799/1000 32799/0301 32799/0801
45570 *	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	45570/0299 45570/1099
45838 *	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300 45838/0800
50004 #	Thiodan EC Insecticide [Bayer Cropscience Pty Ltd]	50004/0899 50004/1099 50004/0702
52163 #	Farmoz Endosulfan 350 EC Insecticide	52163/0899

\* included in the review      # registered subsequently, but subject to outcome of the review.

## 1.2 REASONS FOR ENDOSULFAN REVIEW

The review of endosulfan was initiated in 1995 because of concerns from its use regarding possible health and environmental effects, residues in commodities and possible trade implications. All aspects of the registration and approvals of endosulfan were considered in the review.

Since the commencement of the review, numerous changes have been made to the registered uses for endosulfan. These have resulted from the implementation of the interim report findings and the availability of new information that questioned the appropriateness of current label instructions.

The interim report required additional OH&S and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. The potential for endosulfan as an endocrine disruptor has also been reassessed. This Final Review Report considers the assessment of this additional information.

## 1.3 SCOPE OF THE REVIEW

The initial scope of this review in 1995 covered all active approvals, product registrations and associated label approvals for endosulfan. The review was conducted to determine whether the APVMA could be satisfied that the continued use of products containing endosulfan in accordance with the instructions for their use would not be likely to have any unintended effects that would impact on worker safety, public health, trade and the environment, and whether labels contain adequate instructions.

## 1.4 REGULATORY OPTIONS

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met. In the case of endosulfan, these requirements are that the use of the active constituents and products in accordance with the instructions for its use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
- would not be likely to have an effect that is harmful to human beings; and

- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The requirements for product labels are that the label contains adequate instructions. Such instructions include:

- the circumstances in which the product should be used;
- how the product should be used;
- the times when the product should be used;
- the frequency of the use of the product;
- the withholding period after the use of the product;
- the disposal of the product and its container;
- the safe handling of the product.

There are three possible outcomes to the reconsideration of endosulfan active constituents, products and associated labels. Based on the information reviewed the APVMA may be:

- satisfied that the actives, products and their labels continue to meet the prescribed requirements for registration and approval and therefore confirms the registrations and approvals.
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval.
- not satisfied that the requirements for continued registration and approval continue to be met and suspends or cancels the registrations and/or approvals.

## **2 BACKGROUND**

### **2.1 PREVIOUS REGULATORY ACTION**

#### ***Interim Report (1998)***

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan, in the first cycle of the Existing Chemicals Review Program (ECRP).

In June 1998, following a comprehensive review of endosulfan, the APVMA released its interim report “*The NRA Review of Endosulfan (August 1998)*”. Measures to address the safety of agricultural workers, the environment, and the need to verify residue limits were important outcomes of the review, and relevant label changes were required to take effect by 30 June 1999. This action substantially restricted the use of endosulfan.

Some minor changes to public health standards were recommended, resulting in a reduction of the acceptable daily intake (ADI).

These controls were considered necessary for the continued use of endosulfan. Existing uses were allowed to remain on an interim basis while new data was generated to support uses in the longer term.

A summary of the changes and restrictions arising from the Interim Review are shown in Table 2.1.



**TABLE 2.1:**  
**Summary of APVMA regulatory actions for endosulfan determined in June 1998**

Key Issues	Regulatory Actions
Control of access	<ul style="list-style-type: none"> <li>Endosulfan declared a restricted chemical.</li> <li>Endosulfan products must not be supplied to a person who is not authorised. Authorised persons require training certification.</li> </ul>
Environmental contamination of streams and rivers	<ul style="list-style-type: none"> <li>Targets set for reduction in endosulfan levels in surface waters in cotton growing areas. Agreed to as a 25% reduction in number of measurements in upper quartile of past stream concentration values. Continued use of endosulfan contingent upon meeting those targets by 30 June 2001.</li> <li>Maximum of 2 sprays (or equivalent) per season limit, unless growers could contain irrigation water or storm runoff water (up to 25mm of rainfall) on their farms.</li> <li>Cotton growers to follow the cotton industry <i>Best Management Practices Manual</i>, which focuses on reducing risks to the environment, workers and neighbours.</li> <li>New label statement requiring auditable spray records be kept.</li> <li>New label statements prohibiting application during irrigation, rain or during weather conditions likely to increase spray drift.</li> </ul>
Insufficient worker exposure data	<ul style="list-style-type: none"> <li>Requirement for the generation of worker exposure data for certain agricultural uses of endosulfan, under Australian conditions, by 31 December 1999.</li> <li>New label statement promoting use of enclosed cabs for ground spray applications.</li> <li>New label statement specifying a 2-day re-entry period.</li> <li>New label safety directions.</li> </ul>
Insufficient residues data in commodities	<ul style="list-style-type: none"> <li>Requirement to generate residue data by 30 June 2000 to support existing uses.</li> </ul>
Potential for meat residues	<ul style="list-style-type: none"> <li>Restrictions placed on orchard grazing and feeding treated crop products to cows producing milk for human consumption.</li> <li>Labels changed to include recommended withholding periods for use of crop by-products or fodder as animal feed.</li> </ul>

***Endosulfan residue crisis in exported beef of late 1998 and early 1999***

In November and December 1998, detection of endosulfan residues in beef emerged in cotton growing areas. These problems were severe enough to affect Australia's reputation with its international trading partners and to threaten the viability of segments of the domestic beef industry.

As a result, in March 1999 the APVMA mandated additional changes to all labels to avoid undue prejudice to Australia's international beef trade. These changes, effective from 1 July 1999, were to apply only to use on cotton and were in addition to the changes already required as a result of the outcomes of the interim report. The most significant new restrictions imposed were as follows:

- An absolute limit of 3 sprays (or equivalent) of endosulfan per cotton crop per season;
- Endosulfan to be applied by air only during specified time windows (15 Nov. to 15 Jan. for EC, 1 Dec. to 15 Jan. for ULV);

- Aerial application restricted to crops over a specified height;
- Mandatory downwind buffer zones required unless neighbour gives written permission to waive buffer;
- Mandatory prior notification of neighbours in all directions surrounding the sprayed area;
- Use of high-volume, large-droplet-placement technology required for all EC applications whether by air or by ground.

### ***Spray drift from ULV products***

In March 2001, the APVMA cancelled all registrations and label approvals for ULV products because of further concern over contamination of livestock from spray drift and the resulting risk to Australia's export trade.

### ***Suspension of registration and label approvals***

As discussed above, additional residues data were required as an outcome of the interim report. Following assessment of this additional data, two areas of immediate concern were identified and addressed. These related to human dietary risk from consumption of pears, Brussels sprouts or leafy vegetables, and prejudice to Australia's international meat trade arising from endosulfan residues in beef.

As part of the actions to address these concerns, the APVMA suspended product registrations and label approvals of all (5) endosulfan products in September 2002, and undertook recall action. New instructions for use were issued to allow continued supply of suspended product that specified prohibited crop uses, new withholding period statement for pears and numerous feeding restraints.

## **2.2 OVERSEAS REGULATORY STATUS**

### ***North America***

In the United States endosulfan is registered for similar use patterns as in Australia.

In 2002, the US EPA released a RED (Re-registration Eligibility Decision). Following an assessment of data, it was determined that endosulfan products pose occupational and ecological risks. However, the US EPA believes that these risks can be mitigated through measures that include deletion of some uses, reduction in maximum application rates, inclusion of buffer zones, all products to be restricted, use of closed mixing/loading systems, use of closed cabs for certain situations, and increases to re-entry intervals. The US EPA is also requiring additional data to confirm this decision. In June 2005 the US EPA received requests from registrants of endosulfan products to voluntarily cancel uses on succulent beans, spinach, grapes and peacans.

Canada is also conducting a re-evaluation of endosulfan, which should be completed in 2006. Canada is closely monitoring the outcomes of US regulatory actions.

### ***Europe***

Endosulfan products are registered for use in a number of EU countries (including UK), but are either restricted or banned in some others. A re-evaluation of endosulfan products is currently in preparation by the EU. In June 2005 the EU Commission released notification concerning the non-inclusion of endosulfan in Annex 1 to the Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing the active substance endosulfan.

### ***JMPR***

Endosulfan was previously evaluated by JMPR for residues and toxicology in 1993. A re-evaluation is proposed based on residues, for September 2005.

## **2.3 ALTERNATIVE PRODUCTS**

Alternative products to endosulfan are available for all use patterns. However, endosulfan has a number of important advantages in that it is:

- inexpensive;
- soft on beneficial insects, thus minimising post-application population explosion of harmful insects; and
- a different chemistry, useful for resistance management.

It is anticipated that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan in future.

## **2.4 Public Consultation**

The draft review report was released for a 2 month period public consultation period in May 2004. This attracted a total of 85 submissions from the general public, community groups, individual growers, grower organisations, registrants, Commonwealth and State agencies. A detailed discussion of the main issues raised during public consultation on the draft review report, including the APVMA responses, is presented in Appendix 2.

A key issue from the Draft Review Report was the continued use of endosulfan on cotton and legume vegetables. The APVMA sought assurances that, were uses for cotton and legume vegetables to be retained, appropriate and effective safeguards could and would be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

Other public submissions to the review included requests for changes to withholding periods where this was supported by submitted data, questioned the appropriateness of the dermal absorption factor used in the assessment and provided general comments in regard to the adequacy of labelling.

The public submissions have resulted in some changes to the Occupational Health and Safety and the residues and trade findings that were presented in the draft review report (for details, refer to the OH&S and Residues sections below).

# **3. RESIDUES & TRADE ASSESSMENT**

## **3.1 INTRODUCTION**

The 1998 endosulfan interim report identified the need for additional residue data to support existing uses and MRLs. If the use of endosulfan was to continue the following additional data requirements were determined: Where the requested data were not submitted and MRLs could not be supported or established, the uses would be deleted.

- *Animal feeds* – data for forages, fodder or hays of such plants as cereals (including sorghum and maize), pastures, canola, sunflowers, legume vegetables, potato, peanuts, and legume crops.
- *Human foods* – data for all commodities that were assigned a temporary MRL in the MRL Standard.
- *Processing studies* – cereals, fruits (citrus, apples and grapes), cotton and other oilseeds.
- *Animal commodities* – animal transfer studies in cattle and poultry, including analyses of milk and eggs, respectively.

As an outcome of the interim report, temporary MRLs were recommended for a number of crops to allow additional data to be generated.

Interim regulatory action in conjunction with the temporary MRLs, included limiting the number of applications of endosulfan per season to all crops and introducing residue management strategies with regular surveillance and monitoring in targeted areas. Crop withholding period statements were developed together with animal management statements, to allow treated animal feed commodities to be used whilst managing residues in livestock.

Supplementary residues data received by the APVMA were evaluated and an interim residues report was completed in September 2002. Recommendations in the interim report led to the suspension of existing endosulfan products and new instructions were issued for the supply and use of suspended products, as discussed in section 5.2.1. A copy of the suspension notice is attached to the Residues Technical Report (Appendix 1).

In this report, the data and other information received by the APVMA subsequent to the interim report are reviewed and form the basis of residues conclusions for final regulatory action.

### **3.1.1 MRLs and Label Withholding Period Statements (superseded June 2005)**

The MRLs for endosulfan (superseded June 2005) are listed below:

<b>Table 1</b>		
<b>Code</b>	<b>Food Commodity</b>	<b>MRL (mg/kg)</b>
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2
FB 0018	Berries and other small fruits	T2
VB 0400	Broccoli	T2
VB 0041	Cabbages, head	T2
VB 0404	Cauliflower	T2
GC 0080	Cereal grains	T0.2
FC 001	Citrus fruits	T2
OC 0691	Cotton seed oil, crude	T0.5
MO 0105	Edible offal (mammalian)	T0.2
PE 0112	Eggs	T*0.05
VC 0045	Fruiting vegetables, cucurbits	T2
VO 0050	Fruiting vegetables, other than cucurbits	T2
VP0060	Legume vegetables	T2
MM 0095	Meat (mammalian)[in the fat]	0.2
ML 0106	Milks [in the fat	T0.5
SO 0088	Oilseed	T1
VA 0385	Onion, bulb	T0.2
FP 0009	Pome fruits	T2
PO 0111	Poultry, edible offal of	0.2
PM 0110	Poultry meat [in the fat]	0.2
VD 0090	Pulses	T1
GC 0649	Rice	T0.1
VR 0075	Root and tuber vegetables	T2

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VA 0388	Shallots	T2
VS 0078	Stalk and stem vegetables	T2
FS 0012	Stone fruits	T2
DT 1114	Tea, Green, Black	T30
TN 0085	Tree nuts	T2

**Table 4<sup>1</sup>**

<b><u>Code</u></b>	<b><u>Animal Feed Commodity</u></b>	<b><u>MRL (mg/kg)</u></b>
	Primary feed commodities	0.3

As part of the interim regulatory action in 1998, the MRL for leafy vegetables (including Brassica leafy vegetables) was deleted and the MRL for Brassica (cole and cabbage) vegetables, head cabbages, flowerhead Brassica was deleted and replaced with individual entries for broccoli, cabbage and cauliflower. These changes were associated with concerns regarding short-term dietary exposures.

The following withholding period statements and feeding restraints were present on product labels until June 2005, specifically for residue management in crops and in particular livestock that were fed treated crops and crop fractions.

**Withholding period statements and feeding restraints**

<b>Crop</b>	<b>Withholding period/feeding restraint</b>
Beetroot, cucurbits, green beans, green peas, tomatoes	DO NOT HARVEST FOR 2 DAYS AFTER APPLICATION
Cape gooseberry, capsicums, carrots, eggplant, okra, onions, peanuts, potatoes, shallots, sweet corn, sweet potatoes, taro	DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION
Avocados, bananas, berry fruit, blueberries, cashews, citrus, currants and related fruit, custard apples, grapes, guavas, kiwifruit, longans, lychees, macadamias, mammey apples, mangoes, passion fruit, pawpaws, pecans, persimmons, pistachios, pome fruit, pomegranates, rambutans, raspberries, sapodillas, strawberries, tamarillos	DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION
Adzuki beans, canola (oilseed rape), cereals, chickpeas, cotton, cowpeas, faba beans, field peas, fodder crops (clover, chou moellier, lucerne, medics, peas), linseed, lupins, maize, mung beans, oilseeds, pastures, pigeon peas, safflower, sorghum, soybeans, sunflowers, vetch	DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION
<b>FOR ANIMAL FEEDS (INCLUDING PULSES, VEGETABLES, VEGETABLE AND FRUIT WASTES, FODDER AND FORAGE):</b>	
DO NOT RE-APPLY WITHIN 7 DAYS	
DO NOT GRAZE ORCHARDS AFTER APPLICATION	

<sup>1</sup> Recommended maximum residue limits for pesticides in animal feed commodities.

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Pasture Forage and Pasture Seed Crops	DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 4 WEEKS AFTER APPLICATION. FOR FOLIAR APPLICATIONS, A 42 DAYS SLAUGHTER INTERVAL APPLIES
DO NOT FEED TREATED CROPS OR CROP PARTS (EXCEPT COTTONSEED/MEAL) TO LACTATING COWS PRODUCING MILK FOR HUMAN CONSUMPTION.	

Where there has been at least 4 weeks since the last endosulfan application, the following slaughter intervals are still required to avoid Maximum Residue Limit violations

<b>Crop/Commodity</b>	<b>Observed Crop Harvest WHP</b>	<b>Required Animal Management</b>
<i>Cottonseed/meal</i>	<i>4 weeks</i>	<i>Nil slaughter interval</i>
<i>Apples &amp; apple pomace</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Grain legumes &amp; pulse fodder/stubble</i>	<i>4 weeks</i>	<i>42 day slaughter interval (foliar application only)</i>
<i>Cereal grains</i>	<i>4 weeks</i>	<i>Nil slaughter interval</i>
<i>Cereal fodder/stubble</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Pasture seed legumes</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Tropical and sub-tropical fruits &amp; fruit by-products</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Legume vegetables</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Other vegetables (e.g. leafy vegetables)</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Citrus &amp; citrus pulp</i>	<i>4 weeks</i>	<i>42 day slaughter interval</i>
<i>Note below that maize and sorghum fodder require at least an 8 week WHP combined with a 42 day slaughter interval to avoid Maximum Residue Limit violations. For certain commodities where the WHPs shown below have been observed, the following animal management measures are still required to avoid Maximum Residue Limit violations.</i>		
<b>Crop/Commodity</b>	<b>Observed Crop Harvest WHP</b>	<b>Required Animal Management</b>
<i>Cotton trash</i>	<i>Not applicable</i>	<i>Do not feed to animals</i>
<i>Green beans, green peas</i>	<i>2 days</i>	<i>Do not feed to animals</i>
<i>Maize grain</i>	<i>8 weeks</i>	<i>Nil slaughter interval</i>
<i>Maize fodder</i>	<i>8 weeks</i>	<i>42 day slaughter interval</i>
<i>Other vegetables (beetroot, cucurbits and tomato)</i>	<i>2 days</i>	<i>Do not feed to animals</i>
<i>Peanut hay</i>	<i>7 days</i>	<i>42 day slaughter interval</i>
<i>Sorghum grain</i>	<i>8 weeks</i>	<i>Nil slaughter interval</i>
<i>Sorghum fodder</i>	<i>8 weeks</i>	<i>42 day slaughter interval</i>

The following additional withholding periods and feeding restraints were introduced as part of the suspension of endosulfan products in September 2002:

**Withholding periods and feeding restraints introduced in September 2002 and superseded in June 2005**

- Pears: Do Not Harvest for 28 Days After Application
- Do Not Feed Apple Pomace, Citrus Pulp/Peel, Grape Marc/Pomace To Livestock
- Do Not Feed Pea Vines or Bean Trash to Livestock
- Do Not Feed Fodder, Stubble Or Hay of Pulse Crops (Adzuki Beans, Chickpeas, Cow Peas, Faba Beans, Field Peas, Lupins, Mung Beans, Navy Beans and Pigeon Peas) To Livestock
- Do Not Feed Treated Cow Peas, Field Peas and Pigeon Peas to Livestock

- Do Not Feed Cereal Grains to Livestock
- Do Not Feed Straw, Fodder or Trash from Treated Cereal Crops To Livestock
- Do Not Feed Sunflower Seed, Safflower Seed or Linseed to Livestock
- Do Not Feed Fodder, Stubble or Trash from Oilseed Crops (Canola, Cotton, Linseed, Peanuts, Safflower, Soya Beans, Sunflowers) To Livestock
- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Cut for Stockfeed or Allow Livestock to Graze: vetch, lucerne (seed crops), medics (seed crops), clover (seed crops), chou moellier, forage cereals and pastures (all with heliothis use rates)
- Do Not Feed Wrapper Leaves of Brassica and Cole Crops (Cabbage, Cauliflower and Broccoli) or Sweet Corn Trash to Livestock
- Do Not Feed To Livestock Any Treated Commodity Mentioned Above Which Has Been Bailed or Used in Silage

### 3.1.2 Label Use Patterns

Crop use patterns as shown on revised interim labels are given in Residues technical report (Volume 2 of this document).

## 3.2 DISCUSSION

In response to the interim regulatory requirements for endosulfan, metabolism studies, animal transfer studies, supervised crop trials, storage stability and processing studies have been submitted. The findings from those studies and associated recommendations are discussed in the following sections.

### 3.2.1 Citrus fruit

Data for oranges, mandarins and lemons were provided from trials conducted in Australia, Italy, Greece and Spain. Data for processed commodities such as juice and pomace were also submitted.

Registered use patterns in citrus allow spraying at concentrations ranging from 20 g ai/100L (spined citrus bug, bronze orange bug) to 70 g ai/100L or 735 g ai/ha (heliothis, citrus plant hopper, leaf hopper), with a 14 day withholding period. However, the citrus industry provided data for a lower spray concentration to better reflect current practices in the industry. Therefore the new 1× and 2× spray concentrations are 10.5 and 21 g ai/100L, with a proposed withholding period of 3 days.

Overseas data were generated using spray concentrations of 37.5 and 112.3 g ai/100L, which are in excess of the new citrus use pattern. These data are not suitable for establishment of an MRL, however the processing information can be used to determine processing factors (PF) for juice and pomace.

Data for oranges, mandarins and lemons were generated in Australia. The data corresponding to the proposed GAP are summarised below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Oranges, Vic	10.5 g ai/100L	3	0.049
	21 g ai/100L	3	0.22
Oranges, SA	10.5 g ai/100L	3	0.078
	21 g ai/100L	3	0.034 (pulp); 0.38 (peel)
Lemons, Vic	10.5 g ai/100L	3	0.17
	21 g ai/100L	3	0.70
Lemons, Qld	10.5 g ai/100L	3	0.033

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	21 g ai/100L	3	<0.02 (pulp); 0.36 (peel)
Lemons, SA	10.5 g ai/100L	3	0.16*
	21 g ai/100L	3	0.34
Mandarins, Qld	10.5 g ai/100L	3	0.11
	21 g ai/100L	3	0.18
Mandarins, SA	10.5 g ai/100L	3	0.071
	21 g ai/100L	3	0.14

\* Level of 0.036 mg/kg present in untreated control sample.

Residues in citrus fruit range from 0.033 to 0.17 mg/kg at 3 days following application at the 1× spray concentration. Residues in citrus fruit are in rank order: 0.033, 0.049, 0.071, 0.078, 0.11, 0.16 and 0.17 mg/kg. An MRL of 0.3 mg/kg is recommended for citrus fruit with highest residues (HR) of 0.078, 0.11 and 0.17 mg/kg for oranges, mandarins and lemons, respectively and a supervised trial medium residues (STMR) of 0.078 mg/kg.

In the overseas trials, spray concentrations of 37.5 and 112.3 g ai/100L (3.6× or 10.7×) were employed. Endosulfan residues in pulp, peel, juice and pomace were reported. In nine overseas trials, there was a 6-fold difference between residues found in peel vs whole fruit. In two Australian trials however, the difference between peel and whole fruit was 2-fold.

Residues in juice were <0.02 mg/kg in three orange trials; the mean PF was 0.12. The mean PF for wet pomace was 2.3. To estimate the livestock exposure from feeding of dry pomace, an STMR-P of 0.45 mg/kg is calculated ( $0.08 \text{ mg/kg} \times 2.3 = 0.18 \text{ mg/kg wet wgt}$ ; 0.45 mg/kg dry weight). This figure is included in the livestock dietary burden table (section 2.18).

Using an HR of 0.17 mg/kg in whole fruit and the PF for pomace, residues in wet pomace would be  $0.17 \times 2.3 = 0.39 \text{ mg/kg}$  or 0.97 mg/kg on a dry weight basis. An MRL of 2 mg/kg is recommended for citrus pulp and pomace, dry.

### 3.2.2 Pome fruit

The current use pattern for pome fruit is application at 66.5 g ai/100L with a withholding period of 14 days. Residues data were provided from trials conducted in Australia, Italy, France and Spain. Processing data for juice, cider and pomace were also submitted.

Overseas data for apples were generated using spray concentrations of 56.5 and 113 g ai/100L (0.8× and 1.7×). In the Australian trials, 1× and 2× spray concentrations were used on apples and pears. The data that are comparable to GAP are tabulated below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Apples, NSW	66.5 g ai/100L	14	0.29
		21	0.27
		14	0.38
Apples, Qld	66.5	14	0.53
Apples, Spain	56.5 g ai/100L	12	0.03
		21	<0.01
		28	<0.01
Apples, Spain	56.5 g ai/100L	12	0.05
		21	0.06
		28	<0.01
Apples, France	57 g ai/100L	13	<0.01
		21	<0.01
		28	<0.01
Apples, Italy	56.5 g ai/100L	14	0.23
		21	0.14
		28	0.11



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Apples, Italy	56.5 g ai/100L	14	0.04
		21	0.08
		28	0.03
Pears, Vic	66.5 g ai/100L	14	0.79
		21	0.42
Pears, SA	66.5 g ai/100L	14	0.44
		21	0.37

Allowing for a  $\pm 30\%$  difference in spray concentration at 14 days, the following residues correspond to GAP in rank order: <0.01, 0.03, 0.04, 0.05, 0.23, 0.29, 0.38, 0.44, 0.53 and 0.79 mg/kg. Based on the data at 14 days, the current temporary MRL of 2 mg/kg is appropriate with an HR of 0.53 mg/kg for apples<sup>2</sup> and 0.79 mg/kg for pears.

Applying the HR value for pears in the short-term dietary estimates, the intake exceeds the acute reference dose (ARfD) for the 2 – 6 year group and approaches the ARfD for the general population (99%). To refine the short-term estimate, the horticulture industry agreed to extend the withholding period for apples and pears from 14 days to 28 days.

The HR for apples at 28 days after treatment is 0.11 mg/kg, from trial data generated in Italy. For pears, the highest residues expected at 28 days would be 0.21 mg/kg, using extrapolation from Australian trial data.

It is recommended that the current temporary MRL of 2 mg/kg be amended to 1 mg/kg with a withholding period of 28 days. An STMR is not estimated for the group.

Residues in apple juice in a single Australian trial were 0.022 mg/kg and residues in cider from Italian trials were <0.01 mg/kg. The PFs for juice and cider were 0.06 and 0.04, respectively.

The mean processing factor for wet pomace, calculated from three trials including one Australian trial, is 2.1. Using a HR of 0.11 mg/kg for apples (28 days), residues in wet pomace will approximate 0.23 mg/kg. A processing factor of 5.8 is calculated in the Australian trial for dry pomace. Therefore applying the dry pomace factor to the HR gives a value of 0.64 mg/kg for dry pomace. An MRL of 1 mg/kg is recommended for apple pomace, dry.

### 3.2.3 Grapes

Currently, there is a temporary MRL of 2 mg/kg for berries and other small fruits, which corresponds to registered uses of endosulfan on grapes, currants, blueberries and strawberries. Overseas data were provided for grapes and processed commodities. The registered use pattern for grapes allows application at a spray concentration of 66.5 g ai/100L with a withholding period of 14 days. In trials conducted in Italy and Spain, concentrations of 113 g ai/100L were employed. As the spray concentrations in the studies do not correspond to GAP in Australia, the data do not support existing use patterns. Therefore, the use pattern for grapes should be deleted from all product labels. Similarly, as data were not provided for other berry fruit such as blueberries, currants and strawberries, these uses must also be deleted from product labels. It is recommended that the temporary MRL for berries and other small fruits be withdrawn from the MRL Standard.

<sup>2</sup> Data from the National Residues Survey monitoring program indicated that total endosulfan residues found in apples ranged from 0.05 mg/kg to 0.26 mg/kg. These data were obtained from 1238 samples over the period of 1998 – 2003; various varieties were sampled. The limit of reporting was 0.05 mg/kg.

### 3.2.4 Tropical and sub-tropical fruits – inedible peel

The Codex crop group for tropical fruits – inedible peel includes avocados, bananas, custard apples, kiwifruit, longans, lychees, mammey, mangoes, passionfruit, pawpaw, persimmon, pomegranate, rambutan, sapodilla and tamarillo, all of which are included on registered product labels. Supplementary residues data were generated recognising that there was no support for use on bananas, and that extrapolation to minor crops would be made from the data set provided. In addition, withholding periods shorter than 14 days (as indicated on current labels) were requested to better reflect industry practices. Australian residues data were provided for avocado, custard apples, mangoes, pawpaw, persimmon and lychees. GAP in Australia is application at spray concentrations of 52.5 – 70 g ai/100L with withholding periods of 7 or 14 days, depending on the fruit.

Residues data which correspond to GAP for the various fruits, are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Avocado, Qld	70 g ai/100L	14	0.02
Avocado, Qld	70 g ai/100L	14	0.065
Custard apple, Qld	70 g ai/100L	7	0.1
Custard apple, Qld	70 g ai/100L	7	0.34
Mango, NSW	70 g ai/100L	7	0.20
Mango, Qld	70 g ai/100L	7	0.17
Pawpaw, Qld	70 g ai/100L	7	0.18
Pawpaw, Qld	70 g ai/100L	7	0.095
Persimmon, Qld	70 g ai/100L	7	0.53
Persimmon, Qld	70 g ai/100L	7	0.89
Lychee, Qld	52.5 g ai/100L	7	0.95, 1.62 <sup>①</sup>
Lychee, Qld	52.5 g ai/100L	7	0.84, 1.16 <sup>①</sup>

① Two replicate samples combined and analysed.

The portion of the commodity to which the MRL applies is the whole commodity after removal of the stone or seed, but calculated on a whole fruit basis.

Looking at the data across the whole group, residues are in rank order: 0.02, 0.065, 0.095, 0.1, 0.17, 0.18, 0.20, 0.34, 0.53, 0.84, 0.89, 0.95, 1.16 and 1.62 mg/kg. On the basis of the data set provided, the temporary MRL of 2 mg/kg is appropriate for the whole crop group, with respect to existing and proposed use patterns. The highest residues for avocado, custard apple, mango, pawpaw, persimmon and lychee are 0.065, 0.34, 0.20, 0.18, 0.89 and 1.62 mg/kg, respectively. For the group, an STMR of 0.27 mg/kg is estimated. It should be noted that tamarillo is also to be included in this group.

### 3.2.5 Bulb vegetables

The current MRLs for endosulfan on bulb vegetables are T0.2 mg/kg for onions and T2 mg/kg for shallots. These correspond to application at a maximum rate of 735 g ai/ha and withholding periods of 7 days. As residues data for these crops (or any bulb vegetable) have not been provided, the existing use patterns and temporary MRLs will be deleted as they are no longer supported.

### 3.2.6 Brassica vegetables

Australian data were provided for broccoli, cauliflower, cabbage, and Brussels sprouts. Registered use patterns allow application at 735 g ai/ha or 66.5 g ai/100L with a withholding period of 2 days (cole crops). The horticulture industry has requested a withholding period of 7 days for Brassica vegetables. Data that correspond to GAP in Australia are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Broccoli, Qld	66.5 g ai/100L	7	0.29

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Broccoli, VIC	66.5 g ai/100L	7	0.17
Cauliflower, WA	66.5 g ai/100L	7	0.10
Cauliflower, VIC	66.5 g ai/100L	7	0.016
		7	0.094
Cabbage, Qld	66.5 g ai/100L	7	0.098
Cabbage, VIC	66.5 g ai/100L	7	0.031
		7	0.026
Brussels sprouts, SA	66.5 g ai/100L	7	1.9
Brussels sprouts	6.5 g ai/100L	7	0.14

Residues in Brassica at day 7 are in rank order: 0.016, 0.026, 0.031, 0.094, 0.098, 0.10, 0.14, 0.17, 0.29 and 1.9 mg/kg. Highest residues in broccoli, cauliflower and cabbage are 0.29, 0.1 and 0.098 mg/kg, respectively. The highest residue of 1.9 mg/kg in Brussels sprouts was found following application at 1.8× the maximum rate; scaling for rate, residues of 1.05 mg/kg are estimated at 7 days. Taking into consideration the high value, and only one other data point at GAP for Brussels sprouts, it is recommended that the Brussels sprouts use pattern be removed from product labels. On the basis of the data provided for broccoli, cabbage and cauliflower, MRLs of 1 mg/kg are recommended for broccoli, head cabbage and cauliflower. An STMR of 0.096 mg/kg is estimated for the chronic dietary exposure for broccoli, cauliflower and cabbage.

### 3.2.7 Cucurbits

Endosulfan is registered for use on cucurbits, with application at 66.5 g ai/100L and a withholding period of 2 days. Residues data were provided from trials conducted in Australia, Italy and Spain. In the overseas trials in melons, residues were determined in the pulp, peel and whole fruit. The horticulture industry requested that the current withholding period be extended from 2 days to 7 days. Data corresponding to Australian GAP are summarized below:

Commodity, Trial Site	Spray Conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Musk melon, Italy	56.5	3	<0.15 (whole fruit)
			<0.15 (pulp)
			0.22 (peel)
Musk melon, Italy	56.5	3	0.19 (whole fruit) 0.22
			<0.15 (pulp)
			0.48 (peel)
Rockmelon, VIC	66.5	3	0.55
Cucumber, NSW	66.5	7	0.12 <sup>①</sup>
Cucumber, Qld	66.5	7	0.094 <sup>①</sup>
Zucchini, NSW	66.5	3	0.09
Zucchini, Qld	66.5	3	0.055
Zucchini, Qld	66.5	3	0.087
Zucchini, WA	66.5	3	0.049

① Higher values selected at longer WHPs.

Using ±30% allowance in the spray concentration, Italian trial data for melons can be compared to the Australian spray concentration of 66.5 g ai/100L. Residues in the edible portion of the musk melon were <0.15 mg/kg in all of the overseas trials, at spray concentrations ranging 1 – 2.8× the Australian spray concentration.

Residues in cucurbits at 3 days after application are in rank order: 0.049, 0.055, 0.087, 0.090, 0.094, 0.12, <0.15, 0.22 and 0.55 mg/kg. An MRL of 1 mg/kg is recommended for cucurbits with a withholding period of 3 days. The HRs in rockmelon, cucumber and zucchini are <0.15 (pulp) or 0.55 (whole fruit), 0.12 and 0.09 mg/kg, respectively and the STMR is 0.094 mg/kg for the group.

Comments were received during the public consultation phase in relation to feeding of waste or cull melons to livestock, particularly cattle. As the proposed MRL for cucurbits exceeds the

current Primary Feed Commodity MRL of 0.3 mg/kg, the following feeding restraint has been included on product labels:

## Do Not Feed Treated Melon Crops Or Melons To Livestock

### 3.2.8 Fruiting vegetables

Australian data were provided for capsicum, tomato, eggplant and sweet corn as being representative members of the crop group, which also includes okra and cape gooseberry. The current use pattern is application at 66.5 g ai/100L or 735 g ai/ha and withholding periods of 2 days for tomatoes and 7 days for cape gooseberries, capsicums, eggplant, okra and sweet corn. The horticulture industry has requested a withholding period of 3 days for capsicums and tomatoes.

In the residue trials the application rates employed were 1× and 2× the maximum application rate, with sampling intervals up to 14 days. The data that correspond to GAP (proposed) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Capsicum, Qld	735	3	0.16
Capsicum, SA	735	3	0.40
Tomatoes, Qld	735	3	0.056
Tomatoes, Vic	735	3	0.069
Tomatoes, NSW	735	3	0.094
Eggplant, NSW	735	7	<0.02
Eggplant, Qld	735	7	0.055
Eggplant, Vic	735	7	<0.02
Eggplant, Qld	735	7	<0.02
Sweet corn, Qld	735	7	<0.02
Sweet corn, Vic	735	7	<0.02
Sweet corn, NSW	735	7	<0.02

Residues that correspond to GAP are in rank order: <0.02 (6), 0.055, 0.056, 0.069, 0.094, 0.16 and 0.40 mg/kg. The HRs for capsicum, tomato, eggplant and sweet corn are 0.40, 0.094, 0.055 and 0.02 mg/kg, respectively, with an STMR of 0.038 mg/kg. An MRL of 1 mg/kg is recommended for the fruiting vegetables group.

In relation to sweet corn fodder/trash, the following restraint was included as part of the interim regulatory action for endosulfan:

- *Do Not Feed Sweet Corn Trash To Livestock.*

On registered product labels, there had previously been no directions regarding the feeding of sweet corn fodder or trash to livestock. As data specifically for sweet corn fodder or trash were not provided, some extrapolation can be made from sorghum forage and trash. The use pattern for sorghum is detailed in section 2.14 under cereal crops, where application is at 735 g ai/ha with a withholding period of 4 weeks. Endosulfan residues in sorghum forage/fodder ranged from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. As the withholding period for sweet corn is 7 days, it is possible that residues in sweet corn fodder/trash may be even higher than the levels found in sorghum forage/fodder at 26 to 35 days.

As there was no previous feeding restraint regarding sweet corn fodder/trash and it is typical practice for sweet corn fodder to be used as a livestock feed, it is an outcome of the review that the sweet corn use pattern has been deleted from product labels, as the likely exposure to livestock from sweet corn fodder and trash may be at levels that are unacceptable in relation to existing animal commodity MRLs. Deletion of the use pattern does not result in a change to the MRL or STMR for the crop group.

### 3.2.9 Leafy vegetables

The Codex classification for leafy vegetables includes Brassica leafy vegetables and crops such as chard (silverbeet), Chinese cabbage, choy sum, leafy lettuce varieties (cos lettuce, endive, rocket), cress, Japanese greens (mizuna, indian mustard, komatsuna), head lettuce, spinach, pak choy, bok choy and a variety of other salad greens. Australian residues data were provided for bok choy, silverbeet, and leafy lettuce, which are considered representatives of the crop group.

In addition to the data that were generated in Australia there were several published reports of endosulfan residues in leafy vegetables, which are summarised in Residues Appendix 3. These include JMPR data (1989), review articles and information available from published papers.

The current registered uses of endosulfan on leafy vegetables (cole crops and leaf vegetables), silverbeet and spinach include application at 735 g ai/ha or 66.5 g ai/100L with withholding periods of 2 days for cole crops and silverbeet and 7 days for spinach. There is no specific withholding period statement for other leafy crops, where the use pattern is listed as *cabbages, cauliflower & other cole crops & leaf vegetables* on some product labels. For the purposes of data interpretation, the withholding period closest to label directions is taken as being nil or 0 days.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Spray conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Bok choy, Vic	66.5	0	3.4
Bok choy, Qld	66.5	0	29
Silverbeet, Vic	66.5	0	6.1
Silverbeet, Qld	66.5	0	18
Leafy lettuce, Vic	66.5	0	3.4
Leafy lettuce, Vic	514 g ai/ha	0	16
Leafy lettuce, NSW	66.5	0	16
Leafy lettuce, NSW	66.5	0	6.5
Leafy lettuce, Qld	66.5	0	1.54

There is a large variation in the residues present in the different crops, with levels ranging 1.54 – 29 mg/kg. As there is no clear withholding period statement for leafy vegetables, the 0 day data are taken as being reflective of the levels that would be found at harvest in some members of the crop group. The residues are in rank order: 1.54, 3.4 (2), 6.1, 6.5, 16 (2), 18 and 29 mg/kg.

Using the mean 0 day values from overseas data for the various leafy crops and scaling for the Australian application rate, estimated endosulfan residues in chard, spinach, leaf lettuce, head lettuce, endive and cos lettuce ranged from 7.9 mg/kg to 20 mg/kg. This range of values is comparable to the 0 day data from the Australian trials in silver beet and leafy lettuces. The published data support the findings in the Australian trials.

Based on the data reviewed, an MRL of 40 mg/kg would be recommended for leafy vegetables, with HRs of 18 mg/kg for silverbeet, 29 mg/kg for bok choy and 16 mg/kg for leafy lettuce. As there is a large variation in residues, an STMR cannot be estimated for the crop group.

A longer withholding period has been considered to determine if residues would comply with the current temporary MRL of 2 mg/kg. However, using the 14 day data, the acute reference dose is still exceeded for both the 2 – 6 year age group and the general population. Based on the short-term estimate of intake for both the 2 – 6 year subpopulation and the general population, it is recommended that the leafy vegetables use patterns should be deleted from all product labels, as the estimated dietary exposure is unacceptable using current methods of assessment (section 2.21).

Action was taken to withdraw registered uses of endosulfan on leafy vegetables as part of the suspension of products in September 2002.

### 3.2.10 Legume vegetables

Residues data were provided for green peas and green beans from trials conducted in Italy, France and Australia. In the overseas trials, samples of green plant material were collected to give an indication of residues that may be present in animal feed commodities, such as pea vines. Processing data were also generated with residues being determined in canned peas.

Current use patterns allow application at 735 g ai/ha with a withholding period of 2 days. The horticulture industry has requested that the withholding period be extended to 7 days for both crops. Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Green beans, Qld	735	7	0.15
Green beans, Tas	735	7	<0.02
Green beans, Vic	735	7	0.092
Green peas, Qld	735	7	0.082
Green peas, Qld	735	7	0.12
Green peas, Vic	735	7	0.37
Plant material, France	749	7	1.65 (6.6 dry wgt)*
Plant material, France	780	7	2.2 (8.8 dry wgt)
Plant material, Italy	780	7	1.24 (4.9 dry wgt)
Plant material, Italy	750	7	2.67 (10.7 dry wgt)
Pea hay, Qld	735	7	3.1 (12.4 dry wgt)

\* Using 25% DM for green material.

Data for green peas and beans that correspond to GAP are in rank order: <0.02, 0.082, 0.092, 0.12, 0.15 and 0.37 mg/kg. The HR for green peas is 0.37 mg/kg and for green beans is 0.092 mg/kg. An MRL of 1 mg/kg is recommended for legume vegetables with a withholding period of 7 days; an STMR of 0.11 mg/kg is estimated for the group.

In relation to animal feed commodities, the highest residues found in plant material were 12.4 mg/kg on a dry weight basis, with values ranging from 6.6 to 12.4 mg/kg. The current primary feed commodity MRL in Table 4 of the MRL Standard is 0.3 mg/kg. As an interim measure, the following recommendation was made as part of the suspension of endosulfan products:

- *Do Not Feed Treated Pea Vines or Bean Trash to Livestock*

On registered product labels, there are directions regarding the feeding of green beans and green peas; crop by-products such as pea vines and bean hay are however not specifically mentioned. The directions regarding green beans and green peas are:

- *Do Not Feed To Animals*

Although it is recognised that green peas and beans are primarily grown for human consumption, it is claimed that pea hay and other legume hays and vines are routinely cut and fed to livestock or grazed by livestock following harvest. Due to this potential exposure and the associated trade implications, two alternative approaches were considered for the use of endosulfan on legume vegetables:

1. continue to permit the use, with the following label restraint:
  - **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**
2. delete the uses.



As a feeding restraint would be contrary to common livestock grazing and feeding practices, the APVMA has concluded that the use patterns for green beans and peas will be deleted from product labels, as the likely exposure to livestock from feeding of pea and bean vines and hay may be at levels that are unacceptable in relation to existing animal commodity MRLs.

These options are discussed more fully in section 3.2.21.

### 3.2.11 Pulse crops

Endosulfan is registered for use on a number of pulse crops including adzuki beans, chickpeas, cow peas, faba beans, field peas, lupins, mung beans, navy beans and pigeon peas. In all cases, there are two specific use patterns and application timings. The first is an early pre-emergent application for control of red legged earth mite (RLEM) and blue oat mite at rates of 175 – 350 g ai/ha. The approximate interval between application and harvest would range between 140 and 200 days, depending on the crop.

The second application is at a later stage of crop growth, at a maximum rate of 735 g ai/ha and is primarily for control of heliothis and other pests including loopers, corn earworms and green vegetable bugs. The withholding period for the later application is 28 days. Associated with the late stage application is a slaughter interval of 42 days for livestock that may be fed stubble, hay or fodder resulting from crops that have been treated with endosulfan. This slaughter interval is to allow any residues in animal commodities to fall below the domestic MRLs.

Australian data were generated for chickpeas, cow peas, faba beans, field peas, lupins and navy beans, as representatives of the pulse crop group. Trials were designed to reflect residues resulting from both use patterns, the early mite treatment and the late stage heliothis treatment. In many of the trials, four replicate samples were analysed separately, and these are individually tabulated to give an indication of the variation between replicate plots, especially in the trash/fodder samples.

Data that correspond to GAP (mite and heliothis treatment) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Navy beans, Qld	735	41	0.031, 0.036, 0.046, 0.053
Navy beans, Qld	735	26 (1 spray)	0.012, 0.018
		26 (2 sprays)	<0.015, 0.040
		33 (2 sprays)	0.026, 0.051
Faba beans, NSW	350	196	<0.015, <0.015
	350 + 735	60	0.027, 0.028, 0.028, 0.1
Cow peas, Qld	735	28	0.30, 0.31, 0.32, 0.35
		35	0.16 (2), 0.22, 0.26
Cow peas, Qld	735	28	0.24, 0.27, 0.32, 0.35
		35	0.14 (2), 0.16, 0.19
Field peas	350	157	<0.015, <0.015
	350 + 735	49	0.006 (2), 0.007, 0.011
Lupins	350	203	<0.015, <0.015
	350 + 735	49	0.023, 0.055
Chickpeas	350	142	<0.015, 0.006
	350 + 735	38	0.12, 0.15, 0.20, 0.21
Navy bean trash/stubble	735	28	6.1, 12.7, 15, 16.1
Navy bean trash/stubble	735	26 (1 spray)	2.4, 6.3
		26 (2 sprays)	1.3, 1.8
		33 (2 sprays)	0.7, 1.4
Faba beans	350	196	0.034, 0.035
Cow pea trash/stubble	735	28	23, 29, 35, 37
		35	25, 30, 31, 46,
Cow peas trash/stubble	735	28	20, 25, 29, 47

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Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
		35	26 (2), 32, 33
Field pea forage	350	47	<0.1, <0.1
Field pea straw	350	157	0.035, 0.047
	350 + 735	49	0.32, 0.37, 0.40, 0.48
Lupin forage	350	61	<0.1, <0.1
Lupin straw	350	203	<0.1, <0.1
	350 + 735	49	0.19, 0.24
Chickpea forage	350	38	0.17, 0.22, 0.27, 0.29
Chickpea straw	350	157	0.06, 0.17
Chickpea straw	350 + 735	49	2.2, 4.3, 4.5, 9.4

LOD = 0.005 mg/kg in grain; LOQ = 0.1 mg/kg in grain, forage and straw

Residues in pulses are below the current temporary MRL of 1 mg/kg, with a 28 day withholding period. Although residues in cow peas at 28 days are above the primary feed commodities MRL of 0.3 mg/kg, current residues management advice indicates that a 42 day slaughter interval applies to livestock that may be fed treated pulses, therefore a feeding restraint for pulses is not required.

Residues in forage, stubble, straw and trash range from <0.1 to 47 mg/kg across the crop group. The current primary feed commodity MRL of 0.3 mg/kg is clearly exceeded for a number of those feed commodities. Applying an additional 42 days slaughter interval for livestock is only appropriate to those feed commodities in which residues are <2 ppm. The highest residues were found in cow pea fodder, where a slaughter interval of 70 days (on clean feed) would be required for livestock that would be exposed to fodder from treated crops.

As it is common agricultural practice to allow livestock to graze forage, straw and stubble of treated pulse crops, it is considered that a feeding restraint on product labels would be contrary to common practices. In addition, as a slaughter interval of 42 days on clean feed is not sufficient to allow endosulfan residues in animal commodities to fall below the current animal commodity MRLs, it is recommended that the late use pattern for control of heliothis and other pests (application at 735 g ai/ha with a 28 day withholding period) be deleted from all product labels. The early mite control treatment can be supported, and therefore on the basis of the data provided, residues in pulses are in rank order: 0.006 and <0.015 (7) mg/kg. An MRL of \*0.1 mg/kg is recommended for pulses, with a nil withholding period for harvest.

Endosulfan residues in pulse forage (field peas, lupins and chickpeas) range from <0.1 to 0.29 mg/kg for samples taken at 38 to 61 days after treatment. The highest residues of 0.29 mg/kg dry weight were found in chickpea forage at 38 days after treatment. The data support an MRL of 0.3 mg/kg for pulse forage with a grazing withholding period of 49 days. This recommendation is made recognising that residues in forage should decline to below the current primary feed commodities MRL (0.3 mg/kg) within 49 days after treatment.

Endosulfan residues in pulse straw and stubble ranged from <0.1 mg/kg to 0.17 mg/kg for samples taken at harvest (157 to 203 days after treatment). An MRL of 0.3 mg/kg is recommended for pulse straw and fodder with a withholding period similar to that for harvest of the grain, i.e. nil.

### 3.2.12 Root and tuber vegetables

Current GAP for root and tuber vegetables (potato, carrot, beetroot, sweet potato, taro) allows application at 735 g ai/ha with withholding periods of 2 days for beetroot and 7 days for carrots, potatoes, sweet potatoes and taro. Taro is found on only two registered product labels<sup>3</sup>.

<sup>3</sup> Thiodan EC Insecticide and Farmoz Endosulfan 350EC Insecticide.



The horticulture industry has requested that the withholding periods for all root and tuber vegetables be extended to 14 days.

Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Beetroot, Qld	735	14	0.20
Carrot, SA	735	14	0.06
Carrot, SA	735	14	0.095
Carrot, WA	735	14	0.037
Potato, Vic	735	14	<0.02
Potato, Qld	735	14	<0.02
Potato, WA	735	14	<0.02
Sweet potato, Qld	735	14	<0.02

Residues in root vegetables are in rank order: <0.02 (4), 0.037, 0.06, 0.095 and 0.2 mg/kg. An MRL of 0.5 mg/kg is recommended for root vegetables with a withholding period of 14 days for all root vegetables. The HRs for beetroot, carrot, potato and sweet potato are 0.2, 0.095, 0.02 and 0.02 mg/kg, respectively. An STMR of 0.028 mg/kg for the crop group is estimated for chronic intake purposes.

### 3.2.13 Stalk and stem vegetables

The current registered use pattern for celery is 66.5 g ai/100L with a withholding period of 2 days. This use is only found on one product label<sup>4</sup>. Australian data were provided for celery and rhubarb to allow consideration of a group MRL. The horticulture industry has requested withholding periods of 7 days for celery and rhubarb. As there is no use pattern for rhubarb, the proposed GAP only is considered.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Celery, Qld	735	7	0.59
Celery, Vic	735	7	0.26
Rhubarb, Qld	735	7	0.059
Rhubarb, Qld	735	7	0.34

Residues in celery at 7 days after application are 0.26 and 0.59 mg/kg. These levels are below the temporary MRL of 2 mg/kg for stalk and stem vegetables.

The data that correspond to proposed GAP are in rank order: 0.059, 0.26, 0.34 and 0.59 mg/kg. The HRs for celery and rhubarb are 0.59 and 0.34 mg/kg, respectively. There are an insufficient number of data points to estimate an STMR for the group. On the basis of the data provided, an MRL of 1 mg/kg is recommended for stalk and stem vegetables with a withholding period of 7 days.

### 3.2.14 Cereal crops

Use of endosulfan on cereals includes two specific application timings, an early pre-emergent application for control of RLEM at 175 or 350 g ai/ha and applications at a later stage of crop growth for control of armyworm at 525 g ai/ha and heliothis at a rate of 735 g ai/ha. The use patterns for sorghum and maize differ from other cereal crops, as the only registered uses in these two crops are for heliothis control at 735 g ai/ha. The withholding period in all cases is 4 weeks for harvest.

<sup>4</sup> Nufarm Endosulfan 350EC Insecticide.

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In the residue trials, samples from four replicate plots following two applications were analysed separately (as for pulses) and these are individually tabulated to give an indication of the variation between replicate plots, especially in the fodder/trash material. Data that correspond to GAP (heliethis control) for sorghum are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Sorghum, NSW	735	26	0.55, 0.78, 0.88, 1.1
		31	0.60, 0.66, 0.74, 0.94
Sorghum, NSW	735	29	0.42, 0.44, 0.56, 0.87
		35	0.27, 0.31 (2), 0.34
Sorghum, Qld	735	27	0.31, 0.37, 0.43, 0.44
		32	0.25, 0.34, 0.39, 0.51
Sorghum, NSW	735	27	1.5, 1.6, 1.7, 2.1
		34	0.88, 0.9, 1.0 (2)
Sorghum fodder/trash	735	26	30, 43, 55, 79
		31	22, 26, 39, 47
Sorghum fodder/trash	735	29	7, 15, 23, 31
		35	12, 13, 15, 21
Sorghum fodder/trash	735	27	5, 6 (2), 7
		32	3 (3), 5
Sorghum fodder/trash	735	27	47, 49, 55, 63
		34	16, 28, 36, 43

The data for sorghum can be extrapolated to maize; data for sorghum fodder can be extrapolated to maize and sweet corn fodder.

The registered uses of endosulfan on sorghum and maize are for control of heliothis, sorghum midge, sorghum head caterpillar and peach moth, and application timings are typically from head-emergence onwards. The data for sorghum clearly show that residues in grain at 28 days after application are greater than the current temporary MRL of 0.2 mg/kg for cereal grains. In the sorghum trials sampling intervals ranged from 26 to 51 days after application, and in the majority of the trials, residues in sorghum were above the temporary MRL for cereal grains and the primary feed commodities MRL, even at 51 days after application.

Registered labels offer contradictory advice with respect to sorghum and maize grain and corresponding fodder/stubble/trash. The residue management statements advise that a withholding period of 8 weeks would be required for grain used for livestock feed with a nil slaughter interval. However in the crop listing, sorghum, maize and other cereals may be harvested after 4 weeks for human consumption.

Residues in sorghum fodder range from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. The data clearly show that residues far in excess of the primary feed commodity MRL of 0.3 mg/kg may be present in sorghum fodder at 4 to 5 weeks after application. If livestock were exposed to the highest level of 79 mg/kg, approximately 80 to 90 days on clean feed would be required for residues in meat (fat) to fall below the domestic MRL of 0.2 mg/kg. The interim recommendation for sorghum and maize fodder as part of the suspension of endosulfan products was:

- *Do Not Feed Treated Sorghum or Maize Fodder to Livestock; and*
- *If livestock have been fed treated sorghum or maize grain or fodder, animals must be kept on clean feed for at least 90 days before slaughter.*

As discussed above in section 2.11 (pulse crops), it is common practice to feed sorghum, maize and their crop parts to livestock; sorghum is predominantly grown for livestock feed. As a feeding restraint would be contrary to common livestock grazing and feeding practices and a slaughter interval of 90 days is considered impractical, the use patterns for sorghum and maize should be deleted from product labels.

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Data that correspond to GAP for other cereal grains, except sorghum and maize are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Barley, Vic	350	158	0.008, 0.01
	350 + 735	42	0.66, 1.0, 1.1, 1.3
Barley, NSW	350	189	0.009, 0.05
	350 + 735	53	0.55, 0.46, 0.62, 0.72
Wheat, WA	350	203	<0.005 (2)
	350 + 735	49	<0.005 (2)
Wheat, NSW	350	130	<0.005 (2)
	350 + 735	35	<0.005, 0.046, 0.048, 0.099
Barley forage	350	70	0.079, 0.083
Barley straw	350	158	0.21, 0.22
Barley straw	350	158	0.1, 0.36
Barley straw	350 + 735	42	4.3, 5.1, 5.7, 6.4
Barley straw	350 + 735	42	1.6, 2.4, 2.9, 4
Wheat forage	350	61	<0.005 (2)
Wheat straw	350	203	<0.005, <0.005
Wheat straw	350	130	0.03, 0.03
Wheat straw/trash	350 + 735	49	0.24, 0.32
Wheat forage	350	55	0.25, 0.29
Wheat straw	350 + 735	35	0.39, 0.81, 1.4, 1.6

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in grain, forage and straw.

The data for barley and wheat can be extrapolated to other cereal grains such as oats, rye and triticale. The withholding period for cereal grains is 28 days. The results show that residues in grain following the late application for heliothis control are greater than the current temporary MRL of 0.2 mg/kg at 28 days after application and are greater than the primary feed commodities MRL of 0.3 mg/kg. However, for the pre-emergent mite treatment, residues comply with the current MRL.

The residues management advice on registered labels is again contradictory in relation to cereal grains, and a withholding period of 4 weeks with a nil slaughter interval is indicated. The barley data indicate that a slaughter interval of up to 20 days on clean feed may be required for livestock that may be fed barley grain from treated crops.

Residues in barley and wheat straw/fodder (heliothis treatment rates) are greater than the primary animal feed commodities MRL of 0.3 mg/kg at intervals longer than 4 weeks. Label advice is required for livestock that are exposed to fodder or straw from treated crops. If animals were exposed to the highest levels of 6.4 mg/kg in barley straw, approximately 50 days on clean feed would be required for residues in fat to comply with the current animal commodity MRLs.

Residues data indicate that current use patterns (critical GAP heliothis control) for cereals require a slaughter interval for livestock in addition to the crop withholding periods, in order that the animal commodity MRLs are not violated. As it is common practice to feed cereal grains and their straw/hay to livestock, it is recommended that the late stage applications for heliothis control and other pests should be deleted from product labels. The use patterns that will remain are early pre-emergent applications for mite control. On the basis of that use pattern only, the temporary cereal grains MRL of 0.2 mg/kg may be amended to 0.1 mg/kg with a nil withholding period for harvest.

Residues in wheat and barley forage range from <0.1 mg/kg to 0.29 mg/kg at intervals of 55 to 70 days after treatment. On the basis of the data provided, a grazing withholding period of 10 weeks is recommended together with an MRL of 0.3 mg/kg for cereal forage. Residues in wheat and barley straw ranged from <0.1 to 0.36 mg/kg at intervals ranging 158 to 203 days after application. An MRL of 0.4 mg/kg is recommended for cereal straw and fodder, with a nil withholding period for harvest.

### 3.2.15 Tree nuts

Endosulfan is registered for use on cashews, macadamias, pecans and pistachios. The current use pattern is 52.5 g ai/100L or 525 g ai/ha and a withholding period of 14 days for the nuts mentioned above. The horticulture industry has requested that the withholding period for macadamias be reduced to 2 days.

Residues in macadamias at 2 days after application were <0.01 mg/kg in three trials conducted in NSW and Qld. The temporary MRL of 2 mg/kg adequately covers the current use patterns for cashews, macadamias, pecans and pistachios. On the basis of the data provided, an MRL of 0.05 mg/kg is recommended for tree nuts, with a withholding period of 2 days for macadamias and 14 days for cashews, pecans and pistachios.

### 3.2.16 Oilseeds

For oilseeds (canola, cotton, linseed, peanuts, soy beans, safflower, sunflowers), there are two specific application timings of endosulfan. One is an early pre-emergent application for control of RLEM and blue oat mite at rates of 175 – 350 g ai/ha and the other is application at a later stage of crop growth for heliothis control at rates of 735 g ai/ha. The withholding period for peanuts is 7 days, and 28 days for other oilseeds.

The use patterns for cotton and peanuts only include the late heliothis application, whereas for the other oilseed crops, both early and late applications are permitted.

For cotton, registered labels have a specific page entitled 'Conditions of Use on Cotton'. In the conditions of use, application timings (aerial application) are limited to between 15 November to 15 January in NSW and 1 November to 31 December in Qld, with a maximum of 3 sprays at 735 g ai/ha. These timings would indicate that the period between final application and harvest would approximate 8 to 10 weeks.

The residue management section of product labels lists only cotton seed and meal (4 week withholding period with a nil slaughter interval for livestock), cotton trash and peanut hay. For cotton seed and meal, there is a direction that cotton trash must not be fed to livestock.

For peanut hay, there is a 7 day withholding period with a 42 day slaughter interval for livestock that may be fed treated hay. As data for peanuts and peanut hay were not provided to enable an assessment of the residues and trade situation, the uses should be deleted from all endosulfan product labels.

Data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Canola	350	203	<0.005, <0.005
	350	211	<0.005, <0.005
	350	188	<0.005, <0.005
Cotton, NSW	735	27	0.007, 0.037, 0.047, 0.055
	735	41*	0.009, 0.029, 0.042, 0.080
Soya beans, Qld	735	28	0.018, 0.020, 0.033, 0.042
Sunflowers, NSW	735	29	0.12, 0.21, 0.28, 0.31
		34	0.16, 0.18, 0.23, 0.51
Canola forage	350	61	<0.005, <0.005
	350	47	0.23, 0.25
	350	98	0.09, 0.10, 0.11
	350	79	0.04, 0.05
Canola straw	350	203	0.006, 0.01

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Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
	350	211	0.008, <0.005
	350	188	0.05, 0.05
Cotton lint	735	27	0.069, 0.14, 0.19, 0.33
	735	41*	0.024, 0.066, 0.084, 0.10
Soya bean fodder/trash	735	28	1.5, 3.0, 3.2, 4.4
Sunflowers fodder/trash	735	29	9, 12, 13, 15
		34	39, 62, 59, 83

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in seed, forage and straw/trash. \* Closest interval in trials in relation to 'Conditions of use on cotton'.

In the canola trials, samples of seed and straw/trash were taken at 49 and 54 days after application at 735 g ai/ha, which do not strictly correspond to the critical GAP, therefore those data have not been included in the above table.

Endosulfan residues in cotton seed, soy beans and sunflowers were below the current temporary MRL of T1 mg/kg. The highest levels found were 0.51 mg/kg in sunflower seed.

Residues in fodder and trash of soy beans and sunflowers range from 1.5 to 83 mg/kg. As the levels clearly exceed the primary feed commodities MRL of 0.3 mg/kg, the following interim recommendation was made, noting there was no label direction in relation to feeding of oilseed fodders and trash:

- *Do Not Feed Fodder, Stubble or Trash from Treated Oilseeds (Canola, Cotton, Linseed, Peanuts, Safflower, Soya beans, Sunflowers) to Livestock*

The levels of endosulfan that are found in soybean fodder and sunflower trash would require a slaughter interval of greater than 42 days for any livestock that may have been fed treated commodities. As an interim measure, it was recommended that any livestock that may have been fed any oilseed fodder or trash must be kept on clean feed for 90 days before slaughter.

## Cotton

In relation to cotton, registered labels have a specific page entitled 'Conditions of Use on Cotton'. In these conditions of use, application timings (aerial application) are limited to between 15 November to 15 January in NSW and 1 November to 31 December in Qld, with a maximum of 3 sprays at 735 g ai/ha. These timings would indicate that the period between final application and harvest would approximate 8 to 10 weeks, therefore the withholding period for cotton should be equivalent to 8 to 10 weeks. As of 4 January 2005, new conditions regarding the dates of application to cotton were published, where the dates for ground-based applications were set to match the existing dates for aerial application and the spray window extends from 1 October to 15 January for both NSW and Qld. Therefore the use pattern for cotton is determined by the application timings specified in the conditions of use.

For cotton, sampling in one trial was undertaken at 93 days and in another trial at 27, 41 and 80 days after application. As sampling in only one trial approximated the withholding period of 8 to 10 weeks, only one set of data from 41 days is included in the table below.

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Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Cotton, Qld (2004)	735 (EC)	49	<0.02, <0.02
Cotton, Qld (2003/2004)	735 (EC)	49	<0.02, <0.02
Cotton, NSW (2003/2004)	735 (EC)	48/49	<0.02, <0.02
Cotton, NSW (2003/2004)	735 (EC)	49	<0.02, <0.02
Cotton, NSW 1999	735 (EC)	41*	0.009, 0.029, 0.042, 0.080

\* Closest interval in trials in relation to 'Conditions of use on cotton'.

Residues in cotton fodder are not tabulated, as the control samples in one relevant trial were contaminated, therefore the data must be interpreted with care. The levels of endosulfan in cotton fodder ranged 1 to 12 mg/kg, at intervals of 27 and 41 days after application.

As feeding of cotton fodder, stubble and trash is not considered to be Good Agricultural Practice (GAP), the following feeding restraint was re-emphasised as part of the 1998 interim recommendations for the endosulfan review:

- *Do Not Feed Cotton Forage, Stubble, or Trash to Livestock*

The use of endosulfan for cotton production has previously been linked to residues in beef, for example, from spray-drift, contaminated feed and poor management practice. However, significant measures have been put in place by the APVMA and the cotton industry aimed at preventing endosulfan contamination in meat commodities, with a high level of success.

Never-the-less, the risk of residues in trade for the meat industry remains from the feeding of cotton fodder, stubble and trash, particularly in drought situations.

In assessing the use of endosulfan in cotton, two alternative approaches were considered:

1. continue to permit the use of endosulfan on cotton, with the following label restraint:
  - **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**
2. delete the uses of endosulfan on cotton.

These options are discussed more fully in section 3.2.21.

The oilseeds data (as with pulses and cereals) indicate that endosulfan residues in fodder, straw and trash following application at 735 g ai/ha (heliothis control) were clearly greater than the primary feed commodity MRL of 0.3 mg/kg and slaughter intervals ranging 20 to 90 days on clean feed would be required if livestock were exposed to such levels for prolonged periods. As a 90 day slaughter interval is not considered to be practical, it is recommended that the late stage application for heliothis control (735 g ai/ha) be deleted from product labels for oilseeds (except cotton).

The current temporary MRL of 1 mg/kg is appropriate for the remaining uses on oilseeds, which include mite treatment only. A nil withholding period for harvest is recommended in relation to the above MRL for canola, linseed, soybeans, safflower and sunflowers. For cotton, the withholding period is 8 weeks. As the oilseed MRL of 1 mg/kg will also accommodate the existing cotton seed oil MRL of T0.5 mg/kg, the oil MRL is not required.

Forage data were generated for canola only, at the timings and rates applicable for mite control. Residues ranged <0.1 to 0.25 mg/kg at intervals of 47 to 79 days after application. On the basis of the canola forage data, an MRL of 0.3 mg/kg is recommended for oilseed forage with a grazing



withholding period of 8 weeks. This should allow sufficient time for residues in other oilseed forages to decline to below the maximum feed level of 0.3 mg/kg.

Similarly with straw and fodder of oilseeds, data for canola were generated at the 350 g ai/ha rate and mite application timings. On the basis of the data provided an MRL of \*0.1 mg/kg is recommended for oilseed straw and fodder with a nil withholding period for harvest/grazing.

The majority of submissions received during the consultation period supported of option 1 for use of endosulfan on cotton (see above), with a revised restraint statement for feeding of cotton trash and remaining crop by-products after harvest. On that basis, the oilseed MRL of 1 mg/kg will adequately accommodate residues in cotton seed, with a withholding period of 8 weeks as determined by application dates and timings. As the oilseed MRL will also accommodate residues in cotton seed oil, the existing cotton seed oil MRL of T0.5 mg/kg is not required. The following feeding restraint is recommended:

### **Do Not Feed Cotton Fodder, Stubble or Trash to Livestock**

#### **3.2.17 Pastures and related crops**

Use patterns for clover and medic seed crops, lucerne seed crops, pastures, chou moeiller and vetch are found on a number of product labels. Residues data for pastures were requested as part of the interim regulatory action in 1998, however no new data were generated.

In the 1998 APVMA review of endosulfan, data from the 1989 JMPR were evaluated against registered use patterns<sup>5</sup>. The data were from single applications ranging from 210 to 530 g ai/ha or 0.3 to 0.7× the maximum application rate in Australia. As the data did not correspond to GAP in Australia, additional data were requested.

As new data supporting the existing use patterns have not been provided, the APVMA cannot be satisfied that pastures and related crops will not contain residues at unacceptable levels. Therefore, it is recommended that all use patterns relating to control of pests on pastures, clover and medic crops, lucerne, chou moeiller and vetch must be deleted from all registered labels.

#### **3.2.18 Animal feed commodities and animal commodity MRLs**

A list of animal feed commodities and residues therein is given in Table 1. The data are taken from residue trials described in section 8.

**Table 1: Livestock dietary burden estimates from Australian residues data (Cattle)**

Commodity	HR/STMR-P (mg/kg)	Livestock diet (%)	Residues in feed (ppm)
Citrus pulp	0.45 <sup>①</sup>	20	0.09
Apple pomace	0.64	20	0.13
Pulses	0.016	100	0.016
Pulse forages	0.29	100	0.29
Pulse straw/fodder	0.17	100	0.17
Cereal grains	0.015	100	0.015
Cereal forage	0.29	100	0.29
Cereal straw/fodder	0.36	100	0.36
Oilseed forage	0.25	100	0.25
Oilseed straw/fodder	0.05	100	0.05

① PF × STMR in residue trials.

<sup>5</sup> Page 55 of the APVMA Review of Endosulfan.

It should be noted that residues data were generated for representatives of particular crop groupings, therefore there are other feed commodities from related crops for which data were not provided, but for which valid extrapolation can be made. For example, the data for sorghum fodder can be extrapolated to maize and sweet corn fodder. Similarly, the data for navy beans and cow peas can be extrapolated to other pulse crops such as mung beans, faba beans, field peas, chickpeas, lupins, adzuki beans and pigeon peas. The sunflower data can be extrapolated to safflower and the data for sunflower and canola can be extrapolated to linseed. Similarly the barley straw data can be extrapolated to wheat, oats, rye and triticale.

The current animal commodity MRLs of T0.2 mg/kg in edible offal, 0.2 mg/kg in meat (mammalian)[in the fat] and T0.5 mg/kg in milk (in the fat) are based on a maximum feed level of 0.3 ppm<sup>6</sup>. Existing labels included crop harvest and grazing withholding periods, together with a 42 day slaughter interval for livestock that may graze or be fed a number of commodities treated with endosulfan (see section 8). This withhold from slaughter period was to allow residues in livestock (specifically fat) to decline to below the domestic MRL.

With the deletion of late stage applications in broadacre crops except cotton (specifically application at 735 g ai/ha with a 28 day withholding period), the dietary burden table is significantly different to that previously considered in the interim report. The greatest exposure to grazing livestock is from cereal straw and fodder, following application for mite control.

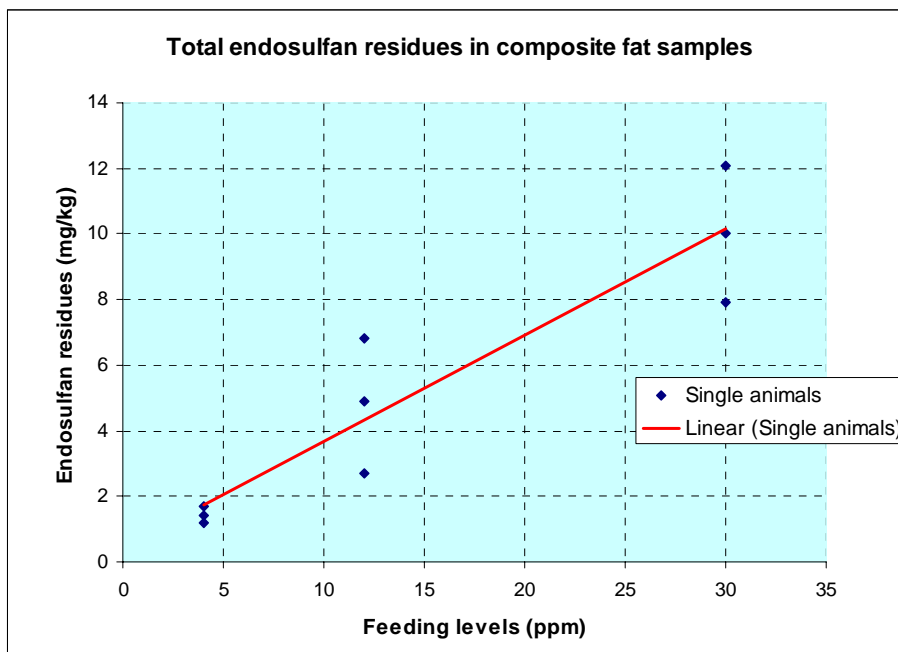
For all feed commodities considered, the exposures approach the maximum feed level of 0.3 mg/kg, with levels ranging from 0.015 to 0.36 mg/kg. However, on the basis of the estimates presented in the dietary burden table, a maximum feed level of 0.4 mg/kg is appropriate. Following dosing for 28 days at a feed level of 4 ppm, maximum residues of 0.07 mg/kg in muscle, 1.7 mg/kg in composite fat, 0.98 mg/kg in liver, 0.08 mg/kg in kidney and 0.08 mg/kg in whole milk, were found. The mean levels (n = 3) of total endosulfan were 0.04 mg/kg in muscle, 1.4 mg/kg in composite fat, 0.7 mg/kg in liver, 0.07 mg/kg in kidney and 0.07 mg/kg in whole milk. The scatter of results for composite fat is shown in figure 3.1.

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<sup>6</sup>The NRA review of Endosulfan (Aug 1998); Agricultural Assessment. Prelim report *Endosulfan Uptake Study* 1996.



**Figure 3.1.**



At higher feed levels, the scatter or variation observed between single animals is greater than that found at the lowest feed level of 4 ppm.

Scaling the residues in fat (highest single animal result) for exposure at a level of 0.4 ppm, residues of 0.17 mg/kg would be expected. This is still within the current MRL of 0.2 mg/kg for meat (mammalian)[in the fat]. Applying the same principle to muscle and edible offal, residues of 0.1 and 0.008 mg/kg are estimated for liver and kidney, respectively, and 0.007 for muscle. It is recommended that the current temporary MRL of 0.2 mg/kg for edible offal (mammalian) be made a permanent MRL.

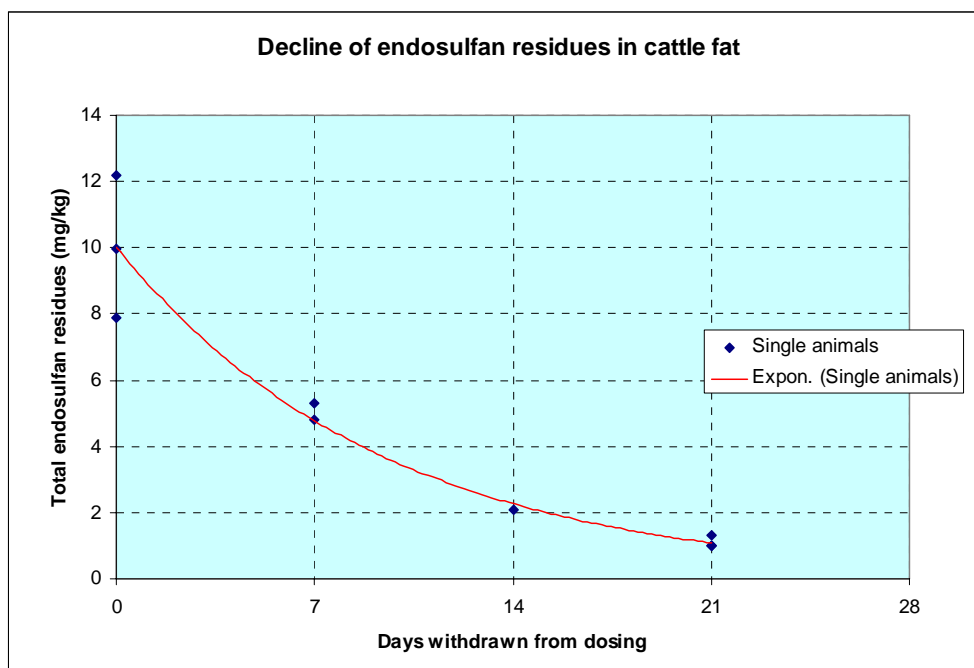
Maximum residues of 0.08 mg/kg were present in whole milk following dosing at 4 ppm for 28 days, which is scaled to 0.008 mg/kg for a maximum feed level of 0.4 mg/kg. After 7 days of dosing, total endosulfan levels appeared to plateau in milk, with an occasional spike at a later sampling point (see section 4.2.1). On the basis of the data for milk, the current temporary entry of 0.5 mg/kg for milk [in the fat] should be amended to 0.02 mg/kg for whole milk.

Residues were determined in cream following dosing at 12 ppm for 9 days, with levels ranging from 0.81 to 1.42 mg/kg. Maximum endosulfan residues in milk following dosing at 12 ppm were 0.22 mg/kg. A mean concentration factor of 4.7 is estimated from these results.

Depuration of residues in muscle, fat, liver and kidney were determined as part of the cattle transfer study. The depletion of endosulfan residues in fat is shown in figure 3.2.

Using the depuration data from the transfer study in dairy cattle (section 9), a half-life of 7 days is calculated in fat. It should be noted however, that the fat samples in the transfer study were analysed as a composite (subcutaneous, omental and perirenal) and therefore the time taken to deplete in individual fat depots cannot be ascertained. Due to differences in individual fat depots and to allow for variation in animals, a half-life of 10 days is considered to be appropriate.

**Figure 3.2.**



On the basis of a depuration half-life of 10 days and to reach a target of 0.1 mg/kg (Codex MRL) in meat [fat] from the current MRL of 0.2 mg/kg, an Export Slaughter Interval (ESI) of 21 days on clean feed is recommended to meet export trade markets.

For poultry, a conservative maximum feed level (MFL) of 0.2 ppm is estimated from residues present in oilseeds, cereal grains and pulses. In the poultry metabolism study provided (section 3.1), hens were dosed orally for 12 days at levels ranging 10 to 12 ppm in the feed. Scaling the radioactive residues present for a maximum feed level of 0.2 ppm, endosulfan residues ( $\alpha$ - and  $\beta$ -endosulfan and endosulfan sulfate) of 0.016 and 0.014 mg/kg would be present in fat, 0.008 mg/kg would be present in skin, 0.008 mg/kg would be present in eggs and 0.003 mg/kg would be present in liver. On the basis of the metabolism study, MRLs of 0.02 mg/kg, 0.05 mg/kg and \*0.01 mg/kg are recommended for eggs, poultry meat [in the fat] and poultry offal.

### 3.2.19 Processing and storage stability

Storage stability data are described in section 8 for both crop and animal matrices. The residues data provided for crops and animal commodities are adequately covered by the storage intervals in the stability studies and therefore the reported residues in supervised trials reflect residues found after treatment.

Processing data were provided as part of the residues studies. These are described in the individual studies in section 8.

### 3.2.20 Trade considerations

The following export data were extracted from *Australian Commodity Statistics 2004*, published by the Australian Bureau of Agriculture and Resource Economics, Canberra.

Australian exports of sheep meat were on average 163 kt mutton and 91 kt lamb per year over the period 1996 – 2003 and were valued up to \$600,000,000 per annum Australia's main export markets for sheep meat in 2003 are shown in the following table.

Export Destination	Export Value (\$m)	
	Mutton	Lamb
Saudi Arabia	65	
USA	67.9	257.5
Chinese Taipei	32.2	
South Africa	11.1	2.1
Japan	29.9	42.3
Singapore	20.4	
Malaysia	15.9	
EU	27.4	92.4
Papua New Guinea	6.1	14.4
Canada	3.6	
Republic of Korea	2.2	
UAE		29.9
Other (unspecified)	92.4	162.4

Australian exports of beef and veal have averaged \$3.2bn over the period 1996 – 2003, with up to \$4.3bn in 2001. The main export markets for beef and veal reported in 2003 are tabulated below:

Export Destination	Export Value (\$m)
Japan	1384.4
USA	1332.3
Republic of Korea	250.7
Chinese Taipei	126.7
Canada	110.9
Malaysia – Singapore	86.8
EU	49.2
Indonesia	38.4
Oceania (NZ, PNG, South Pacific Islands)	26.2
Middle East (Saudi Arabia, UAE, Kuwait)	25.4
Philippines	23
Hong Kong, China	15

Australia exports large quantities of cereal grains, with exports of wheat and flour valued at up to \$3.4bn in 2003-2004 and up to \$4.6bn in 2001 – 2002. The main markets for Australian wheat and flour are the Middle East (Iraq, Kuwait, UAE, Yemen), Asia (Indonesia, Japan, Republic of Korea, Malaysia) and Africa (Egypt, South Africa and Ethiopia). Main markets for grains other than wheat could not be determined.

Cottonseed, cottonseed oil and cottonseed meal are also exported by Australia. Whilst specific data for cotton seed meal were not available, average exports of cotton seed and cotton seed oil over the period 1996 – 2004 averaged 384 kt and 1.36 kt, respectively. The major export destinations for cotton seed are Japan and the Republic of Korea, at 134 and 28 kt, respectively in 2003 – 2004; the values of the export markets were not reported.

MRLs have been set for endosulfan in cereal grains, cotton seed and cattle and sheep commodities in most countries worldwide and by Codex. These are tabulated below:

## Australian Pesticides and Veterinary Medicines Authority (APVMA)

Commodity	Endosulfan MRL (mg/kg)						
	Australia①	Codex	USA	Japan②	Korea	EU	Taiwan
Meat (mammalian) [in the fat]	0.2	0.1 (fat)	0.2 (cattle fat)	0.1	0.1	0.1 (meat & fat)	0.1 (fat)
Edible offal	0.2	—	0.2	0.2	—	0.1	—
Milk	0.02	0.004 F③	0.5 (fat)	0.004③	0.1	0.004③	0.004 F
Cereal grains	0.1	—	—	0.1	0.1	—	—
Wheat grain	0.1	0.2	0.1	0.2	0.1	0.05	—
Cotton seed	1	1	1	1	—	0.3	—

① Proposed MRL ② Provisional MRL listing. ③Based on CCPR policy the figure of 0.004 mg/kg F is equivalent to 0.1 mg/kg in milk fat. The figures reported for Japan and EU do not make the clear distinction of **F** and therefore the value could be misinterpreted. A comparison of the milk MRLs for different countries requires conversion of the values to milk [in the fat], i.e. multiply the Codex CXL by 25.

**Cereal Grains:** The main markets for wheat are the Middle East and Asia, and there appear to be no MRLs set for these countries. The proposed Codex MRL for wheat is higher than that proposed for Australia. There should be no prejudice to trade for wheat exports, once the proposed MRL is established, as most of the major markets accept Codex MRL for trade.

**Cottonseed:** The Australian MRL for cotton seed is included in the oilseed MRL of 1 mg/kg, which is the same as that of Codex, Japan and the USA. The current crude cottonseed oil MRL is the same as that of Codex. However it will be deleted, as residues in oil will be accommodated by the oilseed MRL. Trade in the past has not been prejudiced by the presence of these MRLs for endosulfan and this is not expected to alter in the future, due to the provisional MRLs for endosulfan proposed by Japan.

**Cattle and Sheep:** The Australian MRL for meat fat is twice that of the Codex value. Australia's main markets are in North America, Asia and the Middle East. Most Asian countries that have not established MRLs for endosulfan in meat commodities adopt either the Codex value or the EU value of 0.1 mg/kg. There have been past incidents in Asia particularly when shipments of meat have been rejected for exceeding the Codex MRL and this difference could be seen to prejudice Australia's trade to these markets. To overcome this problem, an Export Slaughter Interval of 21 days is recommended for any livestock that have been exposed to endosulfan residues in feeds.

Export trade in meat is drawn from both grazed animals and from cattle in feedlots situations. The source of endosulfan residues could be from forage crops or supplementary feeds, which include treated crops and crop by-products. Silage, cut fodder and hays could also be sources of endosulfan for export animals. Animal feed commodities that result in residues above 0.4 mg/kg endosulfan (the proposed Maximum Feed Level) should be restricted from feeding to cattle and sheep. With significantly amended use patterns and the corresponding Export Slaughter Interval, residues in meat fat should not exceed the established Codex MRL of 0.1 mg/kg.

### 3.2.21 Meat trade implications from Animal feed commodities

A number of broadacre crops for which endosulfan is registered are used as animal feed commodities, potentially resulting in endosulfan meat residue violations.

For those crops grown primarily or substantially for livestock feed the APVMA has determined that some endosulfan uses will no longer be permitted, where they present an undue risk to trade and alternative risk mitigation measures are unlikely to be complied with. This includes some uses for cereal crops, oil seed crops (except cotton and peanuts) and pulse crops.

Cotton and legume vegetables are not grown primarily for feed purposes. The feeding of cotton fodder, stubble and trash to livestock is known to occur and has the potential to result in endosulfan

residues in meat. It is also not considered to be GAP. Historically, cotton production has previously been responsible for endosulfan residues in beef because of contaminated feeds, spray drift and other poor management practices.

A key issue from the Draft Review Report was the continued use of endosulfan on cotton and legume vegetables. In assessing these uses, two alternative approaches were considered:

1. continue to permit these uses with the following label restraint:
  - **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**
2. delete these uses because of the risk of violative residues in meat.

The APVMA sought assurances that, were uses for cotton and legume vegetables to be retained, appropriate and effective safeguards could and would be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

During the public consultation period submissions were received with support for both of these uses. Additionally submissions were received which did not support the continued use on legume vegetables.

An industry commitment was received from the Australian cotton industry and the livestock industry regarding continued use of endosulfan in cotton. Specifically Cotton Australia and the Cotton Ginners Association have agreed an MOU with the Cattle Council of Australia and the Australian Feedlotters Association that specifies the management practises to be adopted by cotton growers and livestock producers to allow the continued use of endosulfan in cotton. This MOU and associated Best Management Practices and Codes of Practice, have enabled the APVMA to be satisfied with regard to the risks of residue contamination in meat destined for the domestic or trade market. (Attachment 1 contains a copy of the MOU). Endosulfan residues in meat of livestock will continue to be monitored by the National Residues Survey monitoring as is currently the case, and the work of the "Endosulfan Task Force" administered through the Beef Industry Advisory Committee (BIAC), and the SAFEMEAT Committee under the Department of Agriculture Fisheries and Forestry will also continue.

The public comment period elicited few responses from representatives in the horticultural industry.

Continued use of endosulfan in legume vegetables is likely to cause exposure to livestock from feeding of pea and bean vines and hay containing endosulfan residues at levels that are unacceptable in relation to existing animal commodity MRLs.

Legume vegetables are not grown primarily for livestock feed. However, the by-products from these crops e.g. hay, are actively sought after as valuable livestock feeds, particularly in time of drought. These by-products are not always consumed on farm but can be on-sold to third parties for use in processed animal feeds and/or fed directly to livestock.

The horticultural industry is not as well organized as the cotton industry. It is a highly fragmented and diverse group, comprising large numbers of small producers, many from non-English speaking backgrounds, spread over a wide geographical area. In contrast to the cotton industry, the horticultural industry does not have in place adequate mechanisms to managed residues at this time e.g. commodity vendor declarations, BMPs or MOUs. The industry is slowly adopting the use of vendor declarations, but not to any large extent at this time. The response from the horticultural industry noted their inability to control the actions of third parties in respect to the management of residues in livestock.

### 3.2.22 Dietary exposure

The ADI and ARfD for endosulfan are 0.006 and 0.02 mg/kg bodyweight/day, respectively. At the time of publication of the 1998 Endosulfan interim report the National Estimated Daily Intake (NEDI) was equivalent to 339% of the ADI. This estimate was based on temporary MRLs and used available refinements. It is recognised that the NEDI is a conservative estimate of chronic exposure and that excursions above the ADI may be allowed (Residues Appendix 4). Using the supplementary residues data that have been submitted, the NEDI is now equivalent to 27% of the ADI.

The ARfD for endosulfan was set by the TGA in December 2000. The dose is 0.02 mg/kg bodyweight, based on a NOEL of 2 mg/kg bodyweight/day and a 100-fold safety factor from a developmental study in rats. The LOEL was 6 mg/kg bodyweight/day.

In 1998, at the time of publication of the endosulfan review, acute or short-term dietary exposures were not routinely considered in Australia, as the methodology was still under development<sup>7</sup>. The National Estimated Short Term Intake (NESTI, Residues Appendix 2) is calculated using the supplementary residues data corresponding to registered use patterns. For the 2 to 6 year subpopulation, the acute reference dose was exceeded for pears (3.6-fold), leafy vegetables (20 to 27 fold) and Brussels sprouts (1.3 fold). For the 2 years + group (general population), the acute reference dose was exceeded for leafy vegetables (17 to 20-fold); pears approach the acute reference dose.

Short-term dietary intake must not exceed the acute reference dose. To reduce the exposure from residues in pears, the interim regulatory action recommended extension of the withholding period from 14 days to 28 days, to allow residues to decline to acceptable levels:

In addition, the suspension of endosulfan products no longer allow use on leafy vegetables or brussels sprouts. Labels contain a statement to this effect.

The revised short-term dietary exposure ranges from 0 to 82% of the acute RfD for the 2 to 6 years age group and from 0.1 to 71% of the acute RfD for the 2 years and above age group (see Residues Appendix 4, technical report).

## 3.3 CONCLUSIONS FROM RESIDUES ASSESSMENT

The following conclusions were determined following assessment of the residues data. (These conclusions are further considered in conjunction with OHS conclusions in formulating the final review outcomes, shown in section 7).

### 3.3.1 Use pattern variations

#### *Residues data not provided*

For the following crops, residues data were required but were not provided to the APVMA.

- bananas;
- berries and other related fruit such as grapes and currants;
- bulb vegetables, namely onions and shallots;
- pastures, chou moeiller, vetch, lucerne, clover and medic crops; and
- peanuts.

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<sup>7</sup> JMPR first reported short-term estimates of dietary intake in 1999.

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues and have been deleted:

***Short-term dietary concerns were highlighted***

For the following crops short-term dietary concerns were highlighted.

- leafy vegetables, silverbeet, spinach and cole crops (except broccoli, cabbage (head) and cauliflower); and
- Brussels sprouts.

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues and have been deleted:

***Crops produced primarily or substantially for livestock feed***

For the following crops, that are produced either for livestock feed only or are grown and used for human food and for livestock feed, risks from residues in trade were shown to be unacceptable.

- the control of heliothis and other pests at the rate of 735 g ai/ha (2.1 L product/ha) in pulse crops, cereal crops and oilseed crops (except cotton). This includes the use patterns for, maize and sorghum.
- The use pattern for sweet corn .

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not unduly prejudice trade or commerce between Australia and places outside Australia, and have been deleted:

***Crops produced primarily for purposes other than livestock feed***

The following crops are produced primarily for purposes other than livestock feed:

- legume vegetables (green beans and green peas);
- cotton.

The current use of endosulfan in legume vegetables will be deleted due to ongoing concerns that the likely exposure to livestock from feeding of pea and bean vines and hay may be at levels that are unacceptable in relation to existing animal commodity MRLs. As a feeding restraint would be contrary to common livestock grazing and feeding practices, the APVMA has concluded that the use patterns for green beans and peas will be deleted from product labels.

Uses on cotton will be retained, as discussed in section 3.2.21.

### **3.3.2 New label instructions**

In addition to the labelling requirements as defined in the Agvet Labelling Code (2001) and the interim report for the review of endosulfan (1998), the following instructions have been included on all product labels included in this review. Products which are subject to the outcomes of the review will have their labels varied in the same way.

**Livestock feeding restraints:**

- This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.
- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock
- Do Not Feed Treated Melons or Melons Crops To Livestock

- Do Not Feed Treated Tomato Crops To Livestock

### **Livestock Destined for Export Markets**

The label withholding periods for grazing only apply to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

### **Export Slaughter Interval (ESI) – 21 days**

Livestock that have been grazing on or fed treated crops (Except for label exclusions – cotton, melons, tomato, vegetable wastes/wrapper leaves) should be placed on clean feed for 21 days prior to export slaughter.

### **3.3.3 Withholding periods**

The following withholding period statements have been included on product labels in relation to the above MRLs:

<b>Citrus fruit:</b>	Do Not Harvest For 3 Days After Application
<b>Pome fruit</b>	Do Not Harvest For 28 Days After Application
<b>Avocado, Kiwifruit, Mammey, Passionfruit, Pomegranate, Sapodilla:</b>	Do Not Harvest For 14 Days After Application
<b>Custard Apple, Guava, Lychees, Longans, Mango, Pawpaw, Persimmon, Rambutan, Tamarillo:</b>	Do Not Harvest For 7 Days After Application
<b>Broccoli, Cabbage, Cauliflower:</b>	Do Not Harvest For 7 Days After Application
<b>Cucurbits:</b>	Do Not Harvest For 3 Days After Application
<b>Capsicum, Tomatoes:</b>	Do Not Harvest For 3 Days After Application
<b>Cape gooseberry, Eggplant, Okra</b>	Do Not Harvest For 7 Days After Application
<b>Beetroot, Carrot, Potato, Sweet Potato, Taro</b>	Do Not Harvest For 14 Days After Application
<b>Celery, Rhubarb</b>	Do Not Harvest For 7 Days After Application
<b>Cashews, Pecans, Pistachios</b>	Do Not Harvest For 14 Days After Application
<b>Macadamias</b>	Do Not Harvest For 2 Days After Application

	<b>Harvest</b>	<b>Grazing</b>
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lentils, Lupins, Mung beans, Navy beans, Pigeon peas)	Nil	Do Not Graze Or Cut For Stockfood For 7 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat)	Nil	Do Not Graze Or Cut For Stockfood For 10 Weeks After



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		Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers): Harvest: Nil; Grazing	Nil	Do Not Graze Or Cut For Stockfeed For 8 Weeks After Application
Cotton	Do Not Harvest For 8 Weeks After Application	

### 3.3.4 MRLs

The following amendments to the MRL Standard will be made:

**Table 1**

#### Endosulfan

Code	Food	MRL (mg/kg)	
		Delete	Add
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	0.1
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–
VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

**Table 4**

Code	Animal Feed Commodity	MRL (mg/kg)	
		Delete	Add
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1

**Australian Pesticides and Veterinary Medicines Authority (APVMA)**

-	Cereal forage (green)	—	0.3
-	Citrus pulp and pomace, dry	—	2
-	Forage of pulse crops (green)	—	0.3
-	Forage of oilseed crops	—	0.3
AS 0081	Straw and fodder (dry) of cereal grains	—	0.4
-	Straw and fodder (dry) of oilseeds	—	*0.1
-	Straw and fodder (dry) of pulse crops		0.3

**3.3.5 Outcome**

The residues evaluation found that the APVMA could not be satisfied that use of products containing endosulfan 350 g/L in EC formulations would not be an undue hazard to the safety of people using anything containing its residues, and would not unduly prejudice trade or commerce between Australia and places outside Australia. The evaluation concludes that instructions on product labels be varied by deleting:

- uses where no data were provided to support them;
- uses where short-term dietary concerns were highlighted;
- late season use for the control of heliothis and other pests at the rate of 735 g ai/ha (2.1 L product/ha) in pulse crops, cereal crops and oilseed crops (except cotton)
- maize, sorghum and sweet corn; and
- legume vegetables (green beans and green peas).

Labels have been varied as was proposed, and the APVMA is satisfied that continued use and other dealings of products containing endosulfan 350 g/L in EC formulations would not be an undue hazard to the safety of people using anything containing its residues, and would not unduly prejudice trade or commerce between Australia and places outside Australia.

## **4. OH&S WORKER EXPOSURE ASSESSMENT SUMMARY**

### **4.1 INTRODUCTION**

The 1998 APVMA interim report of the review of endosulfan raised concerns, with regard to exposure for workers during certain use and re-entry activities. The OH&S risk assessment at this time was largely carried out using surrogate exposure data due to a lack of suitable exposure data.

The interim report noted that the major use of endosulfan in Australia, at that time, was in cotton production, representing approximately 70% of use, and vegetables, accounting for 20%, with the remaining 10% divided between oilseeds, pome and stone fruits, exotic fruits and other crops, such as pulses and ornamentals. Label instructions permit the use of endosulfan in cereal crops, tobacco, and nursery crops. Current labels include instructions for application by ground and by air, with endosulfan being applied aerially in significant quantities since the major crop is cotton. Ground applications are either by boom spray, airblast, airshear or knapsack with hand wand/nozzle. Endosulfan was noted to be an integrated pest management (IPM) tool in both horticulture and broadacre crops.

Information available at the time of the interim report indicated that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incidents reported overseas indicated that field workers may also experience health effects when re-entering endosulfan treated areas and it was identified that re-entry restrictions are needed on current endosulfan product labels.

Consequently, the APVMA decided that certain uses of endosulfan should continue on a temporary basis until additional worker exposure data were obtained. An interim re-entry period of 2 days (for field and orchard crops and for greenhouses) was recommended until new Australian data was generated. Existing guidance on safe flagging procedures was also identified for upgrading.

Due to the apparent lack of suitable studies (available in Australia or overseas) the APVMA required worker exposure data to be generated under actual Australian use conditions in order to determine the extent and circumstances of exposure to endosulfan in occupational settings. Work practices that were identified by the APVMA for further assessment were:

- Mixer/loaders in ground and aerial applications
- Manual flaggers for aerial applicators
- Orchard ground spray applicators (including re-entry)
- Broadacre ground spray applicators (including re-entry)
- Greenhouse workers
- Workers using hand-directed spray applicators.

The requisite worker exposure studies were conducted by the Australian Centre for Agricultural Health and Safety (Moree) and the Centre for Pesticide Application Safety (Gatton). The studies were based on a protocol approved by the APVMA and NOHSC, and in accordance with standards prescribed by the New England Health Research and University of Sydney Research ethics committees. All studies used the same formulation of endosulfan containing 350 g ai/L, which was considered representative of each of the products under review.

#### 4.1.1 Dermal absorption factor for exposure to concentrates and spray mixtures

The endosulfan draft report (OH&S component report) used a dermal absorption factor of 10%, which was derived from a new *in vitro* dermal absorption study (Davies, 2002) submitted in late 2003. During the public consultation phase, the appropriateness of the dermal absorption factor (10%) used in the OHS risk assessment was questioned as well as the use of cotton dislodgeable foliar residue (DFR) data to determine re-entry intervals for other broadacre and tree crops. Additional re-entry studies on melons, peaches and grapes (Singer, 1995) were submitted for consideration as part of the public consultation (see section 4.2.4 re-entry exposure).

From further consideration of these submitted studies (Refer to volume two of this report for the technical assessment of these studies), it is apparent that endosulfan is less well absorbed across rat skin *in vivo* than *in vitro*. Under identical experimental conditions, human epidermis is at least 30-fold less permeable to endosulfan than rat epidermis.

In light of these new findings the previous worker exposure estimates where dermal absorption figures were derived from animal experimentation results and applied to human exposure scenarios were revisited. A dermal absorption factor of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities has been used in the OHS risk assessment.

Consistent with the EC Guidance Document on Dermal Absorption, factors for endosulfan can be calculated by adjusting the rat *in vivo* absorption values by the ratio of the human to the rat *in vitro* absorption. The dermal absorption factor for concentrate exposure will be  $20\% \times 0.025 = 0.50\%$ , while the factor for exposure to spray mixture will be  $46\% \times 0.033 = 1.52\%$ .

## 4.2 FINDINGS

The revised dermal absorption values and re-entry studies have revised the findings in the Draft Review report. They are reflected in all conclusions from new studies and ensuing regulatory decisions in this report.

### 4.2.1 Orchard applications

#### *Issues identified in interim report*

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for M/L/A for high volume ground rig spraying of large areas (>20 ha/d). This finding was irrespective of the use of tractors with enclosed cabs, and/or wearing of extra layer of protective clothing, and/or use of closed mixing systems.
- Unacceptable MOE for M/L/A for low volume ground rig spraying (mist blower<sup>8</sup>) of small and large areas (study range ~5 to 20 ha/d), using tractors without cabs. These risks were reduced to acceptable levels for small areas only (~ 5 ha/d) by the wearing of extra layer of protective clothing, or use of tractors with enclosed cabs.
- Unacceptable MOE for M/L/A for hand-spraying (knapsack) of large areas. These risks were reduced to acceptable levels by the wearing of extra layer of protective clothing.

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<sup>8</sup> Surrogate for airblast spraying

### ***Conclusions from new studies***

With regard to Mixer/Loader (M/L) and Application (A), endosulfan (using ground air assist application with and without the use of closed cabins, ground air-shear spray and ground boom oscillating spray), acceptable MOE were determined for workers handling up to 40 kg ai/day and a work rate of 30 ha/day, when exposures for individual tasks were considered separately. MOE were acceptable for applicators with and without the use of head / face protection. Thus although required for M/L (due to acute inhalation risks), respirators are not required during application of the diluted product.

MOE for combined exposures (M/L/A/C) were acceptable for air assist with cabin, air shear with cabin, and oscillating boomspray applications.

MOE for combined exposures (M/L/A/C) were acceptable for air assist applications without cabins, where head/face exposure was included in the determination (i.e. where workers were not wearing a respirator/hat).

Acceptable MOE were determined for cleaning down (C) operations following mixing/loading and spraying.

No hand spraying, aerial application or re-entry studies were carried out for orchard applications.

#### **4.2.2 Nursery crop applications**

##### ***Issues identified in interim report***

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for hand spraying of ornamentals (based on an application rate of 0.1 kg/ha per day).
- Risk for workers using hand-held equipment for greenhouse treatment could not be identified due to lack of measured or predicted (modeled) exposure data.

### ***Conclusions from new studies***

Studies were carried out for mixing/loading, hand-held spraying and cleaning down associated with nursery crops. It was not clear from the studies whether high or low-pressure systems were used.

Acceptable MOE were determined for workers mixing/loading and cleaning down operations, where up to 0.5 kg endosulfan was handled per day.

Combined M/L/A and cleaning down exposure provided acceptable MOE for workers carrying out all activities.

No application or re-entry studies were carried out for greenhouses and no re-entry studies were carried out for outdoor nursery crops.

#### **4.2.3 Broadacre applications**

##### ***Issues identified in interim report***

No measured exposure data were available in the interim report (APVMA 1998). Results (from modeling data) indicated:

- *Unacceptable* MOE for M/L/A for low volume boomspray (0.5 –2.1 L product in 100-400 L water) of areas (~50 ha/d) irrespective of the use of tractors with enclosed cabs.
- *Acceptable* MOE for Applicators for low volume (0.5 L product in 400 L water) boomspray of areas (~50 ha/d).

***Conclusions from new studies (Broadacre crops / aerial application)***

Studies were carried out for mixing/loading endosulfan for aerial application and exposure to support workers (markers etc) using vehicles (including ATVs) and cleaning down operations.

Mixer/loader exposures were determined for bulk, mini-bulk and small containers in open and closed systems for aerial application of broadacre crops. The total endosulfan handled/day was 1470 kg ai based on an application rate of 2.1 L/ha and work rate of 2000 ha/day.

Acceptable MOE were determined for mixer/loaders using open/remote or closed base systems for aerial application.

Acceptable MOE were determined for aerial applicators (pilots), and support workers in vehicles and ATVs

Acceptable MOE were determined for workers conducting cleaning down activities.

***Conclusions based on PHED data (Broadacre crops / ground application)***

PHED data for ground application (boom spray) were recalculated using 0.5% and 1.52% dermal absorption rates for mixing/loading and application. Acceptable MOE were determined for workers open mixing/loading endosulfan for treatment of broad acre crops by ground application, with and without the use of gloves.

Acceptable MOE were determined for workers using open cab for ground application of endosulfan to broadacre crops, with and without then use of gloves.

Acceptable MOE were determined for workers open pour mixing and ground boom open cab application (combined activity) to broadacre crops, with and without the use of gloves..

**4.2.4 Re-entry exposure**

***Issues identified in interim report***

The information available for assessment for the interim report did not contain data on worker exposure during re-entry.

Clarke and Churches (1992) investigated re-entry exposure to cotton chippers in NSW. The total potential skin exposure was 12.2 mg/hr seven hours after endosulfan spraying to a 30 cm high crop and 19.8 mg/hr twenty-four hours after endosulfan spraying to a 50 cm high crop (NRA 1998).

A re-entry period of 24 hours was identified as inadequate. Results from this study indicated that a re-entry period would need to consider crop height.

In the absence of data, an interim re-entry period of 2-3 days was proposed pending submission and assessment of further information.

### ***Conclusions from new studies***

Initially re-entry exposure data was submitted only for cotton crops following ground and aerial application. No measured exposure data were provided for workers re-entering treated areas on day 0 and day 1 as the study authors observed the 48 hour re-entry interval stipulated on the label. Margins of exposure for other crops identified on labels were extrapolated from the DFR data in a re-entry study on melons, peaches and grapes (Singer, 1995). Transfer Coefficients determined from measured DFR data, dosimetry data, and generic TC for low and medium exposure were used to calculate the MOE and determine re-entry intervals for cotton, and for other crops .

Acceptable MOEs were obtained on day 0 for workers re-entering cotton fields, orchards and broadacre crops for various re-entry activities.

There are no PPE requirements following the re-entry interval.

## **4.3 CONCLUSIONS FROM OH&S ASSESSMENT**

The following conclusions were determined following the assessment of OHS studies provided after the release of the interim report. These conclusions are further considered in conjunction with residues conclusions in formulating the final regulatory outcome, in section 7.

### **4.3.1 Use patterns**

#### ***Satisfactory data from measurement or modelling***

Acceptable worker exposure levels can be achieved for the use of endosulfan in nursery, orchard and broadacre use patterns. Consequently, on the basis that the APVMA is satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people exposed to it during its handling, it is concluded that the following use patterns will continue to be permitted:

- nursery use applications.
- orchard use; ground rig applications.
- broadacre use applications; aerial applications and ground rig applications.

#### ***No suitable data provided***

Uses of endosulfan for turf and hides were deleted from labels following the interim report on the basis that no information was provided and these uses were not supported by the states. However, these uses remained on two product labels and have been deleted as an outcome of the review.

### **4.3.2 Re-entry periods**

The following re-entry period is considered appropriate for all endosulfan products:

- **Re-entry: Do not allow re-entry into treated areas until the spray has dried.**

### **4.3.3 Safety directions**

The following amended safety instructions are required:

Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing

becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.

When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece respirator. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing].

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water) and contaminated clothing

Precautionary statement: For aerial application, support workers/markers should be protected by enclosed cabs

#### **4.3.4 Outcome**

The occupational health and safety evaluation found that the APVMA could be satisfied that the continued use of products containing endosulfan 350 g/L in EC formulations in all situations as currently permitted (except for turf and hides) would not be an undue hazard to the safety of workers exposed to it during its handling. The evaluation has determined that instructions on product labels be varied by deleting the use on turf and hides. The occupational health and safety evaluation also recommended that labels be varied to include new safety directions, re-entry periods and PPE requirements.

The occupational health and safety evaluation concludes that provided that labels are varied as proposed then the APVMA could be satisfied that continued use and other dealings of products containing endosulfan would not be an undue hazard to the safety of people exposed to it during handling.



## **5. WATER QUALITY MONITORING**

### **5.1 INTRODUCTION**

The APVMA interim report of the endosulfan review (1998) concluded that, although well retained once in the soil, endosulfan contaminates the broader environment through spray drift, volatilisation and particle transport. This may occur aerially and, more importantly, by storm runoff leading to riverine contamination. The major metabolite, endosulfan sulphate, retains the toxicity of endosulfan and persists in soil and sediments.

Particular problems occurred with storm runoff into rivers, as endosulfan has high aquatic toxicity. For example, there have been a number of reported fish kills in NSW and Queensland between the mid 1970s and 1995. Whilst agricultural chemicals are not the only cause of fish kills, and despite difficulties in determining exact causes, cotton pesticides, in particular endosulfan, have been most often implicated as causing the majority of those fish kills (Bowmer *et al.* (1995); Napier *et al.* (1998)).

Pesticide monitoring in cotton growing areas of NSW during the cotton season consistently found endosulfan at concentrations above ANZECC guidelines (ANZECC and ARMCANZ 2000) in at least 50% of samples through the 1990s. Despite limited information, it was believed that a comparable situation existed in Queensland rivers.

Whilst there were indications at the time of the interim report that the situation may have been improving, contamination levels were unacceptably high. A number of measures were put in place by the APVMA to address these problems, including tighter controls and restrictions on use. The cotton industry introduced a Best Management Practice Manual, with guidelines to promote adoption of improved agricultural practices. Amongst other things, the aim of these measures was to minimise the impact of pesticides on riverine environments.

The APVMA interim report concluded that the cotton industry needed to demonstrate improved practices and reduced environmental contamination. The report required that:

*“Trends in environmental contamination and total quantity used will be re-evaluated by 30 June 2001 to determine whether endosulfan use should be continued”.*

As an interim outcome of the review, data was required to be submitted in relation to this requirement and, in addition, the report specified other requirements aimed at reducing environmental impacts from endosulfan use.

To measure the effectiveness of measures taken to protect the waterways in cotton regions, an evaluation has been conducted of river monitoring data provided by the then Department of Land and Water Conservation (Muschal (2000a); Muschal (2000b)). This, together with other related information (Mawhinney, 2003) provides the basis of the following discussion.

### **5.2 DISCUSSION**

Water quality is largely determined by land use, geology, climate, riparian vegetation and stream flow. Agricultural activities have a number of impacts on water quality including the levels of pesticides in waterways.

#### **5.2.1 Water Monitoring in Rivers of NSW**

The Central and North West Regions Water Quality Program (CNWRWQP) was jointly funded by the then Department of Land and Water Conservation and the water users of the Macintyre, Gwydir, Namoi and Macquarie Valleys. The project commenced in the early 1990s and focused on

the impacts of agriculture on water quality. Amongst other things, the levels of pesticides were monitored, at a number of sites, over a ten-year period.

Spray drift, vapour transport and runoff are the main pathways for pesticide transport into river systems. Spray drift and vapour both contribute low level but almost continuous inputs to the riverine ecosystem during the peak spraying season. The likelihood of pesticide drift is influenced by weather conditions, the method of application, equipment used and crop structure. Runoff tends to provide occasional high concentrations of pesticide contamination. Pesticides in runoff can be dissolved in the water, bound within sediments or adsorbed on to suspended particles.

The number and percentage of samples containing endosulfan contamination in the Namoi, Gwydir and Macintyre Valleys in each sampling year are given in Table 5.1. The number of samples includes all sampling sites across each valley, not just those located in the main cotton growing areas.

**Table 5.1: No. & % endosulfan detections across the Namoi, Gwydir and Macintyre Valleys (1991/92 - 2001/02)**

<b>Year</b>	<b>No. Samples</b>	<b>Endosulfan</b>
<b>1991/92</b>	296	174 (59%)
<b>1992/93</b>	299	194 (65%)
<b>1993/94</b>	210	137 (65%)
<b>1994/95</b>	281	135 (48%)
<b>1995/96</b>	291	169 (58%)
<b>1996/97</b>	395	207 (52%)
<b>1997/98</b>	404	196 (49%)
<b>1998/99</b>	400	182 (46%)
<b>1999/00</b>	413	126 (31%)
<b>2000/01</b>	438	76 (17%)
<b>2001/02</b>	290	14 (4.8%)

*No results subsequent to 2001/02 available*

The most commonly detected insecticide was endosulfan, with approximately 50% or more of samples containing residues of endosulfan during 1991-1999. The highest levels of contamination occurred in the periods 1991-94, coinciding with the rapid expansion of the cotton industry and a relatively low awareness of best practice methods compared to today's standards.

In 1998-1999 endosulfan residues were detected in cattle. This led to the introduction of greater restrictions on endosulfan use, and further emphasis on the cotton industries best management strategy. These two factors resulted in a dramatic reduction in endosulfan in the three valleys during 2000-2001 and 2001-2002.

In 2001-02, for the first time since pesticide monitoring commenced in 1990, no endosulfan residues were detected in the Namoi Valley (118 samples collected). This compares to previous years ranging from 32% (1991-92), peaking at 49% (1993-94), to 8% (2000-01). Endosulfan concentrations in the Gwydir River catchment in 2001-2002 were the lowest detected since 1991, although endosulfan and/or metabolites were detected at 9 out of 70 (13%) locations. This compares to previous detections ranging from 80% (1991-92) to 29% (2000-01). Furthermore, in recent years endosulfan concentrations fell below the ANZECC guidelines value for 99% ecosystem protection across all three valleys.

It was noted that this reduction may be due to a combination of factors including the implementation of best agricultural management practices, and a lack of runoff during 2001–02.

A report of the Mid-Lower Lachlan River Pesticide Study (NSW Department of Land & Water Conservation, June 2002) detected endosulfan in 35% of samples measured. However, it should be noted that the analytical procedures used were qualitative only, and not confirmed, and the majority of detections were at or slightly above the limit of detection. For this reason, whilst these results cannot be ignored, any conclusions to be drawn from this study are limited.

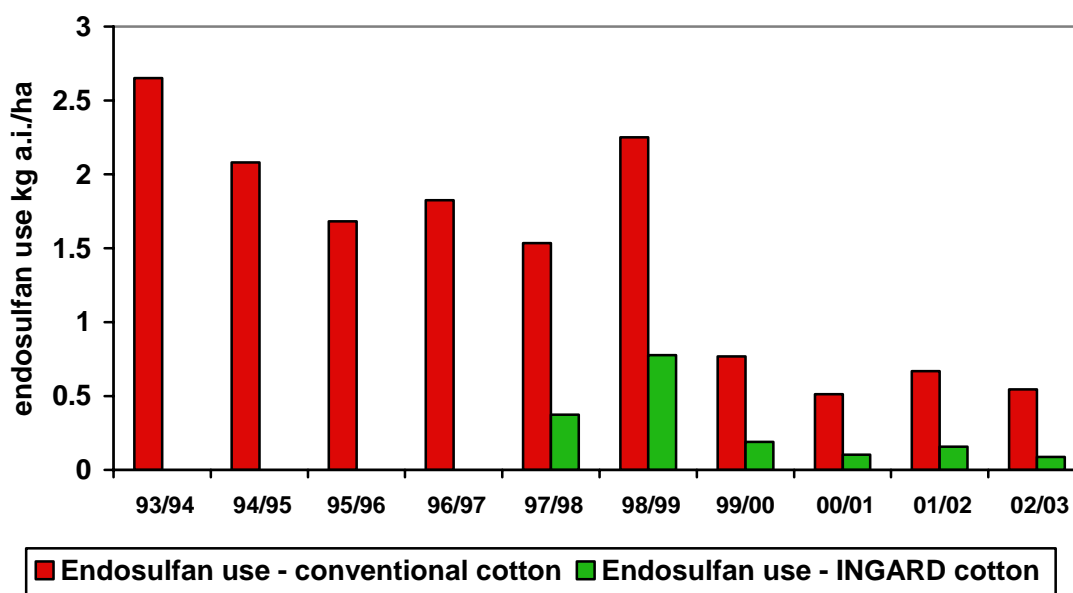
### 5.2.2 Endosulfan Usage

The figure below shows usage rates for endosulfan in Australia for the periods 1993-2003 (personal communication, B Pike, 2003. Data collected the annual Market Survey of Cotton Consultants Australia).

For the years up to 2000, use includes ultra-low volume (ULV) formulations plus emulsifiable concentrate (EC) formulations. Since 2000, only EC has been used. Usage has been converted to kg active ingredient /ha. For all years EC use has been generally consistent between 0.5 and 1 kg ai/ha.

INGARD (genetically modified cotton) was grown in 1996/97 but no specific data is available. It was noted that data for the limited area of Bollgard cotton in trials in 2001-02 indicated a reduction of only 30% endosulfan usage compared to INGARD. Endosulfan is a very good aphicide and it does not flair mites so it has a definite place in managing Bollgard as well.

**Fig 5.1. Endosulfan usage rates in Australia**



### 5.3 CONCLUSION

The monitoring results available to the APVMA adequately demonstrate that measures put in place by the APVMA with the cooperation of the cotton industry, have been effective in reducing endosulfan contamination in surface water.

On this basis it can be concluded that the continued registration of endosulfan would not be likely to have an effect that is harmful to the environment.

#### 5.4 WATER QUALITY REFERENCES

ANZECC and ARMCANZ (2000), *Australian and New Zealand guidelines for fresh and marine water quality*.

Bowmer K.H., Fairweather P.G., Napier G.N. and Scott A.C. (1995). *Review of data on the biological impact of cotton pesticides*. LWRRDC consultancy CWN12. CSIRO Division of Water Resources, Consultancy Report No. 95/13.

Mawhinney, 2003, Personal Communication, NSW DIPNR.

(Muschal M (2000a). *Central & North West Regions Water Quality Program. 1998-99 Report on Pesticides Monitoring*. NSW Department of Land and Water conservation. CNR2000.004.

Muschal M (2000b). *Central & North West Regions Water Quality Program. 1999-2000 Report on Pesticides Monitoring*. NSW Department of Land and Water conservation. CNR2000.067)

Napier G.M., Fairweather P.G. and Scott A.C. (1998). *Record of fish kills in inland waters of NSW and Queensland in relation to cotton pesticides*. WETLANDS (Australia), **17**: 60-71.

NSW Department of Land & Water Conservation (June 2002), *Draft Mid-Lower Lachlan River Pesticide Study 2001 – 2002*.

## 6. ENDOCRINE DISRUPTION

### 6.1 INTRODUCTION

The APVMA interim report on the review of endosulfan (1998) assessed a comprehensive toxicity data package. The major hazard associated with endosulfan was the high acute toxicity through exposure by ingestion, skin contact or inhalation. It was found that endosulfan does not persist for long periods in the tissues or organs of animals, and it was concluded that endosulfan was unlikely to bioaccumulate in humans.

There was no increase noted in the incidence of cancer arising from high concentrations and long exposure periods to endosulfan in the diet. It was also concluded that endosulfan was not likely to have any harmful effects on reproduction or cause birth defects. Endosulfan was not found to cause damage to genetic material and there was no evidence of disruption to the endocrine hormonal system.

In examining the issue of whether endosulfan is a xenoestrogen, the interim report concluded that toxicology studies did not indicate that endosulfan induces any functional aberrations that might result from disruption of endocrine homeostasis. However, a US EPA RED (Reregistration Eligibility Decision), finalised in 2002, identified endosulfan as “a potential endocrine disruptor”.

Subsequent to the interim report, the APVMA decided to re-examine the issue of endocrine disruption for endosulfan. In doing so, the objective was to:

- 1) examine the US EPA RED report and attendant information regarding endosulfan, and identify and clarify variations from previous conclusions reported in the interim report;
- 2) specifically re-examine the issue of possible endocrine disruption caused by endosulfan.

In conducting this re-examination, the conclusions of the interim report relating to the chronic, developmental and reproductive studies have been reconsidered, together with the relevant findings of the US EPA RED report. Additionally all of the published literature relevant to the endocrine disrupting potential of endosulfan to the end of April 2003 has been evaluated.

### 6.2 DISCUSSION

#### *Definition and mechanisms*

Several definitions for *endocrine disruptor* have been proposed.

The OECD (1998) defines an endocrine disruptor as “an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny or (sub)populations”.

The working definition used in the final report of the US EPA Endocrine Disruptor Screening and Testing Advisory Committee (1998) for an endocrine disruptor is “an exogenous chemical or mixture that alters the structure or function(s) of the endocrine system and causes adverse effects at the level of the organism, its progeny, populations or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle”. The National Research Council of the USA has adopted the term *hormonally active agents*, in place of the term *endocrine disruptor chemicals* (1999).

### ***Australian and US EPA policy relating to Endocrine Disruptor Effects***

Australian agencies consider that endocrine disruption is not considered to be an adverse end-point *per se*, but rather is a mode or mechanism of action potentially leading to other toxicological or eco-toxicological outcomes, for example, reproductive, developmental, carcinogenic or ecological effects. These effects are routinely considered in reaching regulatory decisions (at least for pesticides, food additive chemicals and high production volume industrial chemicals for which the required toxicology database is extensive). This position is quite similar to the US EPA position.

The US EPA view of endocrine disruption has resulted from changes in its underlying legislation. The US EPA is required to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring oestrogen, or other such endocrine effects as the Administrator may designate." Consequently, the US EPA has broadened its definition of endocrine disruption to include the androgen and thyroid hormone systems, in addition to the oestrogen hormone system, and also included the evaluation of potential effects in wildlife.

### ***The Australian vs USA position on endosulfan as an endocrine disruptor***

The APVMA interim report on endosulfan stated that:

- "Several recent studies have reported that endosulfan, alone or in combination with other pesticides, may have oestrogenic binding capability, and possibly potential for perturbation of the endocrine system. To date, the available studies show only very weak binding to hormone receptors *in vitro*, and the evidence for any relevance to adverse physiological effects *in vivo* is extremely limited"; and that
- "Long term bioassays, and reproductive and developmental toxicology studies in experimental animals, do not indicate that endosulfan induces any functional aberrations which might result from disruption of endocrine homeostasis."

The US EPA RED stated that:

- "Exposure to endosulfan has resulted in both reproductive and developmental effects in non-target animals. Endosulfan exposure resulted in impaired development in amphibians, reduced cortisol secretion in fish, impaired development of the genital tract in birds and reduced hormone levels and sperm production and produced testicular atrophy in mammals. Additionally, endosulfan has been demonstrated to bind to the human oestrogen receptor and exhibit significant estrogenic activity. Whether the toxicity endpoints are a result of endocrine disruption is not known. However, it is clear that organisms treated with endosulfan did exhibit some toxic effects that have historically been associated with endocrine disrupting chemicals, for example, developmental and reproductive."

Both reports suggested that more information was needed.

Hence the main difference between the Australian and US EPA is primarily definitional. The APVMA report suggested that endosulfan does not appear to be significantly endocrine disruptive in mammals whereas the US EPA RED proposes that the weight of evidence from all studies (including amphibians, fish and birds) supports the designation of endosulfan as a potential endocrine disruptor.

## **6.3 CONCLUSIONS**

From this assessment, it was determined that the overall conclusions and regulatory recommendations of both regulators are very similar.

The APVMA and US EPA reviews of endosulfan evaluated comparable databases and adopted similar regulatory approaches on most issues. The specific issue of whether endosulfan should be categorised as an endocrine disruptor remains as one significant difference between the two agencies. However, this arises mainly from the US EPA inclusion of data from all endocrine systems as well as potential effects in wildlife. Both agencies state that further testing of endosulfan using validated assays would be valuable and might help to further characterise effects related to endocrine disruption.

The APVMA evaluation reported the endocrine-related effects seen in test animals, particularly testicular toxicity, but noted that these appear to arise from homeostatic disturbance resulting from systemic toxicity. The APVMA report concludes that endosulfan binding to the oestrogen receptor is insignificant and considers that the regulatory endpoint chosen is adequately sensitive and protective against potential endocrine disruption by endosulfan.

The US EPA evaluation noted the effects seen in test animals and argued additionally that effects seen in amphibians, fish, birds and hormone receptor studies are indicative of potential endocrine disruption.

It is concluded from the APVMA re-examination of possible endocrine disruption caused by endosulfan that, from a public health perspective, there are no compelling reasons to change the conclusions of the APVMA interim report on the endocrine disrupting potential of endosulfan. While the effects seen in wildlife indicate that endosulfan may have endocrine disrupting potential in some species, the overall weight of evidence is that endosulfan has limited endocrine disrupting potential in mammals. Furthermore, while endosulfan may be relatively persistent in the environment and is capable of long-range transfer, it does not appear to bioaccumulate. The endocrine disrupting potential of endosulfan is not a significant risk to public health under the risk management controls and health standards established by the recent review.

## 7. REVIEW OUTCOMES

In addition to the interim outcomes of the review announced in 1998, subsequent actions taken by the APVMA, and the evaluation of supplementary information, the regulatory actions discussed below have been determined.

### 7.1 Regulatory Actions

Following consideration of the available data, the following outcomes have been reached:

- 1) Revoke the suspension of endosulfan products.
- 2) Vary conditions of label approval.
- 3) Affirm product registrations.
- 4) Cancel product labels that do not contain adequate instructions.

#### Affirm active constituent approvals

At the time of the interim review outcomes, August 1998, the APVMA affirmed the approval of endosulfan active constituents.

#### Revocation of suspension

To implement the findings of the review of endosulfan (variation to labels and affirmation of registration), the APVMA revoked the suspension of endosulfan product registrations and label approvals listed in Appendix 1.

#### Vary conditions of label approval

The APVMA is satisfied that the conditions to which label approvals are currently subject can be varied in the way outlined in sections 7.2 through to 7.6, to ensure that the requirements for continued label approval will be complied with. Therefore the APVMA has varied the conditions of label approval for labels listed in the following table.

Product Number	Product Name [Registrant]	Label approval to be varied
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0801
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	45570/1099
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0800
50004	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0702
52163	Farmoz Endosulfan 350 EC Insecticide [Farmoz Pty Ltd]	52163/0899



## Affirm registrations

The APVMA is satisfied that provided product labels are varied as proposed that the products meet the prescribed requirements for continued registration and therefore affirms product registrations as listed in Appendix 1.

## Cancellation of label approvals

The APVMA is not satisfied that the approved labels listed below contain adequate instructions and cancels these approvals.

Product Number	Product Name [Registrant]	Label approval numbers
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0899 32799/0400 32799/1000 32799/0301
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	455700/0299
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300
50004	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0899 50004/1099

## 7.2 USE PATTERNS

The overall conclusions for the Review are summarised below.

Use Pattern (label)	Review Outcome	Reason for Outcome		
		No data	dietary exposure risk	trade risk
<b>ORCHARDS:</b> Citrus fruits, pome fruits, assorted tropical / subtropical fruits (inedible peel), tree nuts (excluding Banana)	Retain	-	-	-
Bananas	Delete	X	-	-
<b>BROADACRE:</b> Pasture, chou moeiller, vetch, lucerne, clover and medic crops	Delete	X	-	-
Pulse crops ( <i>late season use</i> )	Delete	-	-	X
Pulse crops ( <i>pre-emergent use only</i> )	Retain	-	-	-
Cereal crops (excluding sorghum and maize) ( <i>late season use</i> )	Delete	-	-	X
Cereal crops (excluding sorghum and maize) ( <i>pre-emergent use only</i> )	Retain	-	-	-
Sorghum and Maize	Delete	-	-	X
Oilseed crops (excluding cotton and	Delete	-	-	X

**Australian Pesticides and Veterinary Medicines Authority (APVMA)**

Use Pattern (label)	Review Outcome	Reason for Outcome		
		No data	dietary exposure risk	trade risk
peanuts) ( <i>late season use</i> )				
Oilseed crops (excluding cotton and peanuts) ( <i>pre-emergent use only</i> )	Retain	-	-	
Cotton	Retain (label restraint)	-	-	-
Peanuts	Delete	X	-	-
Legume vegetables	Delete	-	-	X
<b>HORTICULTURE:</b>	Delete	X	-	-
Berries & other related fruit				
Bulb vegetables	Delete	X	-	-
Leafy vegetables	Delete	-	X	-
Cole vegetables (except Broccoli, cabbage (head) and cauliflower)	Delete	-	X	-
Broccoli, cabbage (head) and cauliflower	Retain	-	-	-
Brussel sprouts	Delete	-	X	-
Fruiting vegetables, other than curcurbits (excluding sweet corn)	Retain	-	-	-
Cucurbits	Retain	-	-	-
Sweet corn	Delete	-	-	X
Root & tuber vegetables	Retain	-	-	-
Stalk and stem vegetables	Retain	-	-	-
Stone fruit	(*1)	-	-	-
<b>OTHER:</b>	Retain	-	-	-
Native trees & shrubs, direct seeding				
Nursery and ornamental crops	Retain	-	-	-
Tobacco	Retain	-	-	-
Hides	Delete (*2)	X	-	-
Lawn/turf	Delete (*2)	X	-	-

X potential risk from some use patterns

(\*1) Stone fruit currently not on label, but were assessed in the report. Apricots had dietary concerns.

(\*2) As a result of review outcomes from the interim Endosulfan Report (August 1998). Worker exposure data/support for these use patterns was not provided for assessment.

### 7.3 WITHHOLDING PERIODS

The following withholding period statements have been included on product labels, in relation to the above MRLs:

<b>Crop</b>	<b>Withholding period</b>
Citrus fruit	Do Not Harvest For 3 Days After Application
Pome fruit	Do Not Harvest For 28 Days After Application
Avocado, Kiwifruit, Mammey, Passionfruit, Pomegranate, Sapodilla	Do Not Harvest For 14 Days After Application
Custard Apple, Guava, Lychees, Longans, Mango, Pawpaw, Persimmon, Rambutan, Tamarillo	Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower	Do Not Harvest For 7 Days After Application
Cucurbits	Do Not Harvest For 3 Days After Application
Capsicum, Tomatoes	Do Not Harvest For 3 Days After Application
Cape gooseberry, Eggplant, Okra	Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro	Do Not Harvest For 14 Days After Application
Celery, Rhubarb	Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios	Do Not Harvest For 14 Days After Application
Macadamias	Do Not Harvest For 2 Days After Application

<b>Crop</b>	<b>Harvest</b>	<b>Grazing</b>
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lentils, Lupins, Mung beans, Navy beans, Pigeon peas)	Nil	Do Not Graze Or Cut For Stockfood For 7 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat)	Nil	Do Not Graze Or Cut For Stockfood For 10 Weeks After Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers)	Nil	Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton	Do not harvest for 8 weeks after application	

### 7.4 RE-ENTRY PERIODS

The following re-entry period has been added to endosulfan product labels.

**Re-entry: Do not allow re-entry into treated areas until the spray has dried.**

### 7.5 LIVESTOCK FEEDING RESTRAINTS

The following livestock feeding restraints have been included on all product labels where appropriate:

- This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.

- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock
- Do Not Feed Treated Melons or Melons Crops To Livestock
- Do Not Feed Treated Tomato Crops To Livestock

### **Livestock Destined for Export Markets**

The label withholding periods for grazing only apply to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

### **Export Slaughter Interval (ESI) – 21 days**

Livestock that have been grazing on or fed treated crops (Except for label exclusions – cotton, melons, tomato, vegetable wastes/wrapper leaves) should be placed on clean feed for 21 days prior to export slaughter.

## **7.6 SAFETY DIRECTIONS**

The following amended safety instructions have been included on labels:

*Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.*

*When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece (or half facepiece and goggles) respirator.*

*When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing].*

*After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water), goggles and contaminated clothing*

Precautionary statement: For aerial application, support workers/markers should be protected by enclosed cabs.

## **7.7 Maximum Residue Levels**

The following amendments to the MRL Standard have been made.

**Changes to Table 1 of the MRL Standard for Endosulfan**

Code	Food	MRL (mg/kg)	
		Delete	Add
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	1
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
VP 0060	Legume vegetables	T2	-
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–
VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

**Changes to Table 4 of the MRL Standard for Endosulfan**

Code	Animal Feed Commodity	MRL (mg/kg)	
		Delete	Add
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1
-	Cereal forage (green)	–	0.3
-	Citrus pulp and pomace, dry	–	2
-	Forage of pulse crops (green)	–	0.3
-	Forage of oilseed crops	–	0.3
AS 0081	Straw and fodder (dry) of cereal grains	–	0.4
-	Straw and fodder (dry) of oilseeds	–	*0.1
-	Straw and fodder of pulse crops	-	0.3

## APPENDIX 1: Active constituent approvals and product registrations

### ACTIVE APPROVALS

Approval Number	Active Name	Approval holder
44012*	ENDOSULFAN	EXCEL INDUSTRIES (AUSTRALIA) PTY LTD
44093	ENDOSULFAN	MAKHTESHIM-AGAN (AUSTRALIA) PTY LIMITED
44288	ENDOSULFAN	FARMOZ PTY LTD
44305	ENDOSULFAN	BAYER CROPSCIENCE PTY LTD
57040 <sup>#</sup>	ENDOSULFAN	BECOT PTY LTD T/AS IMTRADE COMMODITIES

<sup>#</sup> Approval granted after the commencement of the review, that is subject to the outcomes of the review

\* Active constituent approval cancelled 1999.

### PRODUCT REGISTRATIONS AND LABEL APPROVALS

Product Number	Product Name [Registrant]	Label approval numbers
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0899 32799/0400 32799/1000 32799/0301 32799/0801
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	455700/0299 45570/1099
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300 45838/0800
50004 <sup>#</sup>	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0899 50004/1099 50004/0702
52163 <sup>#</sup>	Farmoz Endosulfan 350 EC Insecticide [Farmoz Pty Ltd]	52163/0899

<sup>#</sup> Registration granted after the commencement of the review, that is subject to the outcomes of the review

## **APPENDIX 2: Public comments on the Endosulfan draft report (May 2004)**

The endosulfan draft review report was released for public comment in May 2004. Its availability was announced on the APVMA website, APVMA gazette and direct mail to review participants. Eighty Five submissions were received with a number of issues identified.. These are discussed below.

Listed below are respondents views on the issue (***bold, italics***) and the APVMA's response to the comments (normal text). All responses received have been taken into consideration in revising the draft report to produce this report.

### **Dermal absorption factor**

***Dermal absorption values of 0.5% (concentrate) and 1.52% (dilutions) should be adopted for calculation of dermal absorbed dose in the OH&S assessment.***

Following the assessment of the supplementary data, a dermal absorption factor of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities was used in the OHS risk assessment.

***The dermal absorption value used in re-entry calculations should be the value relating to absorption of concentrate product, not diluted product.***

Given the comparatively short time interval between treatment and re-entry, an endosulfan deposition rate of 3.0 µg/cm<sup>2</sup>/h is likely to be approaching the maximum rate at which exposure would occur. If endosulfan accumulated on the skin at a constant rate throughout an 8-hour workday, a peak dermal concentration of 24 µg endosulfan/cm<sup>2</sup> would be attained. This is similar to the mid concentration used in the *in vivo* dermal absorption study of Craine (1988) (at which endosulfan penetration attained 46%) and to the lowest concentration used in the *in vitro* absorption study of Davies (2002). Therefore, the extent of dermal absorption arising from re-entry exposure would be closely similar to that which has been estimated for endosulfan in diluted spray mixture (i.e. 1.52%), rather than the extent of absorption from exposure to concentrated formulations. A dermal absorption factor of 1.52% will be used for re-entry exposure assessment.

### **Re-entry periods**

***Earlier re-entry is permitted once spray is dry on the treated crop, provided cotton overalls buttoned to the neck and wrist and impermeable gloves are worn. Re-entry to cotton fields is acceptable at day 0, based on calculations of re-entry exposure using average study derived transfer co-efficients.***

Following assessment of the supplementary data (re-entry and dermal absorption) the re-entry interval proposed in the draft report has been amended to permit re-entry on day 0 after the spray had dried (refer to the Technical Report).

***The following statement should be added to the re-entry interval section of the endosulfan label: No re-entry restrictions apply for bare earth applications.***

The OHS re-entry risk assessment is conducted based on use pattern information provided on the label. Application to bare earth could not be assessed, however, considering that the risk for

workers entering treated areas is acceptable on day 0 the risk is expected to be acceptable in the pre-emergent stage, where no foliage exists.

***Re-entry exposure calculations in non-cotton crops should use DFR values from specific endosulfan studies in peaches and melons, which are submitted for evaluation.***

DFR values from the re-entry study on melons, peaches and grapes were extrapolated to determine re-entry intervals for non-cotton crops.

***Re-entry exposure in vegetables (excluding cauliflower) should be calculated using a generic TC of 2500.***

Re-entry exposure in vegetables was calculated from DFR data and a generic transfer coefficient of 2500 for vegetables (high exposure).

***Re-entry period of 72 hours and 5day (pecans)be amended to 24 hours.***

The re-entry period has been amended to day 0 following assessment of data provided.

#### **Exposure from open cab vs closed cab**

***One submission suggests differentiating between open and closed cabins for broadacre uses as is the case for the orchard and horticulture uses, or changing orchard and horticulture uses to match broadacre requirements i.e. respirator at all times.***

*Based on supplementary data, the risk for workers using open cabins is acceptable. However, based on the hazard classification, workers should wear a respirator if the concentration of endosulfan in the spray is >1%.*

#### **Endosulfan use in cotton**

***The general public, growers and one community group made submissions in support of the continued use of endosulfan in cotton. Argument was provided including:***

- ***Endosulfan is IPM friendly and has only a moderate impact on beneficial insects***
- ***Cost effective***
- ***Controls heliothis along with a wide range of sucking pests***
- ***Does not flare secondary pests , therefore reducing further insecticide use***
- ***The recent track record of the Australian Cotton industry shows that residue violations in meat can be avoided***
- ***Endosulfan contamination in major water catchments has dramatically been reduced over the last 10 years***

*Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.*

#### **Endosulfan use in legume vegetables**

***Various grower groups provided submissions supporting the continued use of endosulfan on legume vegetables, sweet corn, with appropriate ESI information on labels. One submission made the following comments The APVMA should have regard for NVD and CVD awareness***



***as part of any risk assessment. Concerns that horticultural industries do not use CVDs and development of adequate management practices are required.***

The APVMA will delete use patterns for legume vegetables and sweet corn due to lack of adequate management processes (CVDs) within horticultural industries. The APVMA is not able to recommend a feeding restraint for crops or crop by-products that are typically used as livestock feeds. Any ESI proposal would be unmanageable as indicated in interim regulatory action.

### **Early stage foliar application**

***One submission requested the APVMA to consider other early stage foliar applications for pest control that may still meet residue recommendations.***

Consideration has been given to all foliar application of endosulfan and the review has determined late stage applications to oilseeds including soya beans will be deleted from labels. There was not enough data provided to re-consider other early season uses. If interested parties were to generate appropriate data for this type of assessment then it could be considered as part of the registration process.

### **Dietary intake concerns**

***Registrants, government agencies and individuals supported the deletion uses that cause dietary concerns including the use patterns for grapes and other berry fruit; bananas; bulb vegetables; Brussels sprouts and other unspecified brassica vegetables; leafy vegetables; peanuts; clover, lucerne, medics, pastures. One submission requested the APVMA to reconsider the decision for the deletion of the use pattern in brussel sprouts***

The APVMA review of endosulfan will delete all use patterns for which no residues data were provided, or dietary concerns were identified. The review will delete the use pattern for Brussels sprouts due dietary concerns and large variation in data and few trials. If grower groups or registrants hold appropriate data to support these deleted uses, consideration could be given through the registration process.

### **Livestock feeding**

***Submissions were received supporting deletion of use patterns identified as being high risk for livestock feeding, as well as support for feeding restraints.***

The APVMA will delete all use patterns for which livestock feeding issues were identified as restraints are not easily manageable. feeding restraint for vegetables wastes and wrapper leaves will be retained.

The APVMA is not able to recommend a feeding restraint for crops or crop by-products that are typically used as livestock feeds. It is impractical to recommend a clean feed interval for opportunistic feeding situations where there are no data.

### **Withholding periods/maximum residue limits**

***Several grower organisation requested that some withholding periods be reconsidered, with a view to shortening the proposed WHP where the data provided for the review supported this for tropical fruits –inedible peel; mango, avocado, passionfruit, pawpaw, rambutan, and cucurbits***

Recommend WHP of 7 days for mango, pawpaw, rambutan, custard apple, persimmon. WHP for passionfruit remains at 14 days, due to extrapolation from other crops.

Recommend WHP of 3 days for all cucurbits, as there are no dietary concerns and appropriate data were submitted

***There was a request to extend WHP for cotton to match spray dates stated in Conditions of Use On Cotton.***

WHP for cotton is 8 weeks after application to match spray dates published in APVMA Gazette (January 2005).

*Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.*

***The APVMA was asked to consider whether it is appropriate establish MRLs for livestock feeds that exceed the MFL.***

The proposed MRL's for livestock feeds were reconsidered and the following determinations have been made. Grazing WHPs for forage of cereal grains have been extended from 8 weeks to 10 weeks and for pulses from 6 weeks to 7 weeks; Oilseeds will remain at 8 weeks. MRLs for forage of cereals have been amended from 0.5 mg/kg to 0.3 mg/kg; the MRL for pulse forage has been amended from 0.5 mg/kg to 0.3 mg/kg.

### **Labelling**

***Several submission received argued that feeding restraint statements that were proposed in the draft final review report are not enforceable, due to user of the feed being 3<sup>rd</sup> party to the user on the crop. Extension advice may help to alleviate situations where opportunistic feeding occurs. Use of cotton trash as a livestock feed will continue in drought situations. The APVMA should provide advice to manage such situations. Requests to develop EI information on labels to meet export market MRL was also received.***

The feeding restraint statements have been revised and the APVMA maintains that feeding of some crop waste is not considered to be good agricultural practice. Export Slaughter Intervals (ESI) have been included on labels manage trade and also feeding situations if they occur for all crops excepting cotton, melons, tomatoes and vegetables.. An ESI of 21 days clean feed has been included on the label to cover trade situations and meet Codex MRL.

The Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.

***The APVMA has been requested to provide draft labels at time of public consultation to clarify changes to existing labels.***

This request has been noted and where possible will be accommodated. The review of endosulfan has resulted in many changes and additions to the product labels and use requirements over a long period of time. All previous changes to labels as an outcome of the interim decision in 1998 will remain in force and are currently on the label. All of the proposed amendments resulting from current evaluations were clearly specified in the report.

***Concerns were raised about spray concentrations and rates that are lower than current label rates and have been assessed for citrus use pattern, in absence of efficacy review.***

The Lower rate assessed and lower MRL proposed for citrus fruits was at the request of industry. The Efficacy consideration was undertaken in parallel with the review following data submission prior to 2003. The efficacy of this use pattern was reviewed through the state system with a consolidated reviewers report being made available to the APVMA. The Efficacy review concluded that “The data submitted support the label claim for lower rates on spined citrus bug”.

***Inclusion of a label statement should be considered to account for stubbles that may be treated for mite control.***

The regulatory outcome of this review has resulted in deletion of the late stage heliothis use patterns for cereals, pulses and oilseeds and restriction to bare earth treatments only. The necessity for an additional label statement is unclear and registrant should generate residues data to support their concerns.

***Lack of information on spray drift in the draft final report. APVMA to consider that ground-based application will also have associated drift concerns.***

Trade risks from contamination of pasture or other stock feed caused by spray drift from nearby endosulfan applications have been considered at several stages of the endosulfan review and substantial regulatory measures have been taken to control those risks. The rigorous requirements imposed on endosulfan applications to cotton and the subsequent withdrawal of all ULV formulations of endosulfan have led to greatly reduced risk from spray drift. An increased awareness of risk factors by both endosulfan users and stock producers has also contributed significantly to that lowered risk.

Regulatory actions taken in 2002 have further reduced risks from applications to crops other than cotton by removing a significant number of uses from labels. This report describes additional reduction of crop uses permitted on endosulfan labels. With all late season non-cotton broad-acre uses gone and early season uses quite limited, the situation is vastly changed from what it was only a few years ago and overall spray drift risk from non-cotton applications is very much lower. Concerns raised over bare-earth and early post-emergent spraying for mites are addressed by the large droplet placement requirement and controls for other risk factors on the new endosulfan label.

The APVMA is currently completing and refining a comprehensive review of its approach to spray drift risk assessment and risk management. The outcomes of this review are expected to begin being implemented by the beginning of 2006. As a part of that implementation, all products for which there are potential spray drift concerns will be reviewed in relation to that specific risk and their labels will be updated to match the new spray drift management standards.

Endosulfan products with new approved labels as required by this review's outcomes present a level of spray drift risk control higher than perhaps any other group of products. Current understanding of spray drift risk by endosulfan user and cattle producer industries as well as incorporation of established Commodity Vendor Declarations is high. It is expected that spray drift risk will be adequately managed during the 2005-2006 cropping season.

When the new spray drift risk assessment and risk management guidelines presently under development are adopted, the endosulfan labels will be reassessed and altered where needed to conform to the new standards. This approach is preferable to delaying the completion of the entire endosulfan review with all of its other regulatory features until early 2006 in order to accommodate the completion of the new spray drift management guidelines.

*The APVMA was requested to consider residues data submitted in support of a registration submission.*

*This new data which was submitted as part of a registration submission has been considered where appropriate.*

### **Import tolerances**

*APVMA/AQIS should seek import tolerances for Australia's major meat markets*

Import tolerances are outside the scope of the APVMA review. The necessity for import tolerances for endosulfan is questioned as there are MRLs/tolerances for meat in Australia's major meat export destinations. Refer to section 2.20 of the residues report.

### **Retention of uses**

*A request was received to have use on seed destined exclusively for sowing purposes be retained.*

The APVMA advises that use of endosulfan for commercial seed production may be considered through the minor use permit system. Applicants would need to provide evidence that this use is only minor and that appropriate quality controls are in place to eliminate any potential for treated seed, waste and stubble to be feed to livestock.

*All other comments if not addressed in this appendix have been addressed in the amended Technical Report.*

## Attachment 1: MOU

### **Memorandum of Understanding Between Australian Cotton Industry and Australian Beef Cattle Industry**

This agreement addresses the issue of certain by products of cotton , in particular, cotton gin trash, failed cotton crop and cotton crop residue and the potential for these by products which may have been treated with the pesticide endosulfan, to be fed to livestock and cause residue violations in meat.

It is entered into to ensure that both industries, those being the Australian Cotton Industry and the Australian Cattle Industry each take appropriate actions within their respective industries to ensure that the cotton by products referred to above are not consumed by livestock .

The overall objective of this agreement is to ensure that appropriate and effective safeguards are put in place by both parties to protect against violative residues in meat, and so protect Australia's meat trade.

Towards this objective, the following principles are agreed

to: **The Australian Cotton Industry agrees to the following:**

1. Cotton ginnery will adhere to the principles set out in The Australian Cotton Ginnery Association Code of Practice which relate, to The Management of Cotton Gin Trash and Management of Cotton Gin Motes. The appropriate extract from this code of practice is attached as **Appendix 1** to this document.
2. Individual cotton growers will ensure that livestock do not have access to cotton fields and/or irrigation infrastructure during the growing season where they could access plant material contaminated with endosulfan or other pesticides. Cotton growers will take all due care to ensure such access is precluded and should therefore ensure that;
  - a. All fences are maintained to an appropriate standard which prevent stock access
  - b. Access by gate or ramps or other entry points for stock or machinery is monitored and restricted
  - c. where appropriate, signage is placed on property boundaries and at gates to ensure stock managers are aware of crop treatment.
3. Individual cotton growers will ensure that livestock are not allowed access to fields containing cotton crop residue at the conclusion of the season until cotton crop residue has been ploughed in and an appropriate time has elapsed to allow for the depletion of pesticide residue. Cotton growers will take all due care to ensure such access is precluded.

4. Cotton growers will ensure that Cotton crops which have failed prior to maturity, not to be cut and baled for the purposes of feeding to livestock as fodder and will take all due care to ensure stock access to failed crop material is precluded.
5. Cotton Australia Ltd will reinforce to cotton growers, the legislative requirements set out on registered endosulfan pesticide labels, which relate to the feeding of cotton gin trash, cotton crop residue and failed cotton crop material to livestock.
6. Cotton Australia will insert the principles outlined in points 2,3 and 4 into the appropriate section of the industry Best Management Practices Manual.
7. Cotton Australia will reinforce to cotton growers the legislative requirements set out for use of registered endosulfan pesticide labels which relate to the management of spray drift and communication of spray events to relevant stakeholders
8. Cotton Australia and the Cotton Ginner's Association recognizes the SAFEMEAT™ Commodity Vendor Declaration and By Product Vendor declaration as the primary and most effective means of communicating chemical residue risks in stockfeeds. Cotton Australia and the Cotton Ginner's Association will work with SAFEMEAT™ to expand awareness of the Commodity Vendor Declarations (CVD) And By-Product Vendor Declarations (BPVD) in the Cotton Industry, communicate to CA and ACGA members SAFEMEAT™ updates on the CVD and BPVD, and agree to encourage use of these management tools.

**The Australian Beef Cattle Industry Agrees to the following:**

1. Cattle Council of Australia and the Australian Lot Feeders Association will actively support the position taken by the cotton industry not to allow supply of cotton by-product (including cotton gin trash, failed crop residue, and cotton crop residue) to any person for the purposes of feeding the material to livestock – including drought situations.
2. Cattle Council of Australia and the Australian Lot Feeders Association reinforce through State Member Organisations, Affiliate Member Organisations and Meat and Livestock Australia will reinforce to Cattle producers and the wider the livestock industries the risks associated with feeding of cotton by product to livestock.
3. Cattle Council of Australia and the Australian Lot Feeders Association will through SAFEMEAT continue to support the use of the National Vendor Declaration and accompanying NVDs and CVDs as an effective method of identifying livestock which are at risk of residue violations.
4. Cattle Council of Australia and the Australian Lot Feeders Association will support the continuation of National Residue Survey monitoring for endosulfan residue in meat of livestock and the work of the "Endosulfan Task Force" through the Beef Industry Advisory Committee (BIAC) and SAFEMEAT Committees
5. Cattle Council of Australia and the Australian Lot Feeders Association will assist in the investigation of 'reported actions of either industry's members in not complying with the principles set out in this agreement.
6. Cattle Council of Australia and the Australian Lot Feeders Association will work to insert appropriate information on the risks associated with cotton crop by products into the guidelines and information which support the Cattlecare, NFAS and LPA programs.

**General**

1. In the event of either a cotton industry member or livestock industry member becoming aware of an incident or action involving cotton by product which could place livestock at risk of obtaining endosulfan residue, the matter should be reported to the State Residue Co-ordinator in the appropriate state.
2. Where it becomes necessary for the State Residue Co-ordinator to make further enquiries with respect to a reported incident, initial contact should be made with either Cotton Australia Ltd or Cattle Council of Australia, who agree to notify the other party in a timely manner.
3. It is the responsibility of the State Residue Co-ordinator to advise Safemeat of the situation if it is considered necessary.



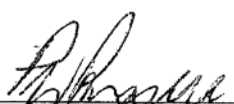
## Definitions

For the purposes of interpreting this document the following definitions should be noted.

- (a) Endosulfan - Any registered pesticide product which has as its active ingredient endosulfan or product which contains endosulfan as one of its ingredients.
- (b) Cotton By-Product - Materials which are a by-product of the production of cotton plants which include cotton gin trash, cotton crop residue and failed cotton crop material.
- (c) Cotton Gin Trash – Bark, cotton stalk fragments, leaves and other material such as dirt, which are separated from cotton lint during the ginning process.
- (d) Cotton Crop Residue - Cotton stalks, desiccated leaves which remain in field after the cotton lint is harvested.
- (e) Failed Cotton Crop Residue - whole cotton plant which has not reached maturity but has been abandoned .

Term and Termination

Cotton Australia, Cattle Council of Australia, Australian Lot Feeders Association and the Australian Cotton Ginners Association agree that this memorandum shall remain in effect until terminated by either party upon 90 days notice to the other party, where it is authorized to do so under its governing legislation. All parties agree that where one group determines that such termination is justified by inadequacy of the existing regulatory mechanisms, or the effectiveness of the MoU in managing risk, that all groups support the immediate review of products containing the active Endosulfan which are used in the cotton industry.



Cotton Australia Ltd

Date: 16/6/05



Australian Cotton Ginners Association

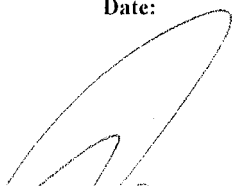
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Cattle Council of Australia

Date:

16/6/05



Australian Lot Feeders Association

Date:

9/6/05

## Appendix 1:

### Australian Cotton Ginners' Association ATTACHMENT 1

# DRAFT CODE OF PRACTICE

## Management of Cotton Gin Trash

Waste cotton gin by- product commonly referred to as *cotton gin trash* has the potential to contain residues of certain <sup>2</sup>*pesticides* which are applied to an actively growing cotton crop during the cotton growing season. If consumed by livestock, the <sup>3</sup>*residues* contained in the trash may accumulate in the meat and/or fat of animals and give rise to unacceptable pesticide residues which may place meat export markets at risk.

All reasonable efforts must be taken to ensure that livestock including beef cattle, dairy cattle, sheep and goats are not fed cotton gin trash or allowed access to this material.

Cotton Ginners will implement the following practices aimed at preventing livestock from gaining access to cotton gin trash and potential pesticide residues.

- (1) Cotton Ginners take all reasonable steps to ensure that cotton gin trash remains under their direct control and supervision until such times as it can be disposed of by approved means.
- (2) The *approved* method of disposal at this point in time will be by composting. The following two methods of composting may be employed:
  - a. Natural Composting — A process where cotton gin trash is placed in 1-1.5 metre high rows and allowed to decompose over time with the assistance of natural rainfall and bacterial action.
  - b. Mechanical Composting - A process where cotton gin trash is placed in 1 — 1.5 metre high rows and allowed to decompose over time with mechanical interventions including maintaining moisture content at optimal levels with the addition of water and the mechanical turning of windrows.
- (3) Composting sites will minimize the generation of dust by the appropriate application of water.

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<sup>i</sup> Waste material including dirt, bark, leaves, bracts, and other vegetative matter removed from cotton lint during the cotton ginning process.

<sup>2</sup> Pesticides are synthetic chemical substances as defined by various state legislation, which may be applied to cotton crops to control insects, weeds, fungi or control cotton plant growth.

<sup>3</sup> Residue refers to the small concentrations of pesticides which may remain on plant material & in soil after application. Pesticides break down at varying rates according to the pesticide's characteristics and may be present after long periods of time in the case of persistent pesticides.

- (4) Composting sites will be located in areas where rainfall runoff can be controlled so as to prevent contaminated water moving to neighbouring properties, or entering water courses or areas where livestock may consume the water.
- (5) Composting sites should be located such that they are not in flood-prone areas.
- (6) In the first instance, cotton gin trash will be composted, if possible, on the property where the ginning facility is located. If available land area is, or becomes a constraint, composting may be conducted on an alternative land area under the control of the ginning organisation or on an area of land owned by another person acting under contract to the ginning organisation. Where composting takes place remotely from the gin site or under contract, the composting site must comply with (3) (4) and (5) above.
- (7) Where it is necessary for gin trash to be removed from the gin site to another location for the purposes of composting, gin operators will take all reasonable steps to ensure that:
  - a. the land area on which composting will be conducted is securely fenced and secured so as to prevent livestock accessing the cotton gin trash /compost .
  - b. during the transporting process, cotton gin trash is prevented from falling from the transport vehicle(s).
  - c. appropriate security including the locking of access gates and regular surveillance of the site is implemented so as to prevent the unauthorized entry and removal of trash by unauthorized persons.
  - d. each section of fence and access gates securing the cotton gin trash /compost bears a prominent sign stating:

"COTTON GIN TRASH / COMPOST  
DO NOT FEED TO LIVESTOCK"
  - e. if the cotton ginner or any person responsible for the security of the cotton gin trash/compost has reason to believe that the compost enclosure has been accessed by unauthorized persons, livestock have accessed the cotton gin trash/compost or material has been removed from the enclosure, then full details must be reported immediately to the *State Residue Co-ordinator* in the appropriate state.

- (8) In the case of a cotton gin operator engaging a landholder in a contract to compost cotton gin trash on his property, the cotton gin operator will include all of the requirements set out in item (7) above in the formal contract. In addition the cotton gin operator will include any additional terms and conditions he deems necessary to ensure the security of the cotton gin trash /compost in the particular circumstances. The cotton gin operator or his representative will further advise the contractor of the risks to livestock posed by cotton gin trash and the importance of security of the cotton gin trash/compost. A representative of the cotton ginning organisation will inspect the contract site on at least a weekly basis to ensure compliance of contract terms and conditions.
- (9) In the case of both cotton gin site and contract composting operations, the cotton ginning organisation will maintain accurate records of composting activities. Records will contain dates and quantities of cotton gin trash placed in composting sites; dates and quantities and details of compost transported, and details of any incidents of unauthorized access or removal of cotton gin trash/ compost.
- (10) Compost from each season will be maintained separately, and remain identifiable so that age of compost can be readily determined.
- (11) Cotton ginner will not supply any person with cotton gin trash for any purpose including garden mulch, direct feeding to livestock or as an ingredient for manufactured stock feed.
- (12) Where the cotton ginning operation is part of a large integrated farm which also operates a livestock enterprise on that farm, the gin operator will ensure that livestock do not have access to the ginning facilities or associated module yards, seed storages, cotton gin trash storages, gin yard water runoff storage dams or cotton gin trash composting areas. In addition, the operator will not use cotton gin trash as a stock feed including as an emergency drought fodder.
- (13) Other than for the purposes of composting cotton gin trash as a contractor to a cotton gin operator, individual growers who seek to obtain gin trash generated from the ginning of cotton grown on their own property, will not be supplied with cotton gin trash by the cotton gin operator.
- (14) Where cotton gin trash has been composted and has degenerated to a material of a soil like nature, it may be used as a soil enhancement material.

- (15) Where state legislation is in force which classifies cotton gin trash as a particular class of waste, cotton gin operators will comply with that legislation in the handling of the material for the purposes of disposal. In complying with that legislation, all reasonable effort will be taken to ensure that any risk of access to the cotton gin trash by livestock is eliminated.
- (16) In the event of cotton gin trash being spilled from a transport vehicle during transport, the gin operator must, upon being made aware of the spill, take immediate action to retrieve the spilled material and remove it to the composting site.

### **Management of Cotton Gin Motes**

Cotton gin motes should not be fed to livestock and as such, from the cotton gin operators position, will be treated the same as cotton gin trash where they are to be disposed of rather than be used for low grade industrial cotton products. Disposal will be by composting in accordance with the code of practice requirements for cotton gin trash.



United States  
Environmental Protection  
Agency

Prevention, Pesticides  
and Toxic Substances  
(7508C)

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EPA 738-R-02-013  
November 2002

# Reregistration Eligibility Decision for Endosulfan







# R.E.D. FACTS

## Endosulfan

### Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0014, endosulfan.

### Use Profile

Endosulfan is a broad spectrum contact insecticide and acaricide registered for use on a wide variety of vegetables, fruits, cereal grains, and cotton, as well as ornamental shrubs, trees, vines, and ornamentals for use in commercial agricultural settings. Total average annual use of endosulfan is estimated at approximately 1.38 million pounds of active ingredient (lbs. ai), according to Agency and registrant estimates. Crops with the highest average percent drop treated are: squash (40%), eggplant (41%), cantaloupe (31%), sweet potato (31%), broccoli (26%), pears (20%), and pumpkins (20%). Crops with the highest sales in 2001 include: cotton (14.2%), cantaloupe (13.2%), tomatoes (12.2%), and potatoes (8.15%).

Endosulfan is formulated as a liquid emulsifiable concentrate ( 9-34% ai) and wettable powder (1-50% ai). The wettable powder formulation is frequently packaged in water soluble bags. Endosulfan can be applied by groundboom sprayer, fixed-wing aircraft, chemigation (potatoes only), airblast sprayer, rights-of-way sprayer, low pressure handwand sprayer, high pressure handwand sprayer, backpack sprayer and dip treatment.

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## Regulatory History

Endosulfan was first registered as a pesticide in the U.S. in 1954 to control agricultural insect and mite pests on a variety of field, fruit, and vegetable crops. A Registration Standard dated September 17, 1981, and a Guidance Document dated April 1982 were issued for endosulfan, which required additional generic and product-specific data for the manufacturing products of the technical registrants. Since the Guidance Document was issued, there have been seven DCIs generated: 10/23/85, 5/19/86, 5/27/86, 1/30/87, 6/19/87, 9/02/92, and 5/10/94 concerning the potential formation of chlorinated dibenzo-p-dioxins and dibenzofurans in technical endosulfan products. An additional DCI was issued in October 1994, which primarily concerned residue chemistry data deficiencies.

Further, in 1991, the technical registrants amended labels to incorporate a 300-foot spray drift buffer for aerial applications between treated areas and water bodies. This setback was adopted in order to address concerns about contamination of water and risks to aquatic organisms. In 2000, the technical registrants amended technical product labels to remove all residential use patterns. Currently, there are 94 endosulfan products registered.

## Human Health Assessment

### Toxicity

Endosulfan generally has been shown to have high acute oral and inhalation toxicity as well as slightly toxic dermal toxicity. It is an irritant to the eyes and is not a dermal sensitizer. Endosulfan is neither mutagenic nor carcinogenic. Endosulfan primarily affects the nervous system. Toxic effects observed in animals from acute, subchronic, developmental neurotoxicity, and chronic/carcinogenic toxicity studies found that endosulfan causes neurotoxic effects, which are believed to result from over-stimulation of the central nervous system. Further, there is evidence (effects observed in a submitted chronic oral toxicity study in rats) that endosulfan acts as an endocrine disruptor. However, further investigation is necessary to determine the relevance and impact of such findings on public health.

### Dietary Exposure

EPA has assessed dietary risk by estimating exposure to endosulfan residues from consumption of food and drinking water that can occur over a single-day (acute) or longer (chronic). Generally, a dietary (food) risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concern. Acute risk estimates from exposures to food, associated with the use of endosulfan exceed the Agency's level of concern for some population subgroups. For example, for exposure resulting from applications of endosulfan, for the most exposed population subgroup, children 1-6 years old, the percent acute PAD value is 150% at the 99.9<sup>th</sup> percentile of exposure from consumption of food alone. The crops that contributed the most to the risks of concern are succulent beans and peas. Chronic dietary (food) exposure estimates are below the Agency's level of concern for all

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subpopulations. For the most highly exposed subpopulation, children 1-6 years old, the percent chronic PAD value is 17% from consumption of food alone.

Drinking water exposure to endosulfan can occur through ground and surface water contamination. EPA used modeled Tier 2 estimates of endosulfan and endosulfan sulfate to estimate risk for acute exposures. Taking into account the supported uses of endosulfan, the Agency concluded that residues of endosulfan in drinking water are of concern. Drinking water estimates for chronic exposures, based on models, from both ground and surface water are not of concern.

### Risk from All Registered Pesticide Endosulfan Exposures

To assess risks from all endosulfan exposures, the Agency combined risk from food and drinking water exposure only. The technical registrants are not supporting residential or other non-occupational uses of endosulfan. As a result, these use patterns have not been considered for regulatory purposes at this time. The acute estimated drinking water concentrations for endosulfan are above the acute drinking water level of comparisons (DWLOCs) for infants <1 year and the most sensitive population subgroup, children 1-6 years old. The chronic estimated drinking water concentrations for the U.S. general population and all population subgroups are below the chronic drinking water levels of comparisons (DWLOCs) for the U.S. general population and all population subgroups and, therefore, are not of concern.

### Occupational Exposure

Occupational handlers can be exposed to endosulfan through mixing, loading and/or applying a pesticide or re-entering treated sites. Occupational handlers of endosulfan include individual farmers or growers who mix, load and/or apply pesticides and professional or custom agricultural applicators. The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture.

Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a NOAEL. Generally, MOEs greater than 100 are not of concern. Restricted Entry Intervals (REIs) are 24 hours on current endosulfan labels. The Agency has determined that there are potential mixer, loader, applicator as well as post-application exposures to occupational handlers. Based on current use patterns, there are some short-term dermal and inhalation risks of concerns for workers who mix, load and apply endosulfan to agricultural sites as well as to those workers who re-enter a treated area following application of endosulfan.

## **Environmental Assessment**

Ecological risks are also of concern to the Agency. The environmental risk assessment suggests that exposure to endosulfan could result in both acute and chronic risks of concern for terrestrial and aquatic organisms. Exposure to

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endosulfan has resulted in both reproductive and development effects in nontarget animals, particularly birds, fish and mammals.

## **Risk Mitigation Measures**

To mitigate human health and ecological risks of concern for endosulfan, the following measures will be implemented:

### Dietary (Food) Risk

- Delete use on succulent beans, succulent peas, spinach, and grapes

### Dietary (Drinking Water) and Ecological Risk

Several mitigation measures are needed to reduce the potential for contamination of drinking water.

- Delete use on pecans;
- Reduce maximum seasonal application rates from 3lbs./ai/A to 2.5 lbs./ai/A for pome fruit, stone fruit, and citrus;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A for melons, cucurbits, lettuce, tomatoes, sweet potatoes, cotton (ground), broccoli, cauliflower, cabbage, kohlrabi, brussels sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, eggplant, potatoes, carrots, dry beans, dry peas, and tobacco;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A for sweet corn, cotton (aerial) and blueberries;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1 lb./ai/A for celery;
- Require 100 ft. spray buffer for ground applications between a treated area and water bodies;
- Require 30 ft. maintained vegetative buffer strip between a treated area and water bodies;
- Require all products to be Restricted Use;
- Restrict use on cotton to AZ, CA, NM, OK and TX only; and
- Restrict use on tobacco to IN, KY, OH, PA, TN and WV only.

### Occupational Risk

- Require all wettable powders to be packaged in water soluble bags;
- Cancel use of wettable powders on tomatoes, sweet corn, sweet potatoes, cotton, small grains, alfalfa (seed), carrots, dry beans, dry peas, pineapples, and tobacco;
- Cancel aerial application using the wettable powder formulation on pome fruits, stone fruits, citrus, blueberries, strawberries, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga

- 
- (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), filberts, walnuts, almonds, and macadamia nuts;
  - Require closed mixing/loading systems for aerial application using the EC formulation on pome fruits, stone fruits, citrus, sweet corn, sweet potatoes, cotton, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), blueberries, small grains, alfalfa (seed), filberts, walnuts, almonds and macadamia nuts;
  - Require closed cabs for airblast applications on pome fruits, stone fruits, citrus, filberts, walnuts, almonds and macadamia nuts;
  - Prohibit use of high pressure handwands with rates greater than 0.005 lbs/ai/gal;
  - Increase REI to 48 hours for all crops except as noted in the following bullets;
  - Increase REI for WP products to 3 days for melons and cucurbits;
  - Increase REI for WP products to 4 days for lettuce, celery, pome fruit, stone fruit, citrus, collard greens, kale, mustard greens, radish, turnip, rutabaga, ornamental trees and shrubs;
  - Increase REI for WP products to 5 days for collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed) and rutabaga (seed);
  - Increase REI for WP products to 9 days for blueberries, broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts;
  - Increase REI for WP products to 12 days for broccoli (seed), cauliflower (seed), kohlrabi (seed), and cabbage (seed);
  - Increase REI for EC products to 3 days for sweet potatoes
  - Increase REI for EC products to 4 days for broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts;
  - Increase REI for EC products to 6 days for blueberries;
  - Increase REI for EC products to 7 days for broccoli (seed), kohlrabi (seed), and cabbage (seed); and
  - Increase REI for EC products to 17 days for sweet corn.

**Stakeholder  
Process**

Given the toxicity and persistence of endosulfan and potential risks to aquatic organisms, the Agency has developed a number of mitigation measures in order to reduce the risks to aquatic organisms outlined in this document. While the Agency believes that these measures will reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan, it also believes that in specific geographic areas where conditions exist that make aquatic organisms especially vulnerable (e.g., shallow, leaky aquifers, highly erodible lands, the presence of especially sensitive organisms and

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high use of endosulfan) additional measures may be identified. In order to more fully evaluate the risks in these vulnerable areas; the risk management strategies that may be in place or could potentially be implemented in such areas (e.g., use of retention ponds) to reduce exposure; and the benefits of the use of endosulfan in those areas, the Agency is planning to conduct a stakeholder process to accomplish this objective. Further, the impacts of atmospheric transport may require additional evaluation during this time period. Additional mitigation measures may be needed following the completion of this process.

## **Additional Data Required**

EPA is requiring the following additional generic studies for endosulfan to confirm its regulatory assessments and conclusions:

- OPPTS 850.2100: Avian acute oral toxicity of bobwhite quail and mallard ducks
- OPPTS 850.2200: Avian subchronic oral toxicity of bobwhite quail and mallard ducks
- OPPTS 850.2300: Avian reproduction study
- OPPTS 850.1075: Freshwater fish acute toxicity study of bluegill sunfish
- OPPTS 850.1300: Early life stage fish
- OPPTS 850.1350: Life cycle invertebrate
- OPPTS 850.1500: Freshwater fish full life cycle using rainbow trout
- OPPTS 850.1075: Estuarine/marine fish acute toxicity study
- OPPTS 850.1035: Estuarine/marine invertebrate acute toxicity study of mysid shrimp
- OPPTS 850.1735: Whole sediment acute toxicity testing using a freshwater invertebrate
- OPPTS 850.1740: Whole sediment acute toxicity testing using a estuarine/marine invertebrate
- OPPTS 850.1735S: Whole sediment chronic toxicity testing using a freshwater invertebrate
- OPPTS 850.1740S: Whole sediment chronic toxicity testing using an estuarine/marine invertebrate
- 164-2 (Special Study): Vegetative buffer effectiveness study
- OPPTS 835.7100: Groundwater monitoring study
- OPPTS 835.7200: Surface drinking water monitoring study
- OPPTS 870.6200: Subchronic Neurotoxicity - Rat
- OPPTS 870.6300: Developmental Neurotoxicity Toxicity Study - Rat
- OPPTS 860.1380: Storage stability (oils seed, non-oily grain and processed commodities)

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- OPPTS 860.1500: Crop field trials for the following raw agricultural commodities: barley hay, and pearled barley; oat forage, hay, and rolled oats; rye forage; wheat forage, and hay
  - OPPTS 860.1500: Crop field trials for tobacco and a pyrolysis
  - OPPTS 860.1520: Magnitude of residue in processed food/feed commodities
  - OPPTS 875.1100: Dermal outdoor exposure for applying dip treatments to trees and roots or whole plants
  - OPPTS 875.1700: Product use information for applying dip treatments to trees and roots or whole plants

The Agency is also requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

## **Regulatory Conclusion**

The Agency has assessed all 80 tolerances for endosulfan and can make a FQPA safety determination based on a review of the dietary (food and drinking water), ecological and occupational risks associated with the supported uses of currently registered pesticides containing endosulfan.

Agricultural uses of endosulfan based on approved labeling pose occupational risks of concern and ecological risks that constitute unreasonable adverse effects on the environment. However, the Agency believes these risks can likely be mitigated to levels below concern through changes to pesticide labeling and formulations. Accordingly, the Agency has determined that endosulfan is eligible for reregistration provided that: (1) additional required data will confirm this decision for occupational exposures associated with the application of dip treatment to roots or whole plants and ecological risks; and (2) the risk mitigation outlined in the RED are adopted, and label amendments are made to reflect these measures. Further, if vulnerable areas in specific geographic areas are identified as a result of the stakeholder process, additional ecological risk mitigation measures may be necessary to protect especially sensitive organisms. The endosulfan RED document includes guidance and time frames for complying with any label changes for products containing endosulfan.

## **For More Information**

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for endosulfan during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460; telephone number 703-305-5805.

Electronic copies of the RED, this Fact Sheet, and all supporting documents are available on the Internet. See <http://www.epa.gov/REDs>.

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The Agency has also established an official record for this action under docket control numbers OPP-34242 and eDocket OPP-2002-0262.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the endosulfan RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the endosulfan RED, or reregistration of individual products containing endosulfan please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is <http://npic.orst.edu>.





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**WASHINGTON, D.C. 20460**

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 31, 2002

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the U.S. Environmental Protection Agency (hereafter referred to as EPA or the "Agency") has completed its review of the available data and public comments received related to the risk assessments for the chlorinated cyclodiene pesticide endosulfan. The public comment period on the preliminary risk assessment phase of the reregistration process commenced on September 13, 2001 and closed on November 13, 2001. The Agency has revised the human health and environmental effects risk assessments based on the comments received during the public comment period and additional data received from the registrant.

Based on its review, the Agency has identified risk mitigation measures that it believes are necessary to address the human health and ecological risks associated with the current uses of endosulfan. The Agency believes that these risk mitigation measures will adequately address human health and ecological risks for endosulfan. However, further mitigation measures for ecological risk may be warranted following the completion of the stakeholder process outlined in this document. The Agency has identified several mitigation measures to address ecological risks. While the Agency believes that these measures will reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan, it also believes that in specific geographical areas where conditions exist that make aquatic organisms especially vulnerable additional measures may be identified. Further, the Agency is unable to fully evaluate the ecological risks associated with the atmospheric transport of endosulfan at this time. In order to more fully evaluate the risks in these vulnerable areas; the risk management strategies that may be in place or could potentially be implemented in such areas to reduce exposure; and the benefits of the use of endosulfan in those areas, the Agency is planning to conduct a public comment and stakeholder process.

EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of endosulfan, and its associated human health risks which address risks from dietary exposure to food and water and occupational exposures. As mentioned above, the Agency will conduct a stakeholder process to address environmental risks in especially vulnerable areas at the completion of which the Agency may identify additional mitigation measures that may be needed. The enclosed "Reregistration Eligibility Decision for Endosulfan," which was approved on July 31, 2002, contains the Agency's decision on the individual chemical endosulfan.

A Notice of Availability for the Reregistration Eligibility Decision (RED) for Endosulfan is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/reregistration/status.htm>.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. In cooperation with the U.S. Department of Agriculture, the Agency held a teleconference on July 29, 2002, during which the results of the human health and environmental effects risk assessments were presented to interested stakeholders. Information discussed during the call, such as endosulfan usage and occupational practices, are reflected in this RED. Also, a close-out conference call was conducted on July 30, 2002 with many of the same participants from the July 29 conference call to discuss the risk management decisions and resultant changes to the endosulfan labels.

A risk mitigation proposal for endosulfan was submitted by the Endosulfan Task Force (ETF), the technical registrant. During the public comment period provided for the preliminary risk assessment, EPA also received comments from the Natural Resources Defense Council, World Wildlife Fund, Pesticide Action Network Asia and the Pacific, Boulder Regional Group, American Society of Consulting Arborists, Gaia Foundation, Rural Action Safe Pest Control Program, and private citizens.

Please note that the endosulfan risk assessment and the attached RED concern only this particular pesticide. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity with other pesticides. The Agency does not currently have data available to determine with certainty whether endosulfan or endosulfan sulfate have a common mechanism of toxicity with any other substances. For the purposes of this decision, the Agency has assumed that there are not any other chemical substances that share a common mechanism of toxicity with endosulfan and has not performed a cumulative risk assessment as part of this reregistration review of endosulfan. If the Agency identifies other substances that share a common mechanism of toxicity with endosulfan, then the cumulative risks of these chemicals will be considered.

As mentioned above, the Agency has identified risk mitigation measures that it believes are necessary to address the human health risks associated with the current uses of endosulfan and measures to reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan. Accordingly, the Agency recommends that registrants implement these risk mitigation measures on an accelerated schedule. Sections IV and V of this RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants for submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this RED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by endosulfan. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern.

There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register. In addition to the public comment period the Agency will initiate a stakeholder process, which will be initiated in the near future to address potentially vulnerable areas.

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a complete DCI, with all the pertinent instructions, is being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Stacey Milan at (703) 305-2505. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen Jones at (703) 308-8047.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Attachment

**Reregistration Eligibility Decision**

**for**

**Endosulfan**

**Case No. 0014**

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## GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data call-in
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium-specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAI	Purified Active Ingredient
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/	
EXAMS	Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing

SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
SGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## Executive Summary

EPA has completed its review of public comments concerning the preliminary risk assessments and is issuing its risk management decision for endosulfan. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision concerning endosulfan. After considering the risks identified in the revised risk assessment, mitigation measures proposed by the Endosulfan Task Force, which consists of the technical registrants of endosulfan, and comments and mitigation suggestions from other interested parties, the Agency developed its risk management decision for uses of endosulfan that pose risks of concern. This decision is discussed fully in this document.

Endosulfan, a dioxathiepin (broadly classified as an organochlorine), is a broad spectrum contact insecticide and acaricide that is used on a wide variety of vegetables, fruits, cereals, and cotton, as well as ornamental shrubs, trees, vines, and ornamental herbaceous plants in commercial agricultural settings. Technical grade endosulfan is composed of two stereochemical isomers:  $\alpha$ -endosulfan and  $\beta$ -endosulfan, in concentrations of approximately 70% and 30%, respectively. Endosulfan was first registered in 1954 to control a broad spectrum of agricultural insect and mite pests on various crops. Use data from 1987 to 1997 indicate an average domestic use of approximately 1.38 million pounds of active ingredient per year.

The Food Quality Protection Act of 1996 (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity with other pesticides. The Agency does not currently have data available to determine with certainty whether endosulfan or endosulfan sulfate have a common mechanism of toxicity with any other substances. For the purposes of this decision, the Agency has assumed that there are not any other chemical substances that share a common mechanism of toxicity with endosulfan and has not performed a cumulative risk assessment as part of this reregistration review of endosulfan. If the Agency identifies other substances that share a common mechanism of toxicity with endosulfan, then the cumulative risks of these chemicals will be considered once the final framework the Agency will use for evaluating cumulative risks is available.

## Overall Risk Summary

The Agency’s human health risk and ecological risk assessments for endosulfan indicate risks of concern. Acute dietary (food) risk exceeds the Agency’s level of concern (>100% aPAD) at the 99.9<sup>th</sup> exposure percentile for children 1-6 years of age (150% aPAD). Significant contributors to acute exposure have been identified as succulent beans and succulent peas. The dietary (food) assessment also concludes that for all commodities, the chronic risk estimates are below the Agency’s level of concern (<100% cPAD) for the U.S. population (<1% of the cPAD)

and all population subgroups with the highest exposed population subgroup, children 1-6 years of age occupying 17% of the cPAD.

Dietary (drinking water) risk for acute exposures, based on models, from both ground and surface water are of concern. Drinking water estimates for chronic exposures, based on models, from both ground and surface water are not of concern. Further, there are some concerns for workers who mix, load and apply endosulfan to agricultural sites as well as to those workers who re-enter a treated area following application of endosulfan.

For ecological effects, the Agency has conducted a screening level assessment for terrestrial impacts and a refined exposure assessment for aquatic impacts of endosulfan use. These assessments indicate that endosulfan is likely to result in acute and chronic risk to both terrestrial and aquatic organisms.

To mitigate risks of concern posed by the uses of endosulfan, the Agency considered the mitigation proposal submitted by the technical registrants, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the dietary (food and drinking water), worker and ecological concerns. Results of the risk assessments, and the necessary label amendments to mitigate those risks, are presented in this RED.

#### Dietary Risk

Acute risk estimates for food and drinking water exceed the Agency's level of concern; therefore, mitigation measures are warranted at this time for dietary exposure to endosulfan. To mitigate the risks from acute food exposure, the following crop uses will be canceled: succulent beans, succulent peas, grapes, and spinach.

Several mitigation measures are needed to reduce the potential for the contamination of drinking water. These include a 100-foot setback for ground applications between treated areas and water bodies, a 30-foot vegetative buffer between treated areas and water bodies, reductions in maximum application rates, reductions in maximum seasonal application rates and reductions in the maximum number of applications allowed per use season. These measures, together with conservative assumptions used in the modeled estimates of drinking water exposure, lead the Agency to believe that risk from drinking water will not exceed its level of concern. Drinking water monitoring data will be required to confirm this conclusion.

#### Occupational Risk

Occupational exposure to endosulfan is of concern to the Agency, and it has been determined that a number of measures are necessary to mitigate these risks. For the agricultural uses of endosulfan, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern. To mitigate these risks several steps are needed including placing all wettable powder (WP) products in water soluble bags, the deletion of some uses from WP products,

deletion of aerial application of WP products for some crops, requiring closed mixing/loading systems for aerial applications of the emulsifiable concentrate (EC) formulation for some uses, requiring closed cabs for all airblast applications except for ornamental trees/shrubs and reductions in application rates.

The risks to workers reentering treated fields are of concern for several crops. These risks can be mitigated provided the restricted entry intervals recommended in this document are established.

### Ecological Risk

Ecological risks are also of concern to the Agency. The environmental risk assessment suggests that exposure to endosulfan could result in both acute and chronic risks of concern for terrestrial and aquatic organisms. To reduce these risks, several mitigation measures are needed. These measures include a 100-foot setback for ground applications between treated areas and water bodies, a 30-foot vegetative buffer between treated areas and water bodies, reductions in single maximum application rates, reductions in maximum seasonal application rates, reductions in maximum numbers of applications allowed in a single growing season and deletion of use on pecans.

### Stakeholder Process to Address Aquatic Risks and Long Range Transport

Given the toxicity and persistence of endosulfan and potential risks to aquatic organisms, the Agency has developed a number of mitigation measures in order to reduce the risks to aquatic organisms outlined in this document. While the Agency believes that these measures will reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan, it also believes that in specific geographic areas where conditions exist that make aquatic organisms especially vulnerable (e.g., shallow, leaky aquifers, highly erodible lands, the presence of especially sensitive organisms and high use of endosulfan) additional measures may be identified. In order to more fully evaluate the risks in these vulnerable areas; the risk management strategies that may be in place or could potentially be implemented in such areas (e.g., use of retention ponds) to reduce exposure; and the benefits of the use of endosulfan in those areas, the Agency is planning to conduct a public comment and stakeholder process to accomplish this objective. Further, the impacts of atmospheric transport may require additional evaluation during this time period. Additional mitigation measures may be needed following the completion of this process.

Endosulfan is a semivolatile and persistent cyclodiene pesticide that can migrate over a long distance through various environmental media such as air, water, and sediment. Once endosulfan is applied to crops, it can either persist in soil as a sorbed phase or be removed through several physical, chemical, and biological processes. Recent studies suggest that secondary emissions of residual endosulfan continue to recycle in the global system while they slowly migrated and are redeposited via wet deposition in the Northern Hemisphere. The occurrence of endosulfan in remote regions like the Great Lakes, the Arctic, and mountainous

areas is well documented. Endosulfan can also enter the air as adsorbed phase onto suspended particulate matter, but this process does not appear to be a major contributor to long range transport like volatilization.

The presence of endosulfan in the remote areas like Arctic and the Great Lakes requires further understanding of the transport mechanisms from the atmosphere. The potential impact of atmospheric deposition of endosulfan into surface water and its potential effect on water quality and aquatic organisms in the non-use areas is not well documented. Despite the progress made in recent years in estimating the persistence and long-ranged transport of chemicals using models, a validated global model has not been published because of uncertainties involved in the source inventories, chemical fate data, degradative pathways and exposure analyses. Future work will be aimed at developing a comprehensive screening tool that can be used reliably in risk assessments for regulatory purposes. Part of the stakeholder process will include an evaluation of to what extent data related to long range transport may be necessary.

## **I. Introduction**

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the current scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine the need for additional data on health, and environmental effects and to determine whether the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996.

FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Endosulfan belongs to a group of pesticides called organochlorines. Although chemical class is not necessarily equivalent to a common mechanism of action, in some cases, chemicals within the same class have been shown to share a common mechanism of action and are being considered together for purposes of a cumulative assessment (e.g., the organophosphates). Specifically, endosulfan belongs to the chlorinated cyclodiene (organochlorine) class of insecticide/acaricide. The Agency does not currently have data available to determine with certainty whether endosulfan or endosulfan sulfate have a common mechanism of toxicity with any other substances. For the purposes of this decision, the Agency has assumed that there are not any other chemical substances that share a common mechanism of toxicity with endosulfan and not performed a cumulative risk assessment as part of this reregistration review of endosulfan. If the Agency identifies other substances that share a common mechanism of toxicity with endosulfan, then the cumulative risks of these chemicals will be considered once the final framework the Agency will use for evaluating cumulative risks is available.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups and other interested parties.



This document summarizes the Agency's revised human health and ecological risk assessments, its progress toward tolerance reassessment and the reregistration eligibility decision for endosulfan. This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page <http://www.epa.gov/pesticides/endosulfan>, and in the public docket.

## II. Chemical Overview

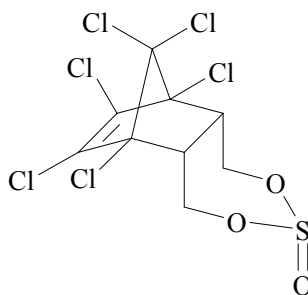
### A. Regulatory History

Endosulfan is a broad spectrum insecticide and acaricide first registered for use in the United States in 1954 to control agricultural insect and mite pests on a variety of field, fruit, and vegetable crops. A Registration Standard dated September 17, 1981, and a Guidance Document dated April 1982 were issued for endosulfan, which required additional generic and product-specific data for the manufacturing products of the technical registrants. In addition, Data-Call-Ins (DCIs) were issued in June 1987 and September 1992 concerning the potential formation of chlorinated dibenzo-p-dioxins and dibenzofurans in technical endosulfan products. Since the Guidance Document was published in April 1992, there have been a total of seven DCIs issued (10/23/85, 05/19/86, 05/27/86, 01/30/87, 06/19/87, 09/02/92, and 05/10/94). Another DCI was issued in October 1994, which primarily concerned data residue chemistry deficiencies.

In 1991, the technical registrants amended labels to incorporate a 300-foot spray drift buffer for aerial applications between treated areas and water bodies. This setback was adopted in order to address concerns about contamination of water and risks to aquatic organisms. In 2000, the technical registrants amended technical product labels to remove all residential use patterns. Further, the registrants have agreed to restrict the annual maximum use rate for all uses to 3lbs. active ingredient per acre.

### B. Chemical Identification

Endosulfan:



- **Common name:** Endosulfan
- **Chemical name:** 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide
- **Chemical family:** Organochlorine
- **Case number:** 0014
- **CAS registry number:** 115-29-7
- **OPP chemical code:** 079401
- **Empirical formula:** C<sub>9</sub>H<sub>6</sub>CL<sub>6</sub>O<sub>3</sub>S
- **Molecular weight:** 406.95 daltons
- **Trade and other names:** Thiodan<sup>®</sup>
- **Basic manufacturers:** Bayer CropScience, Makhteshim-Agan of North America, FMC Corporation, Gowan, Platte Chemical, and Drexel Company.

Endosulfan is often referred to generically as a “cyclodiene-type” insecticide, but it contains only one double bond. Technical endosulfan (70%  $\alpha$ - and 30%  $\beta$ -endosulfan) is a light to dark brown crystalline solid. The melting point of the  $\alpha$ -isomer ranges from 108-110<sup>0</sup> C and the melting point of the  $\beta$ -isomer is 208-210<sup>0</sup> C. The melting point of technical endosulfan ranges from 70 to 100<sup>0</sup> C. The vapor pressure of  $\alpha$ -endosulfan is 3.0 x 10<sup>-6</sup> mm Hg,  $\beta$ -endosulfan 7.2 x 10<sup>-7</sup> mm Hg, and technical endosulfan 1 x 10<sup>-5</sup> mm Hg at 25 <sup>0</sup>C. Technical endosulfan has a water solubility that varies from insoluble to ~0.33 mg/L at 25 <sup>0</sup>C, but has appreciable lipophilicity (log P<sub>ow</sub> 4.445 to 5.689).

### C. Use Profile

The following information is based on the currently registered uses of endosulfan:

**Type of Pesticide:** Insecticide/Acaricide

#### Summary of Use Sites:

Food Crops: barley, beans (dry and succulent), blueberries, broccoli, brussels sprouts, cabbage, carrots, cauliflower, celery, collards, kale, corn (fresh only), cucumbers, eggplants, grapes, peppers, oats, lettuce, melons, mustard greens, pineapples, rye, potatoes, pumpkins, spinach, squash, sweet potatoes,

strawberries, tomato, turnip, apples, apricots, almonds, cherries, filberts, macadamia nuts, nectarines, peaches, pecans, pears, plums, prunes, walnuts, and wheat.

Other Agricultural Sites: Alfalfa (seed only), radish (seed only), cotton, rutabaga (seed only), clover (seed only), kohlrabi (seed only), and tobacco.

Residential: None

Public Health: None

Other Nonfood: Christmas tree plantations, woody plants, peaches (root dip only), cherry and plum roots and crowns, whole strawberry plants, shade trees, citrus (non-bearing), tobacco, nursery stock, ornamental plants and shrubs.

**Target Pests:**

Agricultural: Meadow spittlebug, Army cutworm, Aphids, Bean leaf skeletonizer, Cowpea curculio, Cucumber beetle, Flea beetle, Green stink bug, Leafhoppers, Mexican bean beetles, Cabbage looper, Cabbage worm, Cabbage aphid, Cucumber beetles, Whitefly, Cutworms, Diamondback moth, Corn earworm, Boll weevil, Bollworm, Lygus bugs, Thrips, Melonworm, Pickleworm, Rindworm, Squash beetle, Squash bug, Blister beetle, Potato beetle, Rose chafer, Pepper maggot, Cinch bug, Crown mite, June bug, Harlequin bug, Grape phylloxera, and Grape leafhopper.

Orchards: Aphids (including Apple aphids, Black cherry aphid, Black peach aphid, Green peach aphid, Rosy apple aphids, Black pecan aphid, Filbert aphid, Rusty plum aphids, Woolly apple aphids), Apple rust mites, Green fruitworm, Tarnished plant bug, Tentiform leafminers, Whitefly leaf hoppers, Peachtree borer, Peach twig borer, Plum rust mite, Bud moth, Bud mites, Twig mites, Filbert leafroller, Filbert bud mite, Pecan nut casebearer, and Spittlebug.

Ornamental Trees and Shrubs: Leather leaf fern borer, Aphids, Cyclamen mite, Rose chafer, Whitefly, Dogwood borer, Lilac borer, Colley spruce gall adelgid, Douglas fir needle midge, Walnut aphid, and Stink bug.

**Formulation Types Registered:** Endosulfan is formulated for occupational use as a technical grade manufacturing product (95 percent active ingredient [ai]), emulsifiable concentrate (EC) (9 percent to 34 percent active ingredient), and a wettable powder (WP) (1 percent to 50 percent active ingredient). The wettable powder is frequently packaged in water soluble bags.

## **Methods and Rates of Application:**

Equipment - Endosulfan can be applied by groundboom sprayer, fixed-wing aircraft, chemigation (potatoes only), airblast sprayer, rights-of-way sprayer, low pressure handwand sprayer, high pressure handwand sprayer, backpack sprayer and dip treatment.

Rates of Application- The crop groupings with their corresponding maximum label application rates are as follows (both formulations unless noted, EC = emulsifiable concentrate, WP = wettable powder formulations):

***Agricultural crops (vegetables and field crops)***: alfalfa (seed only, 1 lb ai/A EC); barley, rye, oats and wheat (0.75 lb ai/A); beans and tomatoes (1 lb ai/A); clover (0.5 lbs ai/A EC); blueberries (1.5 lb ai/A); broccoli, cabbage, collard, lettuce, melons, and mustard greens (1 lb ai/A or 2 lb ai/A for seed); brussels sprouts, carrots, cauliflower, celery, cucumbers, eggplants, peas, peppers, potatoes, pumpkins, spinach, and squash (1 lb ai/A); cotton and corn (fresh only) (1.5 lb ai/A); grapes (1.5 lb ai/A or 0.005 lb ai/gallon); kale (0.75 lb ai/A or 2 lb ai/A for seed); kohlrabi, radish, turnip and rutabaga (2 lb ai/A seed only); strawberries, pineapples and sweet potato (2 lb ai/A); and tobacco (1.5 lb ai/A WP, 1 lb ai/A EC).

***Fruit and nut trees (orchard crops)***: apples (2.5 lb ai/A or 0.005 lb ai/gal); apricots, peach, and nectarines (3 lb ai/A or 0.0025 lb ai/gal); almonds, cherries, pears, plums, and prunes (2.5 lb ai/A or 0.04 lb ai/gallon); filberts (hazelnuts 2lb ai/A or 0.005 lb ai/gallon); macadamia nuts (3.0 lb ai/A or 0.01 lb ai/gallon); pecans (3 lbs ai/A or 0.0075 lb ai/gallon); walnuts (2 lb ai/A or 0.02 lb ai/gallon WP, 2.5 lb ai/A or 0.04 lb ai/gallon EC). A currently registered label (EPA reg # 34704-516) contains a higher application rate (7.5 lb ai/A) for pecans and macadamia nuts than is listed above. At this time only the 3.0 lb ai/A rate for pecans and macadamia nuts is being supported and this assessment therefore only assesses these crops for a 3.0 lb ai/A maximum application rate.

***Ornamental Trees and Shrubs***: shade trees, citrus (non-bearing and nursery stock), shrubs, nursery stock, Christmas tree plantations, and woody plants (1 lb ai/A or 0.01 lb ai/gallon).

***Root dip***: cherry, peaches, and plum roots and crowns (0.05 lb ai/gallon) and whole strawberry plants (0.01 lb ai/gallon EC).

***Bark Treatment***: apricot, cherry, grapes, nectarines, peach, plums and prunes (see above for application rates, applied with high pressure handwands and rights-of-way sprayers).

Use Classification: General use

#### D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of endosulfan, based on available pesticide survey usage data for the years 1990 through 1999. A full listing of all uses of endosulfan, with the corresponding use and usage data for each site, has been completed and is in the “Quantitative Use Assessment” document dated September 10, 2000, which is available in the public docket and on the Agency’s website:

<http://www.epa.gov/pesticides/endosulfan>. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Total average annual use of endosulfan is estimated at approximately 1.38 million pounds of active ingredient (lbs ai), according to Agency and registrant estimates.

This long-term average is not necessarily consistent with some recent trends. Data from USDA (*Agricultural Chemical Usage, Field Crop Summary*, 1999, 2000, 2001; *Agricultural Chemical Usage, Fruit and Nut Summary*, 1999; *Agricultural Chemical Usage, Vegetable Summary*, 2000) and other EPA sources appear to indicate declining use of endosulfan in U.S. agriculture. This decline is driven mainly by replacement of endosulfan by other insecticides for use on small grains and soybeans. Usage on fruit and nut crops may also be decreasing, although the decline is not as clear and may be sensitive to yearly fluctuation in pest problems. Usage on vegetable crops appears steady and may be increasing. Within these broad categories, there may be significant shifts in use patterns in response to the dynamics of the agricultural system (e.g., changes in crop area), pest populations (e.g., pest outbreaks) and changes in pesticide availability (e.g., new pesticides registered and restrictions on old pesticides).

**Table 1. Endosulfan Estimated Usage**

Crop	Lbs. A.I. Applied (wgthd Avg. in 000 pounds) <sup>1</sup>	Percent Crop Treated (Weighted Avg.)	Percent Crop Treated (Likely Max)
<i>Food Commodities</i>			
Alfalfa (seed) (non food)	10	<1%	<1%
Almonds	<1	<1%	<1%
Apples	110	13%	20%
Apricots/Nectarines	2	2%	4%
Barley	<1	1%	1%
Beans, Dry	5	1%	3%
Beans, Lima	Not Available	2%	6%
Beans, Snap Fresh	2	2%	6%
Beans, Snap Processed	3	2%	6%
Blueberries	1	2%	6%
Broccoli	16	13%	26%
Brussels Sprouts	<1	2%	10%

Crop	Lbs. A.I. Applied (wghtd Avg. in 000 pounds) <sup>1</sup>	Percent Crop Treated (Weighted Avg.)	Percent Crop Treated (Likely Max)
Cabbage, Fresh and Processed	18	14%	27%
Cantaloupes	39	31%	57%
Carrots	1	2%	5%
Cauliflower	4	9%	32%
Celery	2	6%	11%
Cherries, Sweet and Tart	5	3%	7%
Citrus - Grapefruit	3	1%	5%
Citrus - Oranges	4	<1%	1%
Citrus - Other <sup>2</sup>	<1	<1%	<1%
Collards	1	6%	7%
Corn, Sweet	4	<1%	1%
Cucumbers, fresh and processed	27	8%	15%
Eggplant	3	41%	83%
Grapes	17	1%	6%
Hazelnuts (Filberts)	2	7%	18%
Lettuce	58	14%	31%
Macadamia Nuts	<b>Not Available</b>	7%	30%
Melons, Honeydew	6	19%	58%
Mustard Greens	<b>Not Available</b>	6%	17%
Oats/Rye	<1	<1%	<1%
Peas, Dry	<1	<1%	4%
Peas, Green	1	<1%	4%
Pears	35	20%	48%
Pecans	59	11%	18%
Peppers (bell and hot)	14	12%	17%
Peaches	29	7%	17%
Pineapple (flowering ac)	1	2%	6%
Plums and Prunes	8	3%	7%
Potatoes, White	120	10%	16%
Potatoes, Sweet	20	31%	46%
Pumpkins	11	20%	30%
Roots/Tubers	13	4%	6%
Spinach, Fresh	1	4%	11%
Strawberries	9	14%	21%
Squash	44	40%	84%
Tomatoes	55	6%	11%
Vegetables, Other Leafy	<b>Not available</b>	<1%	5%
Walnuts	1	0%	1%

Crop	Lbs. A.I. Applied (wgthd Avg. in 000 pounds) <sup>1</sup>	Percent Crop Treated (Weighted Avg.)	Percent Crop Treated (Likely Max)
Watermelon	40	12%	17%
<i>Non-Food Sites</i>			
Cotton	286	2%	4%
Tobacco	63	8%	12%
<i>Ornamentals</i>			
Horticultural Nurseries Stock	50	Not Available	Not Available

<sup>1</sup> Usage data primarily covers 1990 to 1999. Calculations of the above numbers are displayed as rounded.

<sup>2</sup> Calculations of the above numbers may not appear to agree because they are displayed as rounded: to the nearest 1000 for acres treated or lb. a.i.

#### Sources:

Agricultural (Crop) Sites: USDA Agricultural Chemical Usage Reports, NCFAP, and various proprietary data sources, including Doane, Maritz, Mike Buckley.

Pineapple estimates from Calvin Oda, Pineapple Growers Assoc. of Hawaii, 4/21/99, memo to Nako;

Macadamia nut estimates from Alan Yamaguchi, Hawaii Macadamia Nut Assoc., 4/21/99, personal communications with Nako.

USDA, Biological and Economic Assessment of Pest Management in the United States Greenhouse and Nursery Industry, NAPIAP Report, 1-CA-96;

1993 Certified/Commercial Pesticide Applicator Survey; Kline; SRI.

### III. Summary of Endosulfan Risk Assessments

The purpose of this summary is to assist the reader in better understanding the conclusions reached in the assessments by identifying the key features and findings of the risk assessments conducted for endosulfan. Following is a list of EPA's revised human health and ecological risk assessments and supporting information that was used to formulate the findings and conclusions for the pesticide endosulfan. The listed documents may also be found on the Agency's web page at [www.epa.gov/pesticides/](http://www.epa.gov/pesticides/) and in the public docket.

#### Human Health Risks

- *Assessment of the Dietary Cancer Risk of Hexachlorobenzene and Pentachlorobenzene as impurities in Chlorothalonil, PCNB, Picloram, and several other pesticides*, February 26, 1998.
- Product Chemistry Chapter for the Reregistration Eligibility Decision, December 18, 1998.
- *Review of Endosulfan Incident Reports*, January 18, 2000.
- *Re-Evaluation of Toxicology Endpoint Selection for Dermal and Inhalation Risk Assessments and 3X Safety Factor for Bioaccumulation*, February 7, 2002.
- *Revised Residue Chemistry Chapter For The Endosulfan Reregistration Eligibility Decision (RED) Document*, February 14, 2002.
- *Report of the FQPA Safety Factor Committee*, February 14, 2002.
- *Third Revision of Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*, February 26, 2002.
- *Anticipated Residues and Revised Chronic Dietary Exposure Analyses*, February 28, 2002.

- *New FQPA and PDP Data, Anticipated Residues, and Revised Acute and Chronic Dietary Exposure Analyses, April 22, 2002.*
- *Supporting documentation for findings of FQPA Safety Committee on February 11, 2002, May 9, 2002.*
- *Reevaluation of the HED Risk Assessment for the Endosulfan Reregistration Eligibility Decision (RED) Document, May 30, 2002.*
- *New FQPA, PDP, and Processing Data, Anticipated Residues, and Revised Acute and Chronic Dietary Exposure Analyses, July 19, 2002*

## **Environmental Fate and Ecological Effects**

- *Final EFED Risk Assessment for the Reregistration Eligibility Decision on Endosulfan, February 26, 2002.*
- *Endosulfan and Endosulfan Sulfate: Drinking Water EECs in Surface Water for Use in the Human Health Risk Assessment, July 3, 2002.*

### **A. Human Health Risk Assessment**

EPA issued its preliminary risk assessments for endosulfan on January 31, 2001 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are listed below:

- Adjusted dietary risk estimates to reflect FQPA Safety Factor of 10X.
- Use of new toxicological endpoints for dermal risk assessment. These data affect the lowest observed adverse effect level, and no observed adverse effect level used in the dermal risk assessments.
- 2000 PDP data was incorporated in the dietary assessment.
- Processing factors for pear juice, pineapple juice, raisins, and canned fruits and vegetables were incorporated in the dietary assessment.
- Recalculated Tier II drinking water EECs incorporating the Index Reservoir and Percent Cropped Area.
- Incorporated updated % crop treated values.

### **1. Dietary Risk from Food**

#### **a. Toxicity**

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is sufficiently complete except for the data identified in Section V, and that it supports a reregistration eligibility determination for all currently registered uses. Further details on the toxicity of endosulfan can be found in the document “Endosulfan: Reevaluation of the



HED Risk Assessment for the Endosulfan Reregistration Eligibility Decision (RED) Document,” dated May 30, 2002, and related documents. A brief overview of the studies and safety factors used for the dietary (food) risk assessment is outlined in Table 2 in this document.

#### **b. FQPA Safety Factor**

The FQPA Safety Factor of 10X was retained for endosulfan. A weight-of-the-evidence approach indicated that there were no reliable data available to address concerns or uncertainties raised by the following matters: 1) evidence for increased susceptibility of young rats, (2) additional evidence for endocrine disruption, 3) uncertainty regarding the neuroendocrine effects in the young, and 4) the need for a developmental neurotoxicity study (DNT). The FQPA safety factor (10x) is applicable for all populations when assessing acute and chronic dietary exposure. There are no longer any residential uses for this chemical, so the FQPA Safety factor does not apply to the short-term or intermediate-term exposure scenarios. More information concerning the FQPA Safety Factor can be found in the document “ Endosulfan: Report of the FQPA Safety Factor Committee” dated February 13, 2002, and related documents.

Although developmental toxicity was only seen at or above parentally toxic doses, there were treatment-related clinical signs of neurotoxicity following oral exposures in the rat, rabbit, and dog, and via the dermal route in rats. The acute neurotoxicity study was reviewed and found to be acceptable/guideline. The subchronic neurotoxicity study has not been received by the Agency and remains a data gap. The Agency re-reviewed the hazard and exposure data for endosulfan and concluded that a DNT study in rats should be requested for endosulfan due to concern for: 1) fetal effects reported in the open literature; 2) the severity of effects seen in female offspring of the F<sub>0</sub> generation (increased pituitary) and F<sub>1b</sub> generation (increased uterine weights) at the high-dose when compared to the toxicity observed in parental animals at this dose in the two-generation reproduction study in rats; and 3) because the subchronic neurotoxicity study will only address the neuropathological concerns resulting from exposure to endosulfan in adults. A developmental neurotoxicity study will provide the critical data needed to determine the potential toxic effects of endosulfan on the developing fetal nervous system.

Under the conditions of the available Agency guideline studies, there is no evidence of enhanced susceptibility of the offspring to exposure to endosulfan. However, a recent review by the Agency for Toxic Substances and Disease Registry [*Toxicological Profile for Endosulfan (Update)*. ATSDR. September 2000] reported the results of non-guideline studies which demonstrated that young rats may be more susceptible than older rats upon exposure to endosulfan. Studies conducted by Sinha *et al.* (1995 & 1997) and Zaidi *et al.* (1985) illustrate effects to the offspring at doses lower than those showing effects in adults. Sinha *et al.* (1995 & 1997), treated both three week and three month old rats orally. Decreased intratesticular spermatid count and increased percentage of abnormal sperm were seen in three week old rats at doses lower than those eliciting similar effects in three month old rats. Zaidi (1985) dosed neonatal rat pups for 25 days intraperitoneally and found increased serotonin binding to the frontal cortical membranes of the brain and increased aggressive behavior. Adults exposed in a similar manner did not display these effects.

There is evidence for endocrine disruption both in studies submitted to the Agency and those published in the open literature. In an National Cancer Institute (NCI) chronic toxicity/carcinogenicity study in rats, endosulfan induced testicular atrophy and parathyroid hyperplasia. In the multi-generation reproduction study, increased pituitary and uterine weights were seen. Endosulfan is considered to be a potential endocrine disruptor. Substances that act as endocrine disruptors may perturb the endocrine system in a variety of ways including, but not limited to, interfering with the synthesis, secretion, or transport of hormones in the organism. The endocrine system integrates a variety of CNS-pituitary-target organ pathways that not only affect reproductive or sexually regulated parameters but also regulate a wide array of bodily functions and homeostasis.

### c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary (food) risk of a chemical and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD / FQPA safety factor). The RfD is calculated by taking the no observed adverse effect level (NOAEL) from an appropriate study and dividing it by an uncertainty factor (i.e., NOAEL/UF). A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern. In the case of endosulfan, the FQPA safety factor is 10x; therefore, the acute or chronic PADs are equivalent to the acute and chronic RfDs divided by 10, respectively. The aPAD for endosulfan is 0.0015 mg/kg/day. The cPAD for endosulfan is 0.0006 mg/kg/day. The basis for the aPAD and the cPAD are summarized in Table 2 below.

**Table 2. Summary of the Toxicological Endpoints for Endosulfan**

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	NOAEL = 1.5 UF = 100 FQPA SF = 10	Oral LOAEL = 3 mg/kg/day; based on increased incidence of convulsions seen in female rats within 8 hours after dosing.	Acute neurotoxicity study in rats
		<b>Acute RfD = 0.015 mg/kg/day</b> <b>aPAD = 0.0015 mg/kg/day</b>	
Chronic Dietary	NOAEL = 0.6 UF = 100 FQPA SF = 10	LOAEL = 2.9 mg/kg/day based on reduced body weight gain, enlarged kidneys, increased incidences of marked progressive glomerulonephrosis; & blood vessel aneurysms in male rats.	Combined chronic toxicity/carcinogenicity study in rats
		<b>Chronic RfD = 0.006 mg/kg/day</b> <b>cPAD = 0.0006 mg/kg/day</b>	

### d. Exposure Assumptions

The Agency conducts dietary (food) risk assessments using the dietary exposure evaluation model (DEEM™), which incorporates consumption data generated in USDA's continuing survey of food intakes by individuals, 1989-1992. For the assessment of dietary

(food) exposure to residues of endosulfan, monitoring data generated through the USDA Pesticide Data Program (PDP) and through the Food and Drug Administration (FDA) Surveillance Monitoring Program were used for most crops. Anticipated residue values from crop residue field trial studies, and percent crop-treated data were used for cotton, macadamia nuts, filberts, pecans, and walnuts.

The Agency has developed procedures for handling FDA surveillance monitoring data in dietary exposure analyses in order to generate more refined probabilistic dietary exposure estimates. In the FDA data, if there are significant differences between domestic and import samples, either in terms of likelihood of detected residues or residue levels themselves, then it would be most desirable to “weight” the FDA data such that it better reflects the proportionate “mix” between domestic and foreign produce which the U.S. population consumes. Additional estimates of the percent of commodity imported as well as imported %CT are also incorporated. The crops for which these procedures were incorporated are dried beans, blueberries, cauliflower, fresh sweet corn, melons (except cantaloupe), fresh succulent peas, hot peppers, plums, and summer squash.

For acute probabilistic dietary risk assessments, the entire distribution of single-day food consumption events is combined with a distribution of residues to obtain a distribution of exposure in mg/kg/day. Chronic dietary (food) risk assessments use the three-day average of consumption for each subpopulation combined with residues in commodities to determine average exposure in mg/kg/day.

#### e. Food Risk Characterization

Generally, a dietary (food) risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency’s risk concern. Acute risk estimates from exposures to food, associated with the use of endosulfan exceed the Agency’s level of concern for some population subgroups. For example, for exposure resulting from applications of endosulfan, for the most exposed population subgroup, children 1-6 years old, the percent acute PAD value is 150% at the 99.9th percentile of exposure from consumption of food alone. The crops that contributed the most to the risks of concern are succulent beans and succulent peas. The results of the acute dietary (food) assessment are summarized in the Table 3.

**Table 3. Summary of Acute Dietary (food) Risk Assessment**

<b>Population Subgroup</b>	<b>aPAD</b>	<b>Food Exposure</b>	<b>% aPAD</b>
U.S. General Population	0.0015	0.0012	80%
All Infants	0.0015	0.0014	94%
Children 1-6	0.0015	0.0022	150%
Children 7-12	0.0015	0.0014	95%

Chronic dietary (food) exposure estimates are below the Agency’s level of concern for all subpopulations. For the most highly exposed subpopulation, children 1-6 years old, the percent chronic PAD value is 17% from consumption of food alone.

## **2. Dietary Risk from Drinking Water**

Dietary (drinking water) exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment. Limited water monitoring data exist for endosulfan; therefore, modeling was used to estimate drinking water risks from these sources.

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than the other two.

### **a. Surface Water**

The Tier II PRZM-EXAMS screening model is used to estimate upper-bound environmental concentrations (EECs) in drinking water derived from surface water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. The Agency also used the recently implemented Index Reservoir (IR) and Percent Crop Area (PCA) modifications to the Tier II PRZM-EXAMS model to calculate upper-bound EECs for endosulfan and its degradate, endosulfan sulfate, in drinking water derived from surface water. Applying the IR and PCA modifications, acute modeled EECs for endosulfan in surface water range from 4.49 ppb to 23.86 ppb depending on the crop site. Chronic modeled EECs for endosulfan in surface water range from 0.53 ppb to 1.5 ppb, depending on the crop site.

Monitoring data for endosulfan and endosulfan sulfate in surface water are available but not of sufficient quality to be used in a quantitative risk assessment. A review of the STORET database for  $\alpha$ - and  $\beta$ -endosulfan, unspecified endosulfan residues, and endosulfan sulfate showed numerous detections. The STORET data are not reliable enough to enable an accurate quantitative assessment of the endosulfan distribution throughout the U.S., but it does give some insight into where endosulfan is being found. The mean concentration found in this data is 0.17 ppb, with a standard deviation of 0.98 ppb. The 90<sup>th</sup> percentile value (one in ten year value) was 0.31 ppb and the median value was 0.03 ppb. However, as mentioned above, there are limitations to this data which make it unuseable for quantitative risk assessment. As such, the data do not necessarily represent the most vulnerable sites or sampling at peak exposure times and little is known about actual sample conditions. In addition, the limits of detection vary widely depending on the purpose of the monitoring and the availability of analytical methods and equipment so that reported non-detections do not necessarily mean that endosulfan was not present where a non-detect was reported.

The National Sediment Quality Survey (U.S. EPA, 1997) reported detections of endosulfan residues in stream sediments in 30 out of 76 watersheds tested for endosulfan. The watersheds are located in 12 states, ranging from Rhode Island to California and from Mississippi to Michigan. As with the STORET data, one of the sources of data used in the survey, this summary provides more of a qualitative evaluation of the extent to which endosulfan may be found in the environment rather than a quantitative assessment of endosulfan occurrence.

The U.S. Geological Survey (USGS) in its National Water Quality Assessment (NAWQA) program is not currently analyzing for endosulfan.

#### **b. Ground Water**

The Tier I screening model, SCI-GROW, was used to estimate drinking water concentrations derived from groundwater. The acute and chronic EEC for endosulfan in groundwater is 0.012 ppb. This includes potential residues of endosulfan sulfate in addition to endosulfan. The Agency believes that the potential for endosulfan to reach ground water is limited to acidic to neutral soils and aquifers where preferential flow may be a prevalent pathway to ground water or where the ground water is shallow and is overlain by highly permeable soils. Available evidence suggests that the transformation products – endosulfan sulfate and endosulfan diol – may be persistent. Endosulfan sulfate is similar in mobility to the parent endosulfan.

The Pesticides in Ground Water Database (PGWDB) reports detections of endosulfan, ranging from trace to  $\leq 20$  ppb, in 1.3% of 2410 discrete samples (32 wells). Detections were reported in California, Maine, and Virginia. All sampling was conducted on or before the year 1989. The abbreviated nature of the PGWDB does not capture important factors such as depth of the water table, soil permeability, proximity of crops to wells, usage (application) of the chemical in the years prior to sampling, suitability of the analytical methodology used and/or limits of detection. Endosulfan sulfate was detected in 0.3% of the samples (6 out of 1,969), with detections ranging from  $< 0.005$  to 1.4 ppb. The detections were reported in Indiana and New York. Sampling occurred at or prior to 1990.

#### **c. Drinking Water Levels of Comparison (DWLOC)**

To determine the maximum allowable contribution from water containing pesticide residues permitted in the diet, the Agency first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a “drinking water level of comparison”(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary (food) exposure, does not exceed a level of concern.

The results of the Agency’s drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the documents “Endosulfan: Reevaluation of the HED Risk Assessment for the Endosulfan Reregistration Eligibility Decision (RED) Document” dated May 30, 2002 and “ $\alpha$ - and  $\beta$ -Endosulfan and Endosulfan Sulfate: Drinking Water EECs in Surface Water for Use in the Human Health Risk Assessment” dated July 3, 2002.

Since acute risk exposures to endosulfan in food alone pose a potential risk of concern for children 1-6 years of age additional exposures from water would increase the concern and therefore the DWLOC for this population is zero. These drinking water risk estimates are summarized below in Table 4.

**Table 4. Endosulfan Drinking Water Levels of Comparison for Acute Dietary Exposure**

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day) @ 99.9th percentile	Maximum Allowable Water Exposure (mg/kg/day)	DWLOC <sub>acute</sub> (ppb)	Surface Water Peak EEC (ppb)	Ground Water EEC (ppb)
U.S. Population	0.0015	0.0012	0.0003	3	23.86	0.012
Females (13-50 yrs)	0.0015	0.00098	0.00052	16	23.86	0.012
Infants <1 yr	0.0015	0.0014	0.0001	<1	23.86	0.012
Children 1-6 yrs	0.0015	0.0023	0	0	23.86	0.012

Chronic risk estimates from exposures to food, do not exceed the Agency's level of concern for the U.S. general population and all population subgroups. The chronic dietary (food only) risk estimate is 17% of the cPAD, for the most highly exposed population subgroup, children ages 1-6 years of age. Based on these estimates, the Agency can conclude with reasonable certainty that residues of alpha and beta endosulfan and endosulfan sulfate combined with drinking water, would not likely result in a chronic dietary risk to infants, children, and adults that further exceeds the Agency's level of concern (Table 5).

**Table 5. Drinking Water Levels of Comparison for Chronic Dietary Exposure**

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Allowable Water Exposure (mg/kg/day)	DWLOC <sub>chronic</sub> (ppb)	Surface Water Chronic EEC (ppb)	Ground Water EEC (ppb)
U.S. Population	0.0006	0.000038	0.00056	20	1.5	0.012
Females (13-50 yrs)	0.0006	0.000027	0.00057	17	1.5	0.012
Infants <1 yr	0.0006	0.000045	0.00045	6	1.5	0.012
Children 1-6 yrs	0.0006	0.00010	0.00050	5	1.5	0.012

### 3. Aggregate Risk

An aggregate risk assessment examines the combined risk from dietary exposure (food and drinking water routes) and any non-occupational exposures (residential use). Acute and chronic aggregate risk assessments were conducted for endosulfan. Residential uses of endosulfan have been voluntarily canceled by the technical registrants. Therefore, aggregate short-term exposures were not estimated. Results of the aggregate risk assessment are summarized here, and are discussed in the endosulfan human health risk assessment.

The Agency was only able to quantify food sources of dietary exposure to endosulfan because dietary exposures through drinking water have only been estimated using models.

Neither adequate groundwater or surface water monitoring data were available to estimate potential drinking water exposures to endosulfan.

Acute Aggregate Risk Assessment: Potential acute dietary risks from food sources alone exceed the Agency's level of concern. The most exposed subpopulation, children 1-6, are estimated to consume 150% of the acute PAD at the 99.9th percentile of exposure, based on highly refined exposure estimates. Therefore, there is no additional room in the "risk cup" for exposure via drinking water (DWLOC = 0).

Chronic Aggregate Risk Assessment: In the case of the food component of the chronic aggregate risk assessment, risks are well below the Agency's level of concern. No more than 17% of the chronic PAD is consumed for children 1-6. Further, potential drinking water risks from exposure to drinking water sources do not exceed the chronic DWLOCs and, therefore, do not exceed the Agency's level of concern.

#### **4. Occupational Risk**

Occupational handlers can be exposed to endosulfan through mixing, loading and/or applying a pesticide or re-entering treated sites. Occupational handlers of endosulfan include individual farmers or growers who mix, load and/or apply pesticides and professional or custom agricultural applicators. The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a NOAEL. Generally, MOEs greater than 100 are not of concern. Restricted Entry Intervals (REIs) are 24 hours on current endosulfan labels. The Agency has determined that there are potential mixer, loader, applicator as well as post-application exposures to occupational handlers.

##### **a. Toxicity**

The toxicity of endosulfan is integral to assessing the occupational risk. The Agency has conducted short term dermal and inhalation exposure assessments for the occupational handler. In addition, the Agency has conducted short term and intermediate term postapplication dermal exposure assessments for occupational uses.

All risk calculations are based on the most current toxicity information available for endosulfan, including a 21-day dermal toxicity study in rats for short-term and intermediate-term (post-application only) exposure durations. An uncertainty factor (UF) of 100 was applied to the risk assessment: 10x to account for interspecies extrapolation and 10x to account for intraspecies variability. The toxicological endpoints and other factors used in the occupational risk assessments for endosulfan are listed below.

**Table 6. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessment for Endosulfan**

Route / Duration	NOAEL (mg/kg/day)	Effect	Study	Uncertainty Factors
Short- and Intermediate-term Dermal (one day to one month; one month to several months )	12.0	Mortality in females at 27 mg/kg/day (LOAEL)	21-day dermal toxicity study in rats	Interspecies: 10x Intraspecies: 10x
Short- and Intermediate-term Inhalation (one day to one month; one month to several months )	0.2	Decreased body-weight gain and decreased leukocyte counts in males and increased creatinine values in females at 0.40 mg/kg/day (LOAEL)	21-day inhalation study in rats.	Interspecies: 10x Intraspecies: 10x

Endosulfan is highly toxic following acute oral exposure and moderately toxic following acute inhalation exposure. In rats, oral median lethal doses (LD<sub>50</sub> values) are 82 mg/kg (males) and 30 mg/kg (females). Median lethal concentrations (LC<sub>50</sub> values) in rats following acute inhalation exposure range from 0.16 to 0.5 mg/L. Endosulfan is considerably less lethal, however, following acute dermal exposure (LD<sub>50</sub> is 2.0 g/kg).

Endosulfan is an eye irritant in rabbits (Toxicity Category I) but is not a dermal irritant or sensitizer. Refer to Table 7 below for a summary of the acute toxicity of endosulfan.

**Table 7. Summary of Results from Acute Toxicity Studies of Technical Endosulfan**

Guideline Number	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral	41183502	LD <sub>50</sub> = 82 mg/kg in ♂ LD <sub>50</sub> = 30 mg/kg in ♀	I
870.1200	Acute Dermal	41183503	LD <sub>50</sub> = 2000 mg/kg	III
870.1300	Acute Inhalation	41183504	LC <sub>50</sub> = 0.16-0.5 mg/L	II
870.2400	Primary Eye Irritation	41183505	Eye irritant (Residual opacity at day 13)	I
870.2500	Primary Skin Irritation	41183506	Non-irritant	IV
870.2600	Dermal Sensitization	41183507	Not a dermal sensitizer	NA

## **b. Occupational Exposure**

Three chemical-specific dislodgeable foliar residue studies that were submitted to the Agency by the technical registrant were used to evaluate post-application exposures. Chemical-specific exposure data for handlers were not available for endosulfan, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). In addition, standard assumptions about average body weight, work day, area treated daily and volume of pesticide handled were used to calculate risk estimates. The quality of the data and exposure factors represent the best sources of data currently available to the Agency for completing these kinds of assessments. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure.



The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for endosulfan, which is available in the public docket and on the Agency's web page: <http://www.epa.gov/pesticides/>.

Calculations were completed for a range of maximum application rates for specific crops available from endosulfan labels. These rates were assessed in order to bracket risk levels associated with the various use patterns. Anticipated use patterns and application methods, range of application rates and daily amount treated were derived from current labeling. On the majority of endosulfan product labels, the number of maximum allowable applications typically ranges between 1 and 3 per season or year, and does not exceed 5. The Agency uses acres treated per day values that are thought to represent an eight hour workday for a particular type of application equipment or specific crop.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with baseline protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., increasing levels of protection). The lowest combination of personal protective equipment (PPE) is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation PPE are applied. If MOEs are still less than 100, engineering controls are applied. In some cases, EPA will conduct an assessment using PPE or engineering controls taken from a current label. The levels of protection that formed the basis for calculations of exposure from endosulfan include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical-resistant gloves and a dust/mist respirator.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and an ov respirator.
- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system such as a closed mechanical transfer system for liquids or water soluble packaging for wettable powders. Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no engineering controls that lower the exposures).

### **c. Occupational Handler Risk Summary**

Inhalation and dermal exposure to endosulfan can result from occupational use. The Agency assessed dermal and inhalation risks (MOEs) for each crop currently registered for endosulfan. Dermal and inhalation MOEs were not aggregated but were assessed separately because the end effects seen at the LOAEL were different. It is Agency policy not to aggregate the risks (inhalation plus dermal) if the toxicological effects are not the same. Handler exposures to endosulfan are expected to be short-term only (1 - 30 days) because of the types of crops on which endosulfan is used. For endosulfan, occupational MOEs greater than 100 are not of risk concern to the Agency.

## **(1) Agricultural Handler Risk**

EPA has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with endosulfan. The scenario numbers below correspond to the scenario numbers detailed and discussed in Appendix A of the Occupational and Residential Exposure Chapter of the HED risk assessment dated May 30, 2002. Based on the use patterns, 21 major occupational exposure scenarios were identified for endosulfan:

- (1a) mixing/loading liquid formulations for aerial application;
- (1b) mixing/loading liquid formulation for chemigation;
- (1c) mixing/loading liquid formulations for groundboom application;
- (1d) mixing/loading liquid formulations for airblast application;
- (1e) mixing/loading liquid formulations for rights-of-way sprays;
- (1f) mixing/loading liquid formulations for plant and root dip;
- (2a) mixing/loading wettable powders for aerial application;
- (2b) mixing/loading wettable powders for groundboom application;
- (2c) mixing/loading wettable powders for airblast application;
- (2d) mixing/loading wettable powders for rights-of-way spray application;
- (2e) mixing/loading wettable powders for plant and root dip;
- (3) applying sprays with aerial equipment;
- (4) applying sprays with a groundboom sprayer;
- (5) applying sprays with an airblast sprayer;
- (6) applying sprays with a rights-of-way sprayer;
- (7) applying dip treatment to roots, or whole plants;
- (8) mixing/loading/applying liquids with a low pressure hand wand;
- (9) mixing/loading/applying wettable powders with a low pressure handwand;
- (10) mixing/loading/applying liquids with a high pressure hand wand;
- (11) mixing/loading/applying liquids with backpack sprayer; and
- (12) flagging aerial spray applications.

There were three scenarios that were not evaluated due to a lack of data available to conduct an assessment. These scenarios are mixing/loading/applying wettable powders with backpack sprayer, mixing/loading/applying wettable powders with a high pressure hand wand and application of liquids or wettable powders as a root dip/crown dip.

PPE requirements on current endosulfan labels range from no PPE listed to long sleeved shirt and long pants, waterproof gloves, shoes, socks, chemical resistant headgear, respirator with either an organic vapor removing cartridge with a prefilter or canister approved for pesticides. Mixers and loaders must also wear a chemical resistant apron.

As summarized in Table 8, occupational risks are of concern (i.e., MOEs < 100) for many scenarios, even when maximum PPE are utilized. Handler risks are also of concern for some scenarios with engineering controls. Engineering controls are considered to be the maximum

feasible mitigation. Twelve scenario/application rate combinations have risks that exceed the Agency's level of concern based on application rates supported by the technical registrants. These mainly involve mixing/loading liquids for aerial applications, mixing/loading wettable powders for aerial applications, groundboom applications and airblast applications, application using aerial equipment, application using airblast equipment, application using rights-of-way sprayers and mixing/loading/applying using a high-pressure handwand.

**Table 8. Summary of Occupational Handler Risks to Endosulfan**

Exposure Scenario (Scenario #)	Crop Type/Use <sup>a</sup>	Range of Application Rates (lb ai/A) <sup>b</sup>	Acres Treated Amount Handled/ Day <sup>c</sup>	Baseline <sup>f</sup>		Minimum PPE <sup>g</sup>		Maximum PPE <sup>h</sup>		Engineering Controls <sup>i</sup>	
				Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>
Mixer/Loader Exposures											
Mixing/Loading Liquid Formulations for Aerial Application (1a)	clover	0.5	350	2	67	210	330	-	-	-	-
	pineapple	2.0		0.41	17	52	83	71	170	140	-
	pecans	3.0		0.28	11	35	56	47	110	93	-
	small grains	0.75	1,200	0.32	13	41	65	55	130	110	-
	cotton	1.5		0.16	7	20	32	27	65	54	94
Mixing/Loading Liquid Formulation for Chemigation (1b)	potatoes (Idaho)	1.0	350	0.83	33	100	170	-	-	-	-
Mixing/Loading Liquid Formulations for Groundboom Application (1c)	clover	0.5	80	7	290	910	-	-	-	-	-
	pineapple	2.0		2	73	230	360	-	-	-	-
	small grains	0.75	200	2	78	240	390	-	-	-	-
	cotton	1.5		1	39	120	190	-	-	-	-
Mixing/Loading Liquid Formulations for Airblast Application (1d)	Ornamental Trees/Shrub s	1.0	10	29	1,200	3,700	-	-	-	-	-
	Hazelnuts	2.0	40	4	150	460	-	-	-	-	-
	pecans	3.0		2	97	300	490	-	-	-	-
Mixing/Loading Liquids for Rights- of-way Spray Application (1e)	grapes	0.005	100 Gallons	58	2,300	7,300	-	-	-	-	-
	cherry	0.04		7	290	910	-	-	-	-	-
Mixing/Loading Liquids for Plant and Root Dip (1f)	cherry, peach and plums	0.05	100 Gallons	58	2,300	7,300	-	-	-	-	-
Mixing/Loading Wettable Powders for Aerial Application (2a)	beans	1.0	350	0.65	0.93	14	5	18	10	240	170
	sweet potato	2.0		0.32	0.47	7	2	9	5	120	83
	peach	3.0		0.22	0.31	5	2	6	3	82	56
	small grains	0.75	1,200	0.25	0.36	6	2	7	4	95	65
	cotton	1.5		0.13	0.18	3	1	4	2	48	32
Mixing/Loading Wettable Powders for Groundboom Application (2b)	beans	1.0	80	3	4	62	20	81	41	1,100	730
	sweet potato	2.0		1.4	2	31	10	40	20	540	360
	small grains	0.75	200	1.5	2	33	11	43	22	570	390
	cotton	1.5		0.76	1	16	5	22	11	290	190

Exposure Scenario (Scenario #)	Crop Type/Use <sup>a</sup>	Range of Application Rates (lb ai/A) <sup>b</sup>	Acres Treated Amount Handled/ Day <sup>c</sup>	Baseline <sup>f</sup>		Minimum PPE <sup>g</sup>		Maximum PPE <sup>h</sup>		Engineering Controls <sup>i</sup>	
				Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>
Mixing/Loading Wettable Powders for Airblast Application (2c)	Ornamental Trees/ Shrubs	1.0	10	23	33	490	160	-	-	-	-
	hazelnuts	2.0	40	3	4	62	20	81	41	1,100	730
	peaches	3.0		2	3	41	14	54	27	710	490
Mixing/Loading Wettable Powders for Rights-of-way Spray Treatment (2d)	grapes	0.005	1,000 Gallons	45	65	990	330	-	-	-	-
	walnut	0.02		11	16	250	81	-	160	-	-
Mixing/Loading Wettable Powders for Plants and Root Dip (2e)	cherry, peach, and plum	0.05	100 Gallons	45	65	990	330	-	-	-	-
Applicator Exposures											
Applying Spray with Aerial Equipment (3)	clover	0.5	350	See Eng. Controls						960	1,200
	pineapple	2.0								240	290
	pecans	3.0								160	200
	small grains	0.75	1,200							190	230
	cotton	1.5								93	110
Applying Sprays with a Groundboom Sprayer (4)	clover	0.5	80	1,500	470	-	-	-	-	-	-
	pineapple	2.0	200	380	120	-	-	-	-	-	-
	small grains	0.75		400	130	-	-	-	-	-	-
	cotton	1.5		200	63	-	310	-	-	-	-
Applying Sprays with an Airblast Sprayer (5)	ornamental trees	1.0	10	230	310	-	-	-	-	-	-
	hazelnuts	2.0	40	29	39	48	190	48	-	550	-
	pecans	3.0		19	26	32	130	32	-	370	-
Applying Sprays with a Rights-of-way Sprayer (6)	grapes	0.005	1,000 Gallons	130	720	-	-	-	-	NF	NF
	cherries	0.04		16	90	54	450	72	-	NF	NF
Applying Dip Treatment to Roots, or Whole Plants (7)	cherry, peach, plum roots	0.05	100 gallons	No Data	No Data	ND	ND	ND	ND	ND	ND
Mixer/Loader/Applicator Exposure											
Mixing/Loading/App lying Liquid Formulations with a Low Pressure Handwand (8)	tobacco (drench)	0.005	40 Gallons	42	2,300	9,800	-	-	-	NF	NF
	tomato greenhouse	0.01		21	1,200	4,900	-	-	-	NF	NF
	cherries	0.04		5	290	1,200	-	-	-	NF	NF

Exposure Scenario (Scenario #)	Crop Type/Use <sup>a</sup>	Range of Application Rates (lb ai/A) <sup>b</sup>	Acres Treated Amount Handled/ Day <sup>c</sup>	Baseline <sup>f</sup>		Minimum PPE <sup>g</sup>		Maximum PPE <sup>h</sup>		Engineering Controls <sup>i</sup>	
				Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>	Dermal MOE <sup>d</sup>	Inhalation MOE <sup>e</sup>
Mixing/Loading/App lying Wettable Powders with a Low Pressure Handwand (9)	tomato/ tobacco	0.005	40 Gallons	140	64	-	320	-	-	NF	NF
	walnut	0.02		36	16	120	80	-	160	NF	NF
Mixing/Loading/App lying Liquid with a High Pressure Handwand (10)	tobacco (drench)	0.005	1,000 Gallons	48	23	67	120	110	-	NF	NF
	tomato greenhouse	0.01		24	12	34	58	<b>53</b>	120	NF	NF
	cherries	0.04		6	3	9	15	<b>13</b>	<b>29</b>	NF	NF
Mixing/Loading/App lying Liquid with Backpack Sprayer (11)	tobacco (drench)	0.005	40 Gallons	1,700	2,300	-	-	-	-	NF	NF
	tomato greenhouse	0.01		840	1,200	-	-	-	-	NF	NF
	cherries	0.04		210	290	-	-	-	-	NF	NF
Flagger Exposures											
Flagging Aerial Spray Applications (12)	clover	0.5	350	440	230	-	-	-	-	-	-
	pineapple	2.0		110	57	-	290	-	-	-	-
	pecans	3.0		73	38	67	190	80	-	3,600	-

**Footnotes:**

- a Crops named are index crops which are chosen to represent all other crops at or near that application rate for that use. See the application rates listing in the use summary section of this document for further information on application rates used in this assessment.
- b Application Rates are based on the maximum application rates listed on the endosulfan labels.
- c Daily amount treated are based on Science Advisory Council for Exposure Policy # 9.1.
- d Short- term Dermal MOE = Short- term NOAEL ( mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
- e Short-term MOE = Short- term NOAEL (mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
- f Baseline clothing: long pants, long sleeved shirt, shoes, socks. Chemical resistant gloves are included for mixing/loading/applying liquids with a backpack sprayer and wettable powders with a low pressure handwand (scenarios 9 and 11).
- g Minimum PPE clothing: Baseline clothing plus dust/mist respirator, and chemical resistant gloves.
- h Maximum PPE clothing: Baseline clothing plus organic vapor respirator, double layer of clothes, and chemical resistant gloves.
- i Engineering controls: Enclosed mixing/loading, closed cab, truck or cockpit. Baseline level clothing. Chemical resistant gloves for airblast sprayer application and mixing/loading liquid formulation (scenarios 1 and 5).  
Scenario's calculated MOE exceeds the target MOE at the previous level of mitigation. (MOE > 100)  
NF = Not feasible for this scenario (no available engineering controls). ND = No data.  
Bolded MOE values show a risk of concern at the highest possible level of mitigation for the corresponding scenario.

## (2) Post-Application Occupational Risk

The Agency also assessed post-application risks to workers who may be exposed to endosulfan when they enter previously treated fields, because their skin may contact treated surfaces. Exposures are directly related to the kind of tasks performed. EPA examines the amount of pesticide residue workers may be exposed to as the result of performing these tasks. The Agency evaluates this information to determine the number of days following application

that must elapse before the pesticide residues dissipate to a level where worker MOEs equal or exceed 100 while wearing baseline attire. Baseline attire is defined as long-sleeved shirt, long pants, coveralls, shoes and socks. Based on the results of the post-application worker assessment, the Agency establishes REIs before workers may enter treated areas. At present, endosulfan labels generally have REIs of 24 hours.

The Agency completed a post-application exposure assessment for endosulfan for a number of scenarios as outlined in Table 9 below. The dermal NOAEL of 12 mg/kg/day based on a 21-day dermal toxicity study in rats (Table 6) was used to assess potential dermal exposure to workers re-entering treated fields. The post-application assessment is also based on 8 hours of daily exposure and the default transfer coefficients (Tcs) shown in Table 9. Also, three chemical-specific DFR studies were conducted for endosulfan which were used to determine the values used in conducting the post-application risk assessment.

For post-application risks to endosulfan, an MOE of 100 or greater is not of concern to the Agency. Table 9 summarizes the occupational post-application risk assessment following foliar applications of endosulfan. In summary, REIs as high as 30 days are necessary to achieve an MOE greater than or equal to 100 (e.g. foliar application of the WP on grapes). In general, post-application risks were higher for the wettable powder formulation versus the emulsifiable concentrate.

**Table 9. Summary of Post-application Exposure**

Crop <sup>a</sup>	Maximum Label Application Rate (lbs ai/acre) <sup>d</sup>		Transfer Coefficient <sup>e</sup> (cm <sup>2</sup> /hr)	Activity <sup>f</sup>	Day after Application When MOE $\geq 100$ <sup>g</sup>	
	WP <sup>b</sup>	EC <sup>c</sup>			WP <sup>b</sup>	EC <sup>c</sup>
Table Grapes / Raisins	1.5	1.5	10,000	Cane turning and tying, and girdling	30	6
Juice Grapes	1.5	1.5	5,000	Tying, training, hand harvesting, hand pruning, and thinning.	20	0
Grapes, Table and Juice	1.5	1.5	1,000	Scouting and irrigating	0	0
Apple, Apricot, Cherry, Nectarines, Peach, Pear, Plum, Prune, Christmas Trees, Ornamental Trees / Shrubs including Evergreen Trees and Non-bearing Citrus Trees.	3	3	3,000	Thinning, staking, topping, training, hand harvest, hand pruning and seed cone harvesting	5	0
Apple, Apricot, Cherry, Nectarines, Peach, Pear, Plum, Prune, Ornamental Trees / Shrubs including Evergreen Trees, Non-bearing Citrus Trees. and Christmas Trees.	3	3	1,000	Scouting and irrigating	0	0
Macadamia nuts, Pistachio Nuts, Pecans, Hazelnut, Almonds and Walnut	2	3	2,500	Hand harvesting, pruning, and thinning	0	0
			500	Scouting and irrigating	0	0

Crop <sup>a</sup>	Maximum Label Application Rate (lbs ai/acre) <sup>d</sup>		Transfer Coefficient <sup>e</sup> (cm <sup>2</sup> /hr)	Activity <sup>f</sup>	Day after Application When MOE $\geq 100$ <sup>g</sup>	
	WP <sup>b</sup>	EC <sup>c</sup>			WP <sup>b</sup>	EC <sup>c</sup>
Blueberries, Kohlrabi, Broccoli, and Cabbage.	2	2	5,000	Hand harvesting, pruning, thinning, and irrigating.	14	9
Kohlrabi, Broccoli, and Cabbage.	2	2	4,000	Scouting and irrigating	12	7
Blueberries	2	2	1,000	Scouting and irrigating	3	0
Brussels Sprouts and Cauliflower	1	1	5,000	Topping, irrigating, hand harvesting, and tying.	9	4
			4,000	Scouting and irrigating	7	2
Corn	1.5	1.5	17,000	Detassling	21	17
			1,000	Scouting and irrigating	1	0
Cucumber, Melons, Pumpkin, Squash, Beans, Peas, Celery, Lettuce, Spinach, and Carrots.	1	1	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	4	0
Alfalfa, Barley, Clover, Oats, Rye, Wheat, White Potatoes, Cucumber, Melon, Pumpkin, Squash, Bean, Peas, Celery, Lettuce, and Spinach.	1	1	1,500	Scouting and irrigating	0	0
Carrots	1	1	300	Scouting and irrigating	0	0
Pepper, Eggplant, and Tomato	1	1	1,000	Hand harvesting, staking, tying, pruning, thinning, and training.	0	0
			700	Scouting and irrigating	0	0
Pineapple	2	2	1000	Hand harvesting	3	0
			500	Scouting and irrigating	0	0
Strawberry	2	2	1,500	Hand harvesting, pinching, pruning, and training.	5	0
			400	Scouting and irrigating	0	0
Cotton, Collard Greens, Kale, Mustard Greens, Sweet Potato, Radish, Rutabaga, and Turnip.	2	2	2500	Hand harvesting, pruning, and thinning.	9	3
Cotton, Collard Greens, Kale, Mustard Greens and Sweet Potato.	2	2	1,500	Scouting and irrigating	5	0
Radish, Rutabaga, and Turnip.	2	2	300	Scouting and irrigating	0	0
Tobacco	1.5	1	2,000	Hand harvesting, pruning, striping, thinning, topping, and hand weeding	5	0
			1,300	Scouting and irrigating	2	0

**Footnotes:**

Day 0 = day of application after sprays have dried (12 hours).

a Crops were grouped according to similar application rates, transfer coefficients, and surrogate DFR data sources.

b WP = wettable powder formulation

c EC = emulsifiable concentrate formulation

d maximum application rates as stated on current endosulfan labels.

e Transfer Coefficients from Science Advisory Council on Exposure Policy 3.1<sup>16</sup>

f Activities are from Science Advisory Council on Exposure Policy 3.1.<sup>16</sup> Each activity may not occur for every crop listed in group.

g Day after application when the calculated MOE is greater than the target MOE of 100.

### **(3) Human Health Incident Data**

The Agency has reviewed the Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) databases for reported incident information for endosulfan. A number of accidental human poisonings from exposure to endosulfan in occupational settings have been reported. The data from these sources often lacked specific information on the extent of exposure and the circumstances of exposure. Collectively, however, the incidence information indicate definite poisoning risks from misuse of products that contain endosulfan, or from not wearing personal protective equipment.

Several incidents of acute accidental human exposure to endosulfan have been reported. The clinical signs and symptoms observed in humans following acute accidental exposure to endosulfan are similar to those observed in acute toxicity studies in animals. In humans, acute toxicity caused by endosulfan is characterized by nervousness, agitation, tremors, convulsions, and death. In one incident, a 70 year old woman died about three hours after she swallowed “drops” of an endosulfan formulation. Prior to death the woman experienced vomiting, diarrhea, agitation, tonic-clonic convulsions, dyspnea, cyanosis, and loss of consciousness. In one incident, nine workers experienced at least one convulsion after bagging a 50% wettable powder formulation of endosulfan. Five of the men were said to be wearing a respirator and protective clothing at the time of exposure. Prodromal symptoms included malaise, vomiting, dizziness and confusion. Further, California data show a consistent risk of skin rash or irritation among field workers who come into substantial contact with endosulfan-treated foliage.

#### **B. Environmental Risk Assessment**

A summary of the Agency’s environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see *Final EFED Risk Assessment for the Reregistration Eligibility Decision on Endosulfan*, February 26, 2002, available in the public docket and on the internet at <http://www.epa.gov/pesticides/reregistration/endosulfan>. Major revisions to the ecological risk assessment are listed below:

- Some risk estimates were recalculated to reflect supported application rates.
- Some RQs were recalculated to include endosulfan sulfate exposure.

#### **1. Environmental Fate and Transport**

Technical grade endosulfan is a mixture of two biologically-active isomers, the alpha ( $\alpha$ ) and beta ( $\beta$ ) isomers, which differ in physico-chemical and fate properties. Endosulfan is a persistent, semivolatile compound that has been detected in nearly all environmental compartments, including water and in areas where it is not used (e.g., the Arctic and national parks). The end-use product is a mixture of two endosulfan isomers, typically 70%  $\alpha$ -endosulfan and 30%  $\beta$ -endosulfan. The  $\beta$ -isomer is generally more persistent and the  $\alpha$ -isomer



is more volatile. For both isomers, hydrolysis at pH values greater than 7 is an important degradation route; however, at pH values below 7, both isomers are rather persistent. At a pH of 7,  $\alpha$ -endosulfan and  $\beta$ -endosulfan hydrolyze with half-lives of 11 and 19 days, respectively, and at a pH of 9, the isomers have half-lives of 4 to 6 hours. Under acidic conditions, both isomers are stable to hydrolysis, and microbial degradation in soils becomes the predominant route of degradation. Half-lives in acidic to neutral soils range from one to two months for  $\alpha$ -endosulfan and from three to nine months for  $\beta$ -endosulfan under aerobic conditions. Dissipation rates observed in the field studies, which capture a combination of degradation, transport, and uptake, suggest that endosulfan will persist in the surface soil for weeks to months after application (similar order of magnitude to rates observed in the soil metabolism studies).

The major transformation products found in the fate studies are endosulfan diol (hydrolysis) and endosulfan sulfate (soil metabolism). Both the diol and sulfate transformation products have structures similar to the parent compound and are also of toxicological concern. Available data suggest that endosulfan sulfate will be more persistent than the parent. The estimated half-lives for the combined toxic residues (endosulfan plus endosulfan sulfate) ranged from roughly 9 months to 6 years.

Laboratory studies indicate that  $\alpha$ - and  $\beta$ -endosulfan have a high affinity for sorption onto soils. The average organic carbon partition coefficients ( $K_{oc}$ ) were 10,600 and 13,600 mL/g, for the  $\alpha$ - and  $\beta$ -endosulfan isomers, respectively. These isomers are not expected to be highly mobile in the soil environments; therefore, they should not be frequently detected in ground water; however, due to their persistence, vulnerable aquifers below acidic soils could be prone to contamination. Moreover, horizontal transport is possible via erosion or dissolution in runoff events. Endosulfan can also contaminate surface waters through spray drift. Its high affinity to sorb to soil indicates that endosulfan is likely to be associated predominantly with the sediment phase in runoff. Endosulfan reaching the water column, through spray drift or runoff, will have a propensity to sorb to benthic sediment, and this sediment may eventually become a source of endosulfan redistribution into the overlying waters. Endosulfan may move beyond its use area through atmospheric transport (via volatilization and/or transport in dust particles).

Based on environmental fate laboratory studies, terrestrial field dissipation studies, available models, monitoring studies, and published literature, it can be concluded that endosulfan is a very persistent chemical which may stay in the environment for lengthy periods of time, particularly in acid media. Endosulfan may be transported via dissolution in water/via runoff, adsorption to soil particles/via erosion, vaporization and/or adsorption to dust particles/transport in the air. While atmospheric transport has been documented for endosulfan, the available data is not sufficient to evaluate its potential impacts on non-target organisms. The limited data available show measured concentrations significantly lower than those used in the Agency's risk assessment but exposures to more sensitive species are possible.

Endosulfan has a relatively high potential to bioaccumulate in fish with octanol-water partition coefficients ( $K_{ow}$ ) of 55,500 for  $\alpha$  endosulfan and 61,400 for  $\beta$  endosulfan. Studies suggest that endosulfan bioconcentration factors in fish ranged from 2400X to 11,000X for

combined isomers in whole fish and endosulfan depurated after 24 hours. Rates of depuration in field conditions will depend on the levels of endosulfan in the water column and the length of time those levels are maintained. Studies have revealed tissue residues are composed of both parent and the endosulfan sulfate degradate.

## 2. Risk to Birds and Mammals

The Agency's ecological risk assessment compares toxicity endpoints from ecological studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to nontarget organisms from the use of endosulfan products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the toxicity endpoint values, such as the median lethal dose (LD<sub>50</sub>) or the median lethal concentration (LC<sub>50</sub>). These RQ values are then compared to the Agency's levels of concern (LOCs) which indicates whether a chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. In general, the higher the RQ the greater the concern. When the RQ exceeds the LOC for a particular category (e.g. endangered species), the Agency presumes a risk of concern to that category. The LOCs and the corresponding risk presumptions are presented in Table 10. In addition, the Agency has conducted a more refined, probabilistic assessment for aquatic organisms.

**Table 10. LOCs and Associated Risk Presumptions**

IF...	THEN the Agency presumes...
<i>Mammals and Birds</i>	
The acute RQ > LOC of 0.5,	Acute risk
The acute RQ > LOC of 0.2,	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1,	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk <i>and</i> Chronic effects may occur in Endangered species
<i>Fish and Aquatic Invertebrates</i>	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.05	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk <i>and</i> Chronic effects may occur in Endangered species

### a. Toxicity (Hazard) Assessment

Endosulfan is classified as highly toxic to birds and mammals on an acute exposure basis and moderately toxic to birds on a subacute dietary basis. Chronic toxicity data on birds and mammals revealed that reproduction and growth were the most sensitive endpoints. For birds, at 60 ppm there were significant reductions in the number of eggs laid, number of eggs hatched, adult body weight and feed consumption. In rats, there was an increase in cumulative pup loss and a reduction in litter size at 100 ppm; parental systemic toxicity was based on decreased body weight and offspring toxicity was based on increased pituitary and uterine weights.

The acute and chronic toxicity endpoints for endosulfan are presented in Table 11. Information in the literature has indicated that in birds, endosulfan may impair the development of the genital tract. In mammals, reduced hormone levels, testicular atrophy and reduced sperm production were observed. These data suggest that endosulfan may affect endocrine-mediated pathways.

**Table 11. Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms**

Species	Acute Toxicity				Chronic Toxicity	
	LD <sub>50</sub> (ppm)	Acute Oral Toxicity	5-day LC <sub>50</sub> (ppm)	Subacute Dietary Toxicity	NOEC/LOEC (ppm)	Affected Endpoints
Northern bobwhite quail ( <i>Colinus virginianus</i> )	--	--	805	moderately toxic	60 / 120	reproduction
Mallard duck ( <i>Anas platyrhynchos</i> )	28	highly toxic	1053	slightly toxic	30 / 60	reproduction and growth
Honey bee ( <i>Apis melliferus</i> )	4.5	--	--	--	--	--
Laboratory rat ( <i>Rattus norvegicus</i> )	10	highly toxic	--	--	15 / 75	growth

### 3. Exposure and Risk

The Agency's ecological risk assessment for terrestrial wildlife considers exposure to endosulfan from the ingestion of residues on food. Terrestrial estimated environmental concentrations (EECs) were derived for major crops using labeled application rates and intervals between applications. Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. Exposure estimates for terrestrial animals represent parent endosulfan only and do not take into account residues from the more persistent and assumed to be equally toxic endosulfan sulfate.

Acute high risk, restricted use and endangered species LOCs are exceeded for birds (RQ range: 0.02 - 0.53) and mammals (RQ range: 0.05 - 40) at current application rates for the major crops modeled. Chronic LOCs for birds were exceeded (RQ range: 0.03 - 2.7) following both single and multiple applications on all food items except seeds. Chronic LOCs for mammals were exceeded (RQ range: 0.3 - 5.4) following multiple applications on all food items. Tables 12-14 summarize the risk quotients for terrestrial wildlife.

**Table 12. Avian Acute and Chronic Risk Quotients**

Use/App. Method	Rate (lbs ai/A) x No. Apps. (Interval, days)	Food Items	Max. EEC (mg/kg)	Avg. EEC (mg/kg)	Acute RQ	Chronic RQ
Single Application						
tobacco, tomatoes, potatoes, lettuce (aerial), cantaloupe (ground)	1 lb./A (1)	Short grass	240	27	0.30	0.9
		Tall grass	110	10	0.14	0.3
		Broadleaf plants/Insects	135	11	0.17	0.4
		Seeds	15	1	0.02	0.03
Multiple Applications						
tobacco (aerial), tomatoes (aerial), cantaloupe (ground)	1 lb./A (3) 7-day interval	Short grass	332	81	0.41	2.7
		Tall grass	152	35	0.19	1.2
		Broadleaf plants/Insects	187	41	0.23	1.4
		Seeds	21	4	0.03	0.1

Use/App. Method	Rate (lbs ai/A) x No. Apps. (Interval, days)	Food Items	Max. EEC (mg/kg)	Avg. EEC (mg/kg)	Acute RQ	Chronic RQ
Apples (air blast), grapes (aerial), pecans (air blast)	1.5 lbs./A (2) 10-day interval	Short grass	424	81	0.53	2.7
		Tall grass	194	34	0.24	1.1
		Broadleaf plants/Insects	238	39	0.30	1.3
		Seeds	26	4	0.03	0.13

**Table 13. Acute RQ Values for Small (15 g), Intermediate (35 g) and Large (1,000 g) Mammals Feeding on Short or Tall Grass, Broadleaf Plants/insects, and Seeds**

Site (method) Application Rate (number of applications)	Body Weight (grams)	RQ Short Grass	RQ Tall Grass	RQ Broadleaf Plants/Insects	RQ Seeds
tobacco, lettuce, tomatoes potatoes (aerial), cantaloupe (ground) 1 lb a.i./A	15	23	10	13	0.32
	35	16	7.2	8.9	0.22
	1000	3.6	1.6	2.0	0.05
tobacco (aerial), tomatoes (aerial), cantaloupe (ground) 1 lb. a.i./A (3)	15	32	14	18	0.44
	35	22	10	12	0.31
	1000	5	2.3	2.8	0.06
apples (air blast), grapes (aerial), pecans (air blast) 1.5 lbs. a.i./A (2)	15	40	18	23	0.55
	35	28	13	16	0.39
	1000	6.3	2.9	3.6	0.08

**Table 14. Chronic RQ Values for Mammals Feeding on Short Grass, Tall Grass, Broadleaf Plants/insects, and Seeds Exposed to Endosulfan Following Multiple Applications**

Site (method) Application Rate (number of applications)	RQ Short Grass	RQ Tall Grass	RQ Broadleaf Plants/Insects	RQ Seeds
tobacco (aerial), tomatoes (aerial), cantaloupe (ground) 1 lb. a.i./A (3)	4.4	2.3	2.7	0.3
apples (air blast), grapes (aerial), pecans (air blast) 1.5 lbs. a.i./A (2)	5.4	2.3	2.6	0.3

#### 4. Risk to Aquatic Species

##### a. Toxicity (Hazard) Assessment

Endosulfan is very highly toxic to freshwater and estuarine/marine fish and invertebrates. Table 15 summarizes the most sensitive endpoints used in the hazard assessment of aquatic animals. Acute aquatic toxicity estimates ranged from 0.1 to 166 ppb for endosulfan. Estuarine/marine organisms generally were more sensitive to the effects of endosulfan than their freshwater counterparts. No chronic toxicity data were available for the most sensitive freshwater species (rainbow trout and scuds) thus acute to chronic ratio (0.1) was used to predict

NOEC values for these species. On species where chronic toxicity data were available, the most sensitive endpoints were reduced growth and survival. Information from the open literature has indicated that amphibians exposed to endosulfan exhibited impaired development of tadpoles into adults. In fish, endosulfan treatment has resulted in the reduction of cortisol secretion by head kidney cells. These data suggest that endosulfan may affect endocrine-mediated pathways.

Available acute toxicity data include an EC<sub>50</sub> of 0.58 mg/L for endosulfan diol on *Daphnia magna*, indicating that this intermediate degradate is highly toxic to freshwater invertebrates. Acute toxicity testing of endosulfan sulfate (fish LC<sub>50</sub> = 2.2 ppb; daphnid EC<sub>50</sub> = 580 ppb) indicates the toxicity of the persistent degradate is comparable to that of technical grade parent.

**Table 15. Summary of Acute and Chronic Aquatic Toxicity Estimates**

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC <sub>50</sub> (ppb)	48-hr EC <sub>50</sub> (ppb)	Acute Toxicity	NOEC / LOEC (ppb)	Affected Endpoints
Rainbow trout <i>Oncorhynchus mykiss</i>	0.8	--	very highly toxic	NOEC = 0.1 <sup>a</sup>	--
Bluegill sunfish <i>Lepomis macrochirus</i>	1.7	--	very highly toxic	--	--
Fathead minnows <i>Pimephales promelas</i>	1.5	--	very highly toxic	NOEC = 0.2 LOEC = 0.4	Reduced growth and survival
Scud <i>Gammurus lacustris</i>	--	6	very highly toxic	NOEC = 0.07	--
Water flea <i>Daphnia magna</i>	--	166	very highly toxic	NOEC = 2 LOEC < 7	reduced survival
Striped bass <i>Morone saxatilis</i>	0.1	--	very highly toxic	0.01 <sup>a</sup>	--
Eastern oyster <i>Crassostrea virginica</i>	0.45	--	very highly toxic	0.05 <sup>a</sup>	--
Grass shrimp	1.3	--	very highly toxic	--	--

<sup>a</sup> chronic value predicted using acute to chronic ratio of 0.1 estimated from fathead minnow data (acute = 1.5 ppb; chronic = 0.2 ppb)

## **b. Exposure and Risk**

To assess potential risk to aquatic animals, the Agency uses a computer model to generate EECs of endosulfan in surface water. However, unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the index reservoir and percent crop area factor. These refinements are solely used to assess pesticide exposure to humans from drinking water sources since they are used to predict the levels of endosulfan in a drinking water reservoir from use of endosulfan throughout a watershed rather than predicting the potential exposure to non-target organisms at the field level. Hence, the EECs used to assess exposure to aquatic animals are not the same as the EEC values used to assess human dietary exposure from drinking water sources.

Peak EECs were compared to acute toxicity endpoints to derive acute risk quotients and 21-day EECs were compared to chronic toxicity endpoints (NOAEC) to derive chronic risk quotients for freshwater and estuarine/marine organisms. Exposure estimates for aquatic animals

represent parent endosulfan and residues from the more persistent and equally toxic endosulfan sulfate.

At the current maximum application rates used on the major crops where endosulfan is employed, coupled with a 300-ft spray drift buffer, acute high risk, restricted use and endangered species levels of concern are exceeded for both freshwater and estuarine/marine organisms. Acute RQ values ranged from 1.04 to 34.8 for freshwater fish and from 0.15 to 5 for freshwater invertebrates. Estuarine/marine fish and invertebrates were roughly an order of magnitude more sensitive to the effects of endosulfan, with acute RQ values ranging from 8.7 to 289 for fish and 1.9 to 64.2 for invertebrates. Chronic RQ values ranged from 1.5 to 64 for freshwater fish and from 3.6 to 135.3 for freshwater invertebrates. Chronic RQ values for estuarine ranged from 16 to 704 for fish and 1 to 39.5 for invertebrates.

The following tables summarize the RQs for aquatic organisms using maximum labeled rates and accounting for the 300-foot spray drift buffer. Some sections of the tables do not contain entries either because chronic exposures are not compared against acute toxicity, acute exposures are not compared against chronic toxicity, 21-day exposure are not compared against 56-day toxicity value or 56-day exposure not compared against 21-day toxicity value.

**Table 16. Acute and Chronic Risk Quotients for Freshwater Fish and Invertebrates**

Crop Application Rate (# of apps)	EECs	Acute Risk Quotients		Chronic Risk Quotients	
	Peak / 21-day Average 56-day Average (ppb)	Freshwater Fish LC <sub>50</sub> = 0.83 ppb	Freshwater Invertebrate LC <sub>50</sub> = 5.8 ppb	Freshwater Fish NOEC = 0.11 (ppb)	Freshwater Invertebrate NOEC = 0.07 (ppb)
Apples 1.5 (2)	0.87	1.04	0.15	--	--
	0.25	--	--	--	3.6
	0.16	--	--	1.5	--
Cotton 1.5 (2)	11.67	14.1	2	--	--
	4.9	--	--	--	70
	3.89	--	--	35.4	--
Lettuce 1.0 (3)	4.64	5.6	0.8	--	--
	1.41	--	--	--	20.1
	0.79	--	--	7.2	--
Pecan 1.5 (2)	19.39	23.4	3.4	--	--
	6	--	--	--	85.7
	3.86	--	--	35.1	--
Potato 1.0 (3)	6.07	7.3	1.1	--	--
	2.14	--	--	--	30.6
	1.53	--	--	13.9	--
Tobacco 1.0 (3)	9.72	11.7	1.7	--	--
	2.8	--	--	--	40
	1.72	--	--	15.6	--
Tomato 1.0 (3)	28.9	34.8	5	--	--
	9.47	--	--	--	135.3
	7.04	--	--	64	--

**Table 17. Acute and Chronic Risk Quotients for Estuarine/marine Fish and Invertebrates**

Crop Application Rate (# of apps)	EECs	Acute Risk Quotients		Chronic Risk Quotients	
	Peak 21-day Average (ppb)	Estuarine/marine Fish LC <sub>50</sub> = 0.1 ppb (EEC/LC <sub>50</sub> )	Estuarine/marine Invertebrate LC <sub>50</sub> = 0.45 (ppb) (EEC/LC <sub>50</sub> )	Estuarine/marine Fish NOEC = 0.01 (ppb) (EEC/NOEC)	Estuarine/marine Invertebrate NOEC = 0.24 (ppb) (EEC/NOEC)
Apples 1.5 (2)	0.87	8.7	1.9	--	--
	0.25	--	--	--	1
	0.16	--	--	16	--
Cotton 1.5 (2)	11.67	116.7	25.9	--	--
	4.9	--	--	--	20.4
	3.89	--	--	389	--
Lettuce 1.0 (1)	4.64	46.4	10.3	--	--
	1.41	--	--	--	5.87
	0.79	--	--	79	--
Pecan 1.5 (2)	19.39	193.9	43.1	--	--
	6	--	--	--	25
	3.86	--	--	386	--
Potato 1.0 (3)	6.07	60.7	13.5	--	--
	2.14	--	--	--	8.9
	1.53	--	--	153	--
Tobacco 1.0 (3)	9.72	97.2	21.6	--	--
	2.8	--	--	--	7.2
	1.72	--	--	172	--
Tomato 1.0 (3)	28.9	289	64.2	--	--
	9.47	--	--	--	39.5
	7.04	--	--	704	--

Endosulfan was the most frequently detected insecticide in tadpole and adult frog tissues in a California study (Sparling et. al. 2001). The frequency of occurrence of endosulfan was higher in samples collected in the Sierra Nevada mountains east of the Central Valley. Concentrations and frequency of detections for the pesticide in amphibian tissue follow north-south and west-east patterns consistent with intensified agriculture upwind of the areas with the most serious declines in amphibian populations, several of which are either listed (red-legged frog [*Rana aurora*]) or proposed for listing (yellow-legged frog [*Rana muscosa*] and Yosemite toad [*Bufo canorus*]) as threatened under the Endangered Species Act.

## 5. Probabilistic Assessment

The Agency used probabilistic assessment techniques to conduct a more refined risk assessment for aquatic organisms that was based on actual reported application rates in California coupled with a 300-ft spray-drift buffer. The methods used in this assessment and other probabilistic methods are currently under development, and thus this assessment is not definitive and further refinements in the techniques should be expected. However, this assessment does provide some insight into the expected effects of endosulfan on whole aquatic systems.

This assessment compared a range of EEC values (single annual 96-hour maximum concentrations) from models to a range of LC<sub>50</sub> values for several aquatic species. This analysis provides a first step into probabilistically modeling of overall aquatic effects and provides insights on the range of endosulfan's ecological effects. The assessment estimates that, for the lowest exposure uses (e.g., apples), the use of endosulfan at typical application rates has a 10% probability of detrimentally affecting (LC<sub>50</sub> values being exceeded by modeled EECs) 10% of the aquatic species in a given year. For higher exposure uses (e.g., tomatoes) the use of endosulfan at typical application rates in a given year resulted in a 90% probability that 60% of the aquatic species will be detrimentally affected, a 50% probability that 75% of the species will be detrimentally affected, and a 10% probability that 90% of the species will be detrimentally affected.

## **6. Risks to Endangered Species**

Endangered species LOCs are exceeded for acute and chronic risks to all taxa for endangered/threatened animals – birds, mammals, fish, aquatic invertebrates, amphibians, reptiles and terrestrial for all currently registered uses of endosulfan.

In 1989 the U.S. Fish and Wildlife Service (USFWS) issued a biological opinion on endosulfan in response to the U. S. Environmental Protection Agency's request for consultation. In issuing its opinion the USFWS considered the following factors: (1) potential for exposure of the listed species to the pesticide; (2) information on the chemical toxicity relative to estimated environmental concentrations; (3) potential for secondary impacts; and (4) special concerns not specifically addressed in the preceding factors or unique to the situation being evaluated. Given the evaluation criteria, a total of 130 species (6 amphibians, 77 fish, 32 mussels, 6 crustaceans, 4 miscellaneous aquatic invertebrates, and 5 bird species) were considered potentially affected by the use of endosulfan. Of those organisms potentially affected, the USFWS listed 41 aquatic species as jeopardized, of which the majority (54%) were endangered/threatened species of freshwater mussels. Two terrestrial (avian) species were also classified as being in jeopardy. The remaining potentially affected organisms were listed either as having no potential for exposure or as not being in jeopardy.

The Agency's current assessment of ecological risks uses both more refined methods to define ecological risks of pesticides and new data, such as that for spray drift. Therefore, the Reasonable and Prudent Alternatives and Reasonable and Prudent Measures in the Biological Opinion may need to be reassessed and modified based on these new approaches.

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of endosulfan use to federally listed threatened and endangered species. At that time the Agency will also consider any regulatory changes recommended in the RED that are being implemented. Until such time as this analysis is completed, the overall



environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets which address endosulfan, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to endosulfan at levels of concern.

## **7. Ecological Incident Reports**

A review of the Ecological Incident Information System revealed that since 1971 a total of 91 incidents have been associated with the use of endosulfan. The majority of incidents occurred in California, South Carolina, North Carolina, and Louisiana. The overwhelming majority (96%) of the incidents were associated with the aquatic environment: 82% affected fish while 7% affected aquatic macroinvertebrates. The database indicates that 34% of the endosulfan incidents were a result of either accidental or intentional misuse of the pesticide, 29% resulted from the labeled use of endosulfan and the rest were unspecified. Approximately 32% of the incidents were directly attributable to runoff. However, weather conditions were not specified in the majority of cases, so the contribution of runoff may be underestimated by the reported results.

According to the National Oceanic and Atmospheric Agency's fish-kill database endosulfan was responsible for more fish kills in U.S. estuaries and coastal rivers between 1980 and 1989 than all currently used pesticides at that time. The report noted that endosulfan was one of the most often found of the inventoried pesticides in aquatic biota and in one case affected estuarine biomass.

In 1991, as mentioned earlier, a 300-foot spray drift buffer was put in place on endosulfan labels to address contamination of water bodies. Since this restriction was implemented in 1991 a total of 33 aquatic incidents have been reported, 20 of which were not attributed to misuse. In terms Of these 20 incidents, 7 have been classified as highly probable, 11 have been classified as probable and 3 have been classified as possible. Thus, despite use restrictions to limit degradation of the aquatic environment, endosulfan has continued to access the aquatic environment and result in nontarget mortality.

## **8. Endocrine Disruption**

Exposure to endosulfan has resulted in both reproductive and developmental effects in nontarget animals. Endosulfan exposure resulted in impaired development in amphibians, reduced cortisol secretion in fish, impaired development of the genital tract in birds and reduced hormone levels and sperm production and produced testicular atrophy in mammals. Additionally, endosulfan has been demonstrated to bind to the human estrogen receptor and exhibit significant estrogenic activity. Whether the toxicity endpoints are a result of endocrine disruption is not known. However, it is clear that organisms treated with endosulfan did exhibit some toxic effects that have historically been associated with endocrine disrupting chemicals, *e.g.*, developmental and reproductive effects.

## **9. Long Range Transport**

Endosulfan is a semivolatile and persistent cyclodiene pesticide that can migrate over a long distance through various environmental media such as air, water, and sediment. Once endosulfan is applied to crops, it can either persist in soil as a sorbed phase or be removed through several physical, chemical, and biological processes. Recent studies suggest that secondary emissions of residual endosulfan continue to recycle in the global system while they slowly migrated and were redeposited via wet deposition in the Northern Hemisphere. The occurrence of endosulfan in remote regions like the Great Lakes, the Arctic, and mountainous areas is well documented. Endosulfan can also enter the air as adsorbed phase onto suspended particulate matter, but this process does not appear to be a major contributor long range transport like volatilization.

The presence of endosulfan in the remote areas like Arctic and the Great Lakes requires further understanding of the transport mechanisms from the atmosphere. The potential impact of atmospheric deposition of endosulfan into surface water and its potential effect on water quality and aquatic organisms in the non-use areas is not well documented. Despite the progress made in recent years in estimating the persistence and long-ranged transport of chemicals using models, a validated global model has not been published because of uncertainties involved in the source inventories, chemical fate data, degradative pathways and exposure analyses. Future work will be aimed at developing a comprehensive screening tool that can be used reliably in risk assessments for regulatory purposes.

## **IV. Risk Management and Reregistration Decision**

### **A. Determination of Reregistration Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing endosulfan active ingredients.

The Agency has completed its assessment of the dietary (food and drinking water), ecological and occupational risks associated with the use of currently registered pesticides containing the active ingredient endosulfan. Based on a review of these data and public comments on the Agency's assessments for the active ingredient endosulfan, EPA has sufficient information on the human health and ecological effects of endosulfan to make decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has reassessed all 80 tolerances for endosulfan and can make a FQPA safety determination as detailed below. The Agency has determined that agricultural use of endosulfan, based on the currently approved labeling, pose occupational and ecological risks that constitute unreasonable adverse effects on the environment. However, the Agency believes

that these risks can likely be acceptably mitigated through routine changes to pesticide labeling and formulations. Accordingly, the Agency has determined that endosulfan is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision for occupational exposures associated with the application of dip treatment to roots or whole plants and ecological risks; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. Label changes are described in Section V of this document. Appendix A summarizes the uses of endosulfan that would be eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of endosulfan, and lists the submitted studies that the Agency found acceptable. The additional data that the Agency intends to require are described in Section V. Further mitigation measures and additional data requirements, however, may be warranted following the completion of the stakeholder process outlined in this document.

Based on its evaluation of endosulfan, the Agency has determined that endosulfan products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of endosulfan.

## **B. Phase 3 Comments and Responses**

When making its reregistration decision, the Agency took into account all comments received during Phases 3, 4 and 5 of the Public Participation Process. These comments in their entirety are available in the docket. Comments, which addressed human health and ecological concerns, were received from the technical registrants, represented by the Endosulfan Task Force(ETF), environmental and advocacy groups such as the Natural Resources Defense Council (NRDC), the Farmworker Justice Fund, Inc., the Pesticide Action Network North America (PANNA) and their affiliate, the Pesticide Action Network Asia and Pacific (PANAP), Respiratory and Environmental Disabilities Association of Hawaii, the Rural Action Safe Pest Control Program (RASPCP), the World Wildlife Federation, and private citizens. Agency responses to comments are available on the Agency's web page: <http://www.epa.gov/pesticides/reregistration/endosulfan>.

### Comment Period on this RED

The Agency is providing a 60-day comment period on this RED. While all comments are welcome, those with specific data or information bearing on the risk and benefit assessments are most useful. For example, the Agency is aware that cotton stakeholders are gathering data on the number of acres treated per day by air in AZ and CA which may be used to characterize handler risks in those areas and may impact the maximum application rate allowed for that crop. The Agency has also recently received comments related to tobacco which will be considered during the comment period.

## **C. Regulatory Position**

### **1. FQPA Assessment**

#### **a. “Risk Cup” Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from exposure to endosulfan exceeds its own “risk cup” for pesticidal uses of endosulfan registered by EPA. However, if the use of endosulfan on succulent beans, succulent peas, grapes, pecans and spinach are deleted and the mitigation measures in this document to prevent contamination of surface waters are implemented, the Agency believes that endosulfan will “fit” within its risk cup. Therefore, the Agency has concluded that the tolerances for endosulfan meet the FQPA safety standards, provided the risk mitigation measures outlined in this document are adopted. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as the acute and chronic food exposure. An aggregate assessment was conducted for exposures resulting from food and drinking water for pesticidal uses of endosulfan registered by EPA under FIFRA. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be over acceptable levels, but that the combined risks from all exposures to endosulfan do “fit” within the individual risk cup provided the risk mitigation contained in this decision document are fully implemented.

#### **b. Tolerance Summary**

Tolerances for residues of endosulfan in/on plant and animal commodities are established under 40 CFR §180.182. Tolerances for residues of endosulfan in processed commodities are established under 40 CFR §185.2600. Endosulfan tolerances are currently expressed in terms of the total residues of endosulfan (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide) and its metabolite, endosulfan sulfate (6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide). The current endosulfan tolerance expression does not specify the two stereo isomers of the parent compound.

The Agency has determined that tolerances for crop and livestock commodities should continue to be expressed as residues of the parent ( $\alpha$  and  $\beta$  isomers) and the sulfate metabolite. However, the Agency recommends that the tolerance expression be revised in order to specify the  $\alpha$  and  $\beta$  isomers of the parent.

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, endosulfan tolerances for certain commodities which have been removed from Table 1 need to be revoked, and some commodity definitions must be corrected. In addition, tolerances for commodities for which there are currently no registered uses of endosulfan need to be revoked. A summary of endosulfan tolerance reassessments is presented in Table 18.

### **Tolerances Listed Under 40 CFR §180.182:**

Pending label revisions for some crops, sufficient field trial data have been submitted (or were translated when appropriate) to reassess the established tolerances for the following plant commodities, as defined: almonds; almonds, hulls; apples; apricots; beans; blueberries; broccoli; Brussels sprouts; cabbage; carrots; cauliflower; celery; cherries; collards; corn, sweet (K+CWHR); cottonseed; cotton gin byproducts; cucumbers; eggplant; filberts; grapes; kale; lettuce; macadamia nuts; melons; mustard greens; nectarines; peaches; pears; peas, pistachios, succulent; pecans; peppers; pineapples; plums; potatoes; prunes; pumpkins; spinach; squash, summer; squash, winter; strawberries; sweet potatoes; tomatoes; turnips; and walnuts. Additional data is needed for the uses of endosulfan on wheat, oats, rye, and barley.

The available residue data suggest that the established tolerance levels for the following plant commodities should be decreased from 2.0 to 1.0 ppm: apples; cucumbers; eggplant; melons; pineapples; pumpkins; squash, summer; squash, winter; and tomatoes. The Agency proposes a crop group tolerance for Cucurbit Vegetables Group (Crop Group 9) since adequate data are available for cucumbers, melons, and squash which are the representative commodities of this crop group.

The available residue data suggest that the established tolerance levels for the following commodities should be increased: broccoli (from 2.0 to 3.0 ppm); cabbage (from 2.0 to 4.0 ppm); celery (from 2.0 to 8.0 ppm); lettuce, head (from 2.0 to 11.0 ppm); and lettuce, leaf (from 2.0 to 6.0 ppm); Blueberry (from 0.1 to 0.3 ppm); barley grain (from 0.1 to 0.3 ppm); and barley straw (from 0.2 to 0.4); rye grain (from 0.1 to 0.3); and rye straw (from 0.2 to 0.3 ppm); oats grain (from 0.1 to 0.3); and oats straw (from 0.2 to 0.4 ppm); and wheat straw (from 0.2 to 0.4 ppm).

The expected dietary burdens of endosulfan to beef and dairy cattle were re-calculated following tolerance reassessment of livestock feed items. Livestock feeding studies reflecting the re-calculated dietary burden are available. Following evaluation of feeding data, the Agency concluded: (i) the tolerance for milk fat (=N in whole milk) at 0.5 ppm should be increased to 2.0 ppm; (ii) the tolerances for meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm should be replaced with separate tolerances for meat byproducts (except liver) at 1.0 ppm and liver at 5.0 ppm; and (iii) the tolerance for fat should be increased from 0.2 to 13 ppm.

The available poultry feeding data suggest that it is not possible to establish with certainty whether finite residues of endosulfan will be incurred, but there is no reasonable expectation of finite residues (Category 3 of 40 CFR §180.6). Therefore, tolerances are not required for eggs and poultry tissues.

### **Tolerance to be Proposed Under 40 CFR §180.182:**

Tolerances for the combined residues of endosulfan ( $\alpha$  and  $\beta$  isomers) and its metabolite endosulfan sulfate in/on: pearled barley, barley hay, flour, and bran; oats forage, hay, flour and

rolled oats; rye forage, flour and bran; wheat forage, hay, and aspirated grain fractions must be proposed once adequate field residue data, reflecting the maximum registered use patterns, have been submitted and evaluated.

The apple processing study indicates that the combined residues of endosulfan ( $\alpha$  and  $\beta$  isomers) and endosulfan sulfate concentrated in dried and wet apple pomace (17x and 6x, respectively); no concentration of endosulfan residues was observed in apple juice. A tolerance for dried apple pomace is not required as it is no longer considered a major livestock feed item and its entry has been deleted from Table 1. A tolerance for apple juice is also not warranted. However, based on the highest average field trial combined residues in/on the RAC and a concentration factor of 6x, the maximum expected endosulfan residues in wet apple pomace is 4.62 ppm. Therefore, a tolerance for the combined endosulfan residues in wet apple pomace must be proposed at 5.0 ppm.

The pineapple processing study indicates that the combined residues of endosulfan ( $\alpha$  and  $\beta$  isomers) and endosulfan sulfate concentrated up to 7x in peel and 41x in bran processed from whole pineapples bearing detectable endosulfan residues; no concentration of endosulfan residues was observed in pineapple pulp and juice. According to OPPTS Table 1, residue data are only required for process residue and juice. Pineapple process residue (also known as wet bran) is a waste byproduct from the fresh-cut product line that includes pineapple tops (minus crown), bottoms, peels, any trimmings with peel cut up, and the pulp (left after squeezing for juice). Based on a HAF combined endosulfan residues of 0.44 ppm in/on the RAC and a concentration factor of 41x, the maximum expected total endosulfan residues in pineapple process residue is 18.04 ppm. Therefore, a tolerance for the combined endosulfan residues in pineapple process residue must be proposed at 20 ppm. A tolerance for pineapple juice is not warranted.

The available tomato processing data indicate that endosulfan residues of concern marginally concentrate (1.2x) in tomato paste processed from treated tomatoes. The concentration of residues in tomato paste is not significant enough to warrant a tolerance for this commodity. A tolerance for tomato puree is also not warranted. Processing data for oats, barley, wheat, and rye are required.

#### **Tolerance Listed Under 40 CFR §185.2600:**

Adequate data are available to reassess the established tolerance for dried tea leaves. The established tolerance for dried tea (reflecting less than 0.1 ppm residues in beverage tea) listed under 40 CFR §185.2600 should be moved to 40 CFR 180.182 because the enacted FQPA stipulates that tolerances for pesticide residues in all types of food (raw or processed) be set under the same provisions of the law.

### Pending Tolerance Petition:

Hoechst Celanese Corporation proposed the establishment of tolerances for residues of endosulfan and endosulfan sulfate in dried hops and spent hops imported from Germany, each at 10 ppm. The Agency recommends in favor of the proposed tolerances subject to the registrant limiting the number of applications to three.

**Table 18. Tolerance Reassessment Summary for Endosulfan**

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
<i>Tolerance Listed Under 40 CFR §180.182 (a) (1)</i>			
Alfalfa, fresh	0.3	Revoke	No longer a registered use.
Alfalfa, hay	1.0	Revoke	
Almond	0.2 (N)*	0.3	The available data indicate that residues of endosulfan or endosulfan sulfate were nondetectable in/on almond kernels harvested 39 or 58 days following the last of multiple applications of a representative WP formulation at exaggerated (2.4x) seasonal rate ; the reported limits of detection were 0.2 and 0.1 ppm respectively. A preharvest interval for almonds has presently not been established. [Almond, nutmeat]
Almond, hulls	1.0	1.0	Following applications of a representative WP formulation reflecting the maximum registered use pattern, the combined endosulfan residues in/on almond hulls ranged from 0.12 to 0.77 ppm. [Almond, hulls]
Apple	2.0	1.0	Data reflecting the maximum registered use pattern are unavailable. However, data reflecting applications at exaggerated (2x) seasonal rate indicate that the combined endosulfan residues in/on apples ranged from 0.46 to >0.47 ppm using the EC formulation, and from 0.69 to 0.84 ppm using the WP formulation. The reassessed tolerance is in harmony with the proposed Codex MRL (Step 5/8) of 1.0 ppm for pome fruits. [Apple]
Apricot	2.0	2.0	The available data for peaches may be translated to apricots. [Apricot]
Artichoke, globe	2.0	Revoke	No longer a registered use.
Barley, grain	0.1 (N)	0.3	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on barley grain ranged from <0.15 to <0.30 ppm..
Barley, straw	0.2 (N)	0.4	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on barley straw ranged from <0.15 to 0.35 ppm.
Bean	2.0	2.0 (Bean, dry and succulent)	Following applications of a representative WP or EC formulation reflecting the maximum registered use pattern, the combined endosulfan residues were below 2.0 ppm in/on lima beans, snap beans, red kidney beans, string beans, and sutter red beans . The reassessed tolerance only applies to bans, dry since the succulent bean use is being deleted. [Bean, succulent seed]
Beets, sugar, without tops	0.1 (N)	Revoke	No longer a registered use. [Beet, sugar, root]

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Blueberry	0.1 (N)	0.3	Following applications of a representative EC formulation reflecting exaggerated use pattern, no detectable residues (<0.1 ppm) of endosulfan or endosulfan sulfate were detected in/on blueberries . [Blueberry]
Broccoli	2.0	3.0	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on broccoli ranged from 0.16 to 2.41 ppm using the EC formulation, and from 0.26 to 1.92 ppm using the WP formulation. The registrants may elect to retain the current tolerance level by amending the registered broccoli use pattern <u>and</u> by submitting additional residue data in support of any label amendments.
Brussels sprouts	2.0	2.0	Data reflecting the maximum registered use pattern are unavailable. However, data reflecting applications of a representative EC formulation at exaggerated (3.5x) seasonal rate indicate that the combined residues of endosulfan in/on Brussels sprouts were below 2.0 ppm .
Cabbage	2.0	4.0	Following applications of a representative EC formulation reflecting the maximum registered use pattern, the combined endosulfan residues were 3.1 ppm in/on cabbage with wrapper leaves and nondetectable (<0.02 ppm) in/on cabbage without wrapper leaves . The reassessed tolerance is based on data from cabbage with wrapper leaves.
Carrots	0.2	0.2	Following applications of a representative EC formulation reflecting the maximum registered use pattern, the combined endosulfan residues in/on carrots were generally below 0.2 ppm . [Carrot]
Cattle, fat	0.2	13	The highest residues obtained in milk and tissue samples collected from the highest feeding level of the combined residues of endosulfan ( $\alpha$ and $\beta$ isomers) and endosulfan sulfate in animal commodities are as follows :  Fat of cattle, goats, hogs, horses, and sheep 13.0 ppm Meat byproducts (except liver) of cattle, goats, hogs, and horses 1.0 ppm Liver of cattle, goats, hogs, and horses ..... 5.0 ppm Meat of cattle, goats, hogs, and horses ..... 2.0 ppm Milk, fat ..... 2.0 ppm
Cattle, meat by products	0.2	Cattle, mbyop = 1.0 Cattle, liver = 5.0	[Cattle, meat byproducts (except liver)] [Cattle, liver]
Cattle, meat	0.2	2.0	
Cauliflower	2.0	2.0	Following applications of a representative EC formulation reflecting the maximum registered as well as exaggerated use patterns, the combined endosulfan residues in/on cauliflower were below 0.78 ppm. Due to the limited number of data points reflecting treatments at 1x, the cauliflower tolerance is reassessed at 2.0 ppm .



Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Celery	2.0	8.0	These new residue data reflect application(s) of representative emulsifiable concentrate (EC) and wettable powder (WP) formulations at the respective maximum registered seasonal rates for celery. The combined residues in/on treated untrimmed celery samples ranged from 0.99 to 4.50 ppm following application of the EC formulation, and from 1.18 to 7.0 ppm following application of the WP formulation.
Cherry	2.0	Cherry, sweet = 2.0 Cherry, sour = 2.0	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on <b>sweet cherries</b> ranged from <0.17 to 1.46 ppm using the EC formulation, and from <0.15 to 0.33 ppm using the WP formulation. The combined endosulfan residues in/on <b>sour cherries</b> ranged from <0.15 to 1.35 ppm using the EC formulation, and from <0.15 to 0.19 ppm using the WP formulation. [Cherry, sweet] and [Cherry, sour]
Collards	2.0	2.0	The available data reflecting the maximum registered use pattern for collards are very limited. Following application of a representative EC formulation at 0.75x the maximum registered seasonal rates, the combined endosulfan residues in/on collards harvested 20 days posttreatment were 1.591-1.782 ppm. The data submitted for spinach, sugar beet tops, kale, or mustard greens may additionally be used to estimate endosulfan residues in/on collards.
Corn, sweet (K+CWHR)	0.2	0.20	The reassessed tolerance is contingent upon the requested label revisions specifying the parameters of use patterns for which adequate data are available.
Cottonseed	1.0	1.0	Following applications of a representative EC formulation reflecting the maximum registered use pattern, the combined endosulfan residues in/on cottonseed were below 1.0 ppm. [Cotton, undelinted seed]
Cotton gin byproducts	-	30	The combined residues of endosulfan ( $\alpha$ and $\beta$ isomers) and endosulfan sulfate ranged from 8.27 to 27.5 ppm in/on cotton gin byproducts harvested 13-14 days following a treatment schedule ( <b>after</b> bolls open) similar to the one described above for cottonseed. No cotton gin byproducts data reflecting treatments made to cotton plants <b>until</b> bolls open have been submitted; however, because residues are expected to be lower from this use pattern, the Agency will not require additional cotton gin byproducts data for reregistration.
Cucumber	2.0	Reassign	Tolerance should be revoked with the concomitant establishment of a tolerance for Cucurbit Vegetables (Crop Group 9). Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on cucumbers ranged from 0.26 to 0.66 ppm using the EC formulation, and from <0.16 to 0.40 ppm using the WP formulation. Adequate data are now available for cucumber, melon, and squash which are the representative commodities of Cucurbit Vegetables Group (Crop Group 9). [Cucumber]
Eggplant	2.0	1.0	The available data for tomato may be translated to eggplant.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Filbert	0.2 (N)	0.20	The available data indicate that residues of endosulfan or endosulfan sulfate were nondetectable in/on filbert nuts harvested 76-88 days following the last of multiple applications of representative WP formulations at 1.3-1.6x the maximum registered seasonal rate. The method's limit of detection was not specified. [Filbert]
Goat, fat	0.2	13	The highest residues obtained in milk and tissue samples collected from the highest feeding level of the combined residues of endosulfan ( $\alpha$ and $\beta$ isomers) and endosulfan sulfate in animal commodities are as follows :  Fat of cattle, goats, hogs, horses, and sheep 13.0 ppm Meat byproducts (except liver) of cattle, goats, hogs, and horses 2.0 ppm Liver of cattle, goats, hogs, and horses . . . . . 5.0 ppm Meat of cattle, goats, hogs, and horses . . . . . 2.0 ppm Milk, fat . . . . . 2.0 ppm
Goat, meat byproduct	0.2	Goats, mbyp = 1.0 Goats, liver = 5.0	[Goat, meat byproducts (except liver)] [Goat, liver]
Goat, meat	0.2	2.0	
Grape	2.0	Revoke	Use being deleted as part of dietary risk mitigation.
Hog, fat	0.2	13	
Hog, meat byproduct	0.2	Hog, mbyp = 1.0 Hog, liver = 5.0	[Hog, meat byproducts (except liver)] [Hog, liver]
Hog, meat	0.2	2.0	
Horse, fat	0.2	13	
Horse meat byproduct	0.2	Horses, mbyp = 1.0 Horses, liver = 5.0	[Horse, meat byproducts (except liver)] [Horse, liver]
Horse, meat	0.2	2.0	
Kale	2.0	2.0	Following applications of a representative EC formulation reflecting the maximum registered use pattern, the combined endosulfan residues in/on kale were 1.214-1.295 ppm .
Lettuce	2.0	Lettuce, head = 11 Lettuce, leaf = 6.0	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on <b>head lettuce (with wrapper leaves)</b> ranged from <0.18 to 4.28 ppm using the EC formulation, and from 0.21 to 10.11 ppm using the WP formulation. The combined endosulfan residues in/on <b>leaf lettuce</b> ranged from <0.15 to 4.49 ppm using the EC formulation, and from 0.17 to 5.72 ppm using the WP formulation. In lieu of proposing higher tolerances, the registrants may elect to retain the current tolerance level by amending the registered lettuce use pattern <u>and</u> by submitting additional residue data in support of any label amendments. [Lettuce, head] and [Lettuce, leaf]

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Nut, Macadamia	0.2 (N)	0.20	Following applications of a representative WP or EC formulation reflecting exaggerated use pattern, no detectable residues of endosulfan or endosulfan sulfate were detected in/on macadamia nuts. The analytical method's limit of detection was not specified. [Macadamia nut]
Melon	2.0	Revoke	Tolerance should be revoked with the concomitant establishment of a tolerance for Cucurbit Vegetables (Crop Group 9). Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on cantaloupes ranged from <0.15 to 0.50 ppm using the EC formulation, and from 0.22 to 0.76 ppm using the WP formulation. [Melon subgroup (crop subgroup 9A)]
Milk, fat (=N in whole milk)	0.5	2.0	[Milk]
Mustard greens	2.0	2.0	The available data reflecting the established 21-day PHI for mustard greens are very limited . The data submitted for spinach, collards, kale, or turnip greens may be used to estimate endosulfan residues in/on mustard greens.
Mustard seed	0.2 (N)	Revoke	No longer a registered use.
Nectarine	2.0	2.0	The available data for peaches may be translated to nectarines. [Nectarine]
Oat, grain	0.1 (N)	0.3	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on oat grain ranged from <0.15 to <0.30 ppm..
Oat, straw	0.2 (N)	0.4	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on oat straw ranged from <0.15 to <0.32 ppm..
Peach	2.0	2.0	Following applications of a representative WP formulation approximating the maximum registered use pattern, the combined endosulfan residues in/on peaches were below 2.0 ppm .
Pear	2.0	2.0	Following applications of a representative WP formulation approximating the maximum registered use pattern, the combined endosulfan residues in/on pears were 0.95-1.00 ppm. Due to the limited number of data points reflecting treatments at 1x, the pear tolerance is reassessed at 2.0 ppm .
Pea, succulent	2.0	Revoke	Use being deleted as part of dietary risk mitigation.
Pecans	0.2 (N)	Revoke	Use is being deleted.
Pepper	2.0	2.0	Following applications of a representative WP or EC formulations approximating the maximum registered use pattern, the combined endosulfan residues in/on bell and sweet peppers are not expected to exceed 2.0 ppm .
Pineapple	2.0	1.0	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on pineapples ranged from >0.08 to 0.50 ppm. [Pineapple]

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Plum, Prune	2.0	2.0	Data reflecting the maximum registered use pattern are unavailable. However, data reflecting applications of a representative WP or EC formulation at an exaggerated seasonal rate indicate that the combined endosulfan residues in/on French prunes were below 2.0 ppm. [ <i>Plum</i> ]
Potato	0.2 (N)	0.2	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on potatoes were mostly nondetectable. The analytical method's limit of detection was not specified. [ <i>Potato</i> ]
Prunes	2.0	2.0	Data reflecting the maximum registered use pattern are unavailable. However, data reflecting applications of a representative WP or EC formulation at an exaggerated seasonal rate indicate that the combined endosulfan residues in/on French prunes were below 2.0 ppm. [ <i>Prune</i> ]
Pumpkin	2.0	Reassign	Tolerance should be revoked with the concomitant establishment of a tolerance for Cucurbit Vegetables (Crop Group 9). The available data for cucumber, melon, and summer squash may be translated to pumpkin and winter squash. [ <i>Pumpkin</i> ]
Rape seed	0.2	Revoke	No longer a registered use.
Raspberry	0.1	Revoke	No longer a registered use.
Rye, grain	0.1 (N)	0.3	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on rye grain ranged from <0.15 to <0.30 ppm.
Rye, straw	0.2 (N)	0.3	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on rye straw ranged from <0.15 to <0.30 ppm..
Safflower, seed	0.2 (N)	Revoke	No longer a registered use.
Sheep, fat	0.2	13	
Sheep, meat byproduct	0.2	Sheep, mbyop = 1.0 Sheep, liver = 5.0	[ <i>Sheep, meat byproducts (except liver)</i> ] [ <i>Sheep, liver</i> ]
Sheep, meat	0.2	2.0	
Spinach	2.0	Revoke	Use being deleted as part of dietary risk mitigation.
Squash, summer	2.0	Reassign	Tolerance should be revoked with the concomitant establishment of a tolerance for Cucurbit Vegetables (Crop Group 9). Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on summer squash ranged from <0.15 to 0.23 ppm using the EC formulation, and from <0.15 to 0.25 ppm using the WP formulation.
Squash, winter	2.0	Reassign	Tolerance should be revoked with the concomitant establishment of a tolerance for Cucurbit Vegetables (Crop Group 9). The available data for cucumber, melon, and summer squash may be translated to pumpkin and winter squash.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Strawberry	2.0	2.0	Data reflecting the maximum registered use pattern are unavailable. Data reflecting applications of a representative EC formulation at 0.33-0.67x the maximum seasonal rate indicate that the combined residues of endosulfan in/on strawberries without caps were below 0.60 ppm. By extrapolation to the maximum use rate, the Science Chapter to the Endosulfan Reregistration Standard concluded that residues are not likely to exceed the established tolerance. [Strawberry]
Sugarcane	0.5	Revoke	No longer a registered use.
Sunflower, seed	2.0	Revoke	No longer a registered use.
Sweet potato	0.2	0.15	The available data indicate that endosulfan residues of concern were each <0.05 ppm (nondetectable) in/on sweet potatoes following treatments at the maximum registered use pattern. [Sweet potato]
Tomato	2.0	1.0	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on tomatoes ranged from <0.15 to 0.91 ppm using the EC formulation, and from <0.15 to 0.97 ppm using the WP formulation. [Tomato]
Turnip, greens	2.0	2.0	Data reflecting the maximum registered use pattern are unavailable. The data submitted for spinach, collards, kale, or mustard greens may be used to estimate residues in/on turnip greens. [Turnip, tops]
Walnut	0.2 (N)	0.2	The available data indicate that residues of endosulfan or endosulfan sulfate were nondetectable in/on walnuts harvested 36-39 days following the last of multiple applications of a representative WP and EC formulations at exaggerated (2.7-3.3x) seasonal rate; the limits of detection were not reported. [Walnut]
Watercress	2.0	Revoke	No longer a registered use.
Wheat, grain	0.1 (N)	0.30	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on wheat grain ranged from <0.15 to <0.30 ppm.
Wheat, straw	0.2 (N)	0.40	Following applications reflecting the maximum registered use pattern, the combined endosulfan residues in/on wheat straw ranged from <0.15 to <0.38 ppm.
<b>Tolerance To Be Proposed Under 40 CFR §180.182</b>			
Apple, pomace, wet	None	5.0	The recommended tolerance is based on a HAFT combined endosulfan residue of 0.77 ppm and a concentration factor of 6x.
Corn, sweet, forage	None	12	The submitted data for sweet corn forage and stover indicate that the combined residues of endosulfan ( $\alpha$ and $\beta$ isomers) and endosulfan sulfate were 4.2-12.0 ppm in/on sweet corn forage (n=6 samples) harvested 7 days and 0.76-13.92 ppm in/on sweet corn stover (n=6 samples) harvested 11-45 days following the last of two foliar applications, with a 6- to 7-day retreatment interval of a representative 3 lb/gal EC formulation at 1.0 lb ai/A/application (1x the proposed maximum single and seasonal application rates) using ground equipment.
Corn, sweet, stover	None	14	

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments [Correct Commodity Definition]
Cotton, gin byproducts	None	30	
Cucurbit Vegetables (Crop Group 9)	None	1.0	Adequate data are available for representative commodities.
Pineapple, process residue	None	18	The recommended tolerance is based on a HAFT combined endosulfan residue of 0.44 ppm and a concentration factor of 41x.
Turnip, root	None	0.2	The recommended tolerance is based on translation of data from carrot and potato.
Vegetables Cucurbit, Group	None	1.0	Adequate data are available for representative commodities.
<b><i>Tolerance Listed Under 40 CFR §180.182 (a) (2)</i></b>			
Dried tea	24 (reflecting < 0.1 ppm residues in beverage tea)	24 (reflecting < 0.1 ppm residues in beverage tea)	This tolerance has been moved from 40 CFR §185.2600.

### **Codex Harmonization**

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of endosulfan in/on various plant and animal commodities. The Codex MRLs are expressed in terms of the sum of  $\alpha$ - and  $\beta$ -endosulfan and endosulfan sulfate (fat soluble). When the U.S. tolerance expression is revised to specify the  $\alpha$  and  $\beta$  isomers of the parent, Codex MRLs and U.S. tolerances will be harmonized. A numerical comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 19.

Table 19 indicates that U.S. tolerances and the Codex MRLs for endosulfan are compatible for carrot, cottonseed, fruits, meat, pome fruits (apples), potato, spinach, and sweet potato. For the remainder of commodities listed in Table 19, the U.S. tolerances and the Codex MRLs are incompatible because of differences in registrations or good agricultural practices.

**Table 19. Codex MRLs and Applicable U.S. Tolerances for Endosulfan**

Codex			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL (mg/kg)	Step		
Alfalfa forage (green)	1	5/8	Revoke	No longer a registered use.
Broccoli	0.5	5	3.0	
Cabbages, Head	1	5	4.0	
Cabbages, Savoy	2	5	4.0	
Carrot	0.2	CXL	0.20	Compatibility exists.
Cauliflower	0.5	5	2.0	
Celery	2	5/8	8.0	

Codex			Reassessed U.S. Tolerance ( ppm)	Comments
Commodity, As Defined	MRL (mg/kg)	Step		
Chard	2	5	--	No U.S. registrations.
Cherries	1	5/8	2.0	
Chicory leaves	1	5	--	No U.S. registrations.
Clover	1	5/8	--	No U.S. registrations.
Common bean (pods and/or immature seeds)	0.5	5	2.0	
Cotton seed	1	CXL	1.0	Compatibility exists.
Cotton seed oil, crude	0.5	CXL	–	
Endive	1	5	--	No U.S. registrations.
Fruits	2	CXL	2.0 each for apricots, grapes, nectarines, peaches, pears, plums, prunes, and strawberries	Compatibility exists for some fruit crops.
Garden peas (young pods)	0.5	5/8	--	No U.S. registrations.
Kale	1	5/8	2.0	
Lettuce, Head	1	5/8	11.0	
Lettuce, Leaf	1	5/8	6.0	
Meat	0.2 (carcass fat)	CXL	0.20	Compatibility exists.
Milks	0.02 <sup>1</sup>	CXL	0.50	
Onion, Bulb	0.2	CXL	–	No U.S. registrations.
Plums (including Prunes)	1	5/8	2.0	
Pome fruits	1	5/8	1.0	Compatibility exists.
Potato	0.2	CXL	0.20	Compatibility exists.
Rice	0.1	CXL	–	No U.S. registrations.
Spinach	2	5/8	2.0	Compatibility exists.
Sugar beet	0.1	5/8	Revoke	No longer a registered use.
Sugar beet leaves or tops	1	5/8	--	
Sweet potato	0.2	CXL	0.15	Compatibility exists.
Tea, Green, Black	30	CXL	24 (reflecting <0.10 ppm residues in beverage tea)	
Trefoil	1	5/8	--	No U.S. registrations.

<sup>1</sup> The residue is fat-soluble and MRLs for milk and milk products are derived as explained in the introductions to Volume XIII of Codex Alimentarius.

## 2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other

ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, endosulfan may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

### **3. Labels**

The following risk mitigation measures are necessary to mitigate the risks identified in the endosulfan risk assessment as a result of dietary exposure from food, to workers who handle endosulfan and workers re-entering fields treated with endosulfan, and for ecological risks to non-target organisms. A number of label amendments, in addition to the existing label requirements, are necessary in order to reflect this mitigation

#### **a. Agricultural Use Exposure Reduction Measures**

For agricultural use, the following measures are required, in addition to the existing labeling requirements to address dietary (food), drinking water, occupational handler and ecological risks of concern. See Table 20 for additional information by crop.

##### Dietary (food)

- Delete use on succulent beans, succulent peas, spinach, and grapes.

##### Dietary (drinking water) and Ecological

- Delete use on pecans
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 2.5 lbs./ai/A for pome fruit, stone fruit and citrus.
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A for melons, cucurbits, lettuce, tomatoes, sweet potatoes, cotton (ground), broccoli, cauliflower, cabbage, kohlrabi, brussels sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, eggplant, potatoes, carrots, dry beans, dry peas, and tobacco.
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A for sweet corn, cotton (aerial) and blueberries.



- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1 lb./ai/A for celery.
- Require 100 ft. spray buffer for ground applications between a treated area and water bodies.
- Require 30 ft. maintained vegetative buffer strip between a treated area and water bodies.
- Require all products to be Restricted Use
- Restrict use on cotton to AZ, CA, NM, OK and TX only.
- Restrict use on tobacco to IN, KY, OH, PA, TN and WV only.

### Occupational

- Require all wettable powers to be packaged in water soluble bags.
- Cancel use of wettable powders on tomatoes, sweet corn, sweet potatoes, cotton, small grains, alfalfa (seed), carrots, dry beans, dry peas, pineapples, and tobacco.
- Cancel aerial application using the wettable powder formulation on pome fruits, stone fruits, citrus, blueberries, strawberries, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), filberts, walnuts, almonds, and macadamia nuts.
- Require closed mixing/loading systems for aerial application using the EC formulation on pome fruits, stone fruits, citrus, sweet corn, sweet potatoes, cotton, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), blueberries, small grains, alfalfa (seed), filberts, walnuts, almonds and macadamia nuts.
- Require closed cabs for airblast applications on pome fruits, stone fruits, citrus, filberts, walnuts, almonds and macadamia nuts.
- Prohibit use of high pressure handwands with rates greater than 0.005 lbs/ai/gal.
- Increase REI to 48 hours for all crops except as noted in the following bullets.`
- Increase REI for WP products to 3 days for melons and cucurbits.
- Increase REI for WP products to 4 days for lettuce, celery, pome fruit, stone fruit, citrus, collard greens, kale, mustard greens, radish, turnip, rutabaga, ornamental trees and shrubs.
- Increase REI for WP products to 5 days for collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed) and rutabaga (seed).
- Increase REI for WP products to 9 days for blueberries, broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts.
- Increase REI for WP products to 12 days for broccoli (seed), cauliflower (seed), kohlrabi (seed), and cabbage (seed).
- Increase REI for EC products to 3 days for sweet potatoes
- Increase REI for EC products to 4 days for broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts.
- Increase REI for EC products to 6 days for blueberries.
- Increase REI for EC products to 7 days for broccoli (seed), kohlrabi (seed), and cabbage (seed).
- Increase REI for EC products to 17 days for sweet corn.

## Occupational and Ecological

- Reduce maximum application rate to 2.5 lbs./ai/A for pome fruit, stone fruit, citrus, ornamental trees and shrubs.
- Reduce maximum application rate to 1.5 lbs/a/A for blueberries and cotton (ground).
- Reduce maximum application rate to 1.0 lb/ai/A for broccoli (not for seed), kohlrabi (not for seed), cabbage (not for seed), cauliflower (not for seed) and strawberries.
- Reduce maximum application rate to 0.75 lbs/ai/A for cotton (aerial) and kale.
- Reduce maximum application rate to 0.005 lbs./ai/gal for all tree bark treatments.

### **D. Regulatory Rationale**

The following is a summary of the rationale and mitigation measures for managing risks associated with the current use of endosulfan. Specific label language is set forth in the summary table in Section V.

#### **1. Human Health Risk Mitigation**

##### **a. Dietary (food)**

The following discussion addresses risk mitigation measures pertaining to dietary exposure to residues of endosulfan in food.

##### ***Acute (Food)***

Acute dietary risk from food exceeded the Agency's level of concern for the most highly exposed population subgroup, children 1-6 years old. The risk assessment yielded a percent acute PAD value of 150% for children 1-6 years old. To mitigate the acute dietary risk (food), the registrants have agreed to delete the following uses: succulent beans, succulent peas, spinach and grapes. Based on this mitigation, the acute risk from food exposure falls below the Agency's level of concern with the % aPAD occupied for children 1-6 years old being 80%. Therefore, removal of these uses will fully address acute dietary risk from food.

##### ***Chronic (Food)***

The chronic dietary risk for endosulfan does not exceed the Agency's level of concern (i.e., is less than 100% of the cPAD) for all sub-populations, including the most highly exposed subgroup, children (1-6 years), whose dietary exposure occupies 17% of the cPAD. No mitigation measures are necessary at this time to address chronic dietary risk from food.

##### **b. Drinking Water**

Surface water drinking water estimated concentrations were derived from the PRZM-EXAMS model with the Standard Index Reservoir and percent crop area (PCA). Ground water

estimated concentrations were derived from the SCI-GROW Model. These are screening level models designed to provide high-end estimates of potential pesticide exposure. Such predictions provide a screen to eliminate those chemicals that are not likely to cause concerns in drinking water. Estimated concentrations exceeding the drinking water level of concern (DWLOC) in drinking water risk assessments using the screening model estimates do not necessarily mean a risk of concern actually exists, but may indicate the need for better data (e.g., monitoring studies specific to use patterns and drinking water sources) on which to confirm decisions.

Based on model predictions using currently registered uses, the drinking water EECs for endosulfan and its degradate, endosulfan sulfate, in surface water range from 4.49 ppb (cotton scenario) to 23.86 ppb (apple scenario) for acute exposure, and from 0.53 ppb (cotton scenario) to 1.5 ppb (apple scenario) for chronic exposure. The acute and chronic EEC for endosulfan in groundwater is 0.012 ppb.

The chronic dietary risks from drinking water exposure from ground water and surface water sources do not exceed the Agency's level of concern. The acute dietary risks from drinking water exposure from surface water and ground water sources are above the Agency's level of concern for most subpopulations. The mitigation measures taken to address food risks result in higher DWLOCs and, therefore, more room in the risk cup for water exposures. For the most highly exposed subpopulations the acute DWLOCs following mitigation are 3 ppb for children 1-6 and 2.3 ppb for all infants. When these mitigation measures to reduce the dietary risks from food are considered, the acute dietary risks from drinking water exposure from ground water sources do not exceed the Agency's level of concern. This leaves only acute risks from surface water sources remaining above the Agency's level of concern. The Agency expects that actual exposure from drinking water is unlikely to be as high as the levels used in the development of the surface water estimates based on the rationale discussed below. Therefore, given the anticipated impacts on water resources from implementing the risk reduction measures contained in this document and the characterization of the Agency's water modeling presented below, the Agency believes that the risks from drinking water are not of concern.

The drinking water risk assessments are based on screening level models that are conservative in their estimates of drinking water exposure. Actual exposure is expected to be lower than the EEC's reported in the RED. One reason for this is that the percent cropped area (PCA) assumption for apples used in the model is 0.87, the default assumption. This means the model assumes that 87% of a watershed is planted with apples and that 100% of this crop is treated with endosulfan, which may be unlikely to occur especially considering that the PCA calculated for major crops like corn and cotton using data submitted to the Agency are 0.46 and 0.20 respectively. To add further perspective, the EEC derived from this screening-level model for cotton where a crop-specific PCA has been developed is 4.49 ppb. This is significantly lower than the apple scenario where the default PCA was used and results in risk estimates being below the Agency's level of concern for most subpopulations and nearly so for the most highly exposed subpopulations once food mitigation is considered. Cotton is also the crop where the most endosulfan is used.

The risk reduction measures contained in this RED, including the deletion of the succulent bean, succulent pea, grape, pecan and spinach uses, reductions in maximum application rates, reductions in maximum seasonal application rates, reductions in the maximum number of applications allowed per season, implementation of the 100 ft. setback for ground applications and the implementation of a 30 foot vegetative buffer strip are expected to reduce the amount of endosulfan available to reach surface waters. Buffer strips are expected to be more effective in mitigating acute risk scenarios in the case of endosulfan. This supports the Agency's belief that drinking water risks will be reduced to a level at which the risk cup is not exceeded.

For endosulfan, the Agency is also requiring confirmatory surface water monitoring data to evaluate actual acute concentrations of endosulfan in surface water sources of drinking water. This monitoring data is to be generated from a multi-year sampling program involving community water systems from surface water sources in multiple locations in different regions of the country to represent different use sites, crops, soil types, and rainfall regimes. Water samples are to be analyzed to determine the concentrations of parent endosulfan and each of the environmental degradates of toxicological concern. Also, prior to initiating this sampling program, the registrant is required to submit a study protocol to the Agency to ensure that the sampling locations and procedures are adequate to confirm the drinking water risk management conclusions.

### **c. Aggregate Risk Mitigation**

The Agency's aggregate risk assessment for endosulfan is based on exposure estimates for food and uses a screening-level assessment of modeled estimates for drinking water exposure. Dietary (food) risk estimates are based on a refined assessment that incorporates percent crop treated data, monitoring data, and processing data.

#### ***Acute Exposure***

The acute aggregate risk assessment for endosulfan combines exposure from food and drinking water sources only. Acute dietary (food) risk estimates are below 100% of the aPAD for the US population and all population subgroups when the use deletions mentioned earlier that are needed to mitigate dietary risks are considered. When this mitigation is considered, all infants are the most highly exposed population subgroup and have an acute drinking water level of comparison (DWLOC) of 2.3 ppb. Based on screening-level model predictions of the remaining supported uses, the acute (peak) drinking water estimated concentration in surface water is 23.9 ppb which is of risk concern to the Agency. The screening-level model predictions of acute concentrations in ground water is 0.0012 ppb, which is less than the DWLOC and not of risk concern to the Agency.

However, given the anticipated impacts on water resources from implementing the risk reduction measures contained in this document and the characterization of the Agency's water modeling presented above, the Agency believes that actual acute concentrations of endosulfan in

surface water are less than the DWLOC and are not of concern. To confirm this, surface water monitoring data is required.

### ***Chronic Exposure***

The chronic aggregate risk assessment for endosulfan combines exposure from food and drinking water sources only. Chronic dietary (food) risk estimates are well below 100% of the cPAD for the US population and all population subgroups. Children 1-6 years old are the most highly exposed population subgroup and have in a chronic DWLOC of 5 ppb. Based on screening-level model predictions of the current uses of endosulfan the average (chronic) estimated concentration in surface water is 1.5 ppb, which is not of risk concern to the Agency.

## **d. Occupational Risk Mitigation**

### **(1) Agricultural Handler Risk Mitigation**

It is the Agency's policy to mitigate occupational risks to the greatest extent necessary and feasible with personal protective equipment and engineering controls. In managing these risks, EPA must take into account the economic, social, and environmental costs and benefits of the pesticide's use. A wide range of factors are considered in making risk management decisions for worker risks. These factors include, in addition to the calculated MOEs, incident data, the nature and severity of adverse effects, uncertainties in the risk assessment, the cost, availability and relative risk of alternatives, importance of the chemical in integrated pest management (IPM) programs, and other similar factors.

### **Handlers**

As summarized in Table 8, occupational risks are of concern (i.e., MOEs < 100) for many scenarios, even when maximum PPE (i.e., double layer clothing, gloves, and a respirator) are utilized. Handler risks are also of concern for some scenarios with engineering controls (closed mixing/loading, enclosed cabs). Engineering controls are considered to be the maximum feasible mitigation.

EPA has determined that handler risks from exposure to endosulfan in the scenarios listed below would be adequately mitigated, when other mitigation such as rate reductions are considered, through use of the following PPE: long-sleeved shirt and long pants, shoes, socks, chemical-resistant gloves and an organic vapor respirator.

- Mixing/loading liquids for chemigation.
- Mixing/loading liquids for groundboom application.
- Mixing/loading liquids for airblast applications.
- Mixing/loading liquids for rights-of-way sprayers.
- Mixing/loading liquids for plant and root dips.
- Applying sprays with groundboom equipment.

- Mixing/loading/applying with a low pressure handwand.
- Mixing/loading/applying with a backpack sprayer.

EPA has determined that worker risks from exposure to endosulfan in the scenarios listed below would be adequately mitigated. when other mitigation such as rate reductions are considered, through use of the following PPE: coveralls worn over long-sleeved shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, chemical-resistant apron (for mixing and loading) and a organic vapor respirator.

- Mixing/loading/applying with a high pressure handwand.
- Flagging aerial spray applications.
- Mixing/loading liquid for aerial application for crops with maximum application rates of less than 1.5 lbs/ai/A except for cotton, alfalfa (seed) and small grains.

The mitigation measures needed to address handler risks which are of concern at or above the maximum PPE scenario are outlined, by crop, in Table 20 below. These steps include placing all wettable powder products in water soluble bags, the deletion of some uses from WP products, deletion of aerial application of WP products for crops with maximum application rates greater than or equal to 1.5 lbs/ai/A and for cotton, alfalfa (seed) and small grains, requiring closed mixing/loading systems for aerial applications of the EC formulation for some uses, requiring closed cabs for all airblast applications except for ornamental trees/shrubs, requiring enclosed cockpits for all aerial applications and rate reductions. Scenarios w/ engineering controls for mixing/loading liquids and applying with airblast equipment include the need for baseline clothing plus chemical resistant gloves and a chemical-resistant apron (when mixing and loading). Since all wettable powder products will be packaged in water soluble bags, mixing/loading scenarios for this formulation will also include baseline clothing, chemical resistant gloves and a chemical-resistant apron.

As mentioned earlier there were three scenarios that were not evaluated due to a lack of data available to conduct an assessment. For the mixing/loading/applying wettable powders with backpack sprayer and mixing/loading/applying wettable powders with a high pressure hand wand scenarios, the mitigation to place all wettable powders in water soluble bags will effectively preclude the use of WPs for these equipment types. Therefore, no additional information is required for these scenarios.

### **Post-Application**

EPA completes exposure assessments on postapplication workers for various crops and activities at intervals following the application until risk falls below a target level. For endosulfan, the target level for risk concerns is an MOE of 100.

In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target MOE (100 for endosulfan). Occupational risks are regulated under the FIFRA section

3(c)(5) standard of no unreasonable adverse effects which means that both risks and benefits must be considered in making a risk management decision. This standard may be met at a level below the target MOE when there are benefits associated with a specific activity. As the worker exposure database has improved, risk assessments are now conducted for a variety of post application activities based on the level of exposure for each worker activity. For a specific crop/pesticide combination, the duration required to achieve the target MOE can vary depending on the activity assessed.

In general, EPA prefers to set a single REI for all activities related to a crop or crop group without additional activity-based labeling. This approach is favored because handlers and workers are more likely to understand and comply with simpler labels. Also, permitting entry for some activities during the REI could cause confusion and compromise the effectiveness of the Worker Protection Standard (WPS). However, when the consideration of risks and benefits indicate that a single REI is unworkable, EPA may consider either setting an REI with early entry exceptions for one or more critical tasks or establishing an entry prohibition for a specific task after the REI has expired. For endosulfan, no critical activities have been identified to warrant the use of an activity-based exception or prohibition. However, during the 60-day comment period for this RED, EPA will accept further comments from growers regarding needs for additional REI exceptions for specific activities, and will consider such exceptions where needed if there are adequate MOEs and/or benefits associated with such activities.

In weighing worker risks and benefits, the Agency considered the timing of field activities that are critical to crop production. For many of the endosulfan uses discussed below, scouting and irrigation are critical activities in crop production, and these activities routinely need to be performed soon after application. In evaluating the restricted entry intervals, the Agency considered the exceptions to the WPS that could inform the decision. EPA's proposed REIs take into account the flexibility already provided by these exceptions. Scouting is a handler activity under the WPS, so anyone performing this activity may legally enter the treated field during the REI provided they use the personal protective equipment (PPE) specified on the label. In addition, if the scout is a certified crop advisor as defined in the WPS (40 CFR 170.204(b)), the individual can determine the appropriate PPE to be used. For many of these crops, irrigation equipment is not routinely moved by hand, instead, the primary activity involves entering the field to turn the watering equipment on and off. This activity is allowed during the REI if it meets the requirements of the no contact exception to WPS (40 CFR 170.112(b)). Should irrigation equipment need unexpected repairs during the REI, WPS allows workers to enter a treated field for up to one hour provided early entry PPE is used (40 CFR 170.112(c)).

Based on the Worker Protection Standard, CFR 156.208 (c) 2, if a pesticide triggers a Toxicity Category I determination for Primary Eye Irritation, an REI of 48 hours is required for all products. Since endosulfan meets this criteria, a minimum REI of 48 hours is needed for all endosulfan uses.

**Table 20. Summary of Mitigation Measures for Occupational and Ecological Risk**

Crop*	Risks of Concern	Mitigation
<p>Melons (1 lb/ai/A)</p> <p>Cucumber (1 lb/ai/A)</p> <p>Squash (1 lb/ai/A)</p>	<p>Mixing/Loading WP for aerial application Mixing/Loading WP for ground application</p> <p>High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 64 at current REI of 24 hours MOE = 100 at 4 days MOE = 86 at 3 days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Require all wettable powers to be packaged in water soluble bags.</p> <p>3-day REI for WP (high exposure hand harvesting, pruning, thinning etc.: MOE = 86)</p> <p>Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A</p> <p>Reduce maximum number of applications from 6 per season to 4 per season (except CA where will remain at 3 per season)</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
<p><b>Rationale for Worker Risk Mitigation:</b> For melons, handler risks are not of concern at the 1 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.</p> <p>Due to the need to re-enter fields often due to frequent harvesting an REI of greater than 3 days is not considered to be feasible. Endosulfan is an important resistance management tool and is an important element of integrated pest management programs in some areas especially considering its relatively low impacts on bees. Therefore, the REI is considered acceptable.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and reducing the maximum number of applications per season to four (3 in CA). The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
<p>Lettuce (1 lb./ai/A)</p>	<p>Mixing/Loading WP for aerial application Mixing/Loading WP for ground application</p> <p>High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 64 at current REI of 24 hours MOE = 100 at 4 days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Require all wettable powders to be packaged in water soluble bags</p> <p>4-day REI for WP (high exposure hand harvesting, pruning, thinning etc.: MOE &gt; 100)</p> <p>Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A</p> <p>Reduce maximum number of applications from 3 per season to 2 per season (except CA where will remain at 2 per season)</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>



Crop*	Risks of Concern	Mitigation
<b>Rationale for Worker Risk Mitigation:</b> For lettuce, handler risks are not of concern at the 1 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.  For lettuce, post-application risks are not of concern at the 1 lb. rate provided that the REI for the WP formulation is 4 days.  <b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and reducing the maximum number of applications per season to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.		
Celery (1 lb./ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 64 at current REI of 24 hours MOE = 100 at 4 days  Risks to non-target aquatic organisms for WP and EC	Require all wettable powders to be packaged in water soluble bags  4-day REI for WP (high exposure hand harvesting, pruning, thinning etc.: MOE > 100)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 1 lbs./ai/A  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<b>Rationale for Worker Risk Mitigation:</b> For celery, handler risks are not of concern at the 1 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.  For celery, post-application risks are not of concern at the 1 lb. rate provided that the REI for the WP formulation is 4 days.  <b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 66%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.		
Apples (3.0 lbs/ai/A)  Pears (3.0 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for airblast application Application w/ airblast application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 68 at current REI of 24 hours MOE = 100 at 5 days  Risks to non-target aquatic organisms for WP and EC	Reduce maximum application rate to 2.5 lbs./ai/A  Require all wettable powders to be packaged in water soluble bags  Cancel aerial application using the WP formulation  Require closed mixing/loading systems for aerial application using the EC formulation  Require closed cabs for airblast applications  4-day REI for WP (high exposure hand harvesting, pruning, thinning etc.: MOE > 100 at 2.5 rate)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2.5 lbs./ai/A  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b> For apples and pears, handler risks are not of concern at the 2.5 lb. rate provided that aerial application using WP products is canceled and engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products and closed cabs are used for airblast applications (designed to provide dermal protection).</p> <p>For apples and pears, post-application risks are not of concern at the 2.5 lb. rate provided that the REI for the WP formulation is 4 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate and the maximum single application rate by 17%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
<p>Apricots (3.0 lbs./ai/A)</p> <p>Peaches (3.0 lbs./ai/A)</p> <p>Nectarines (3.0 lbs./ai/A)</p> <p>Plums/Prunes (3.0 lbs./ai/A)</p> <p>Cherries (3.0 lbs./ai/A)</p> <p>Non-Bearing Citrus (3.0 lbs./ai/A)</p>	<p>Mixing/Loading Liquid for aerial application</p> <p>Mixing/Loading WP for aerial application</p> <p>Mixing/Loading WP for airblast application</p> <p>Application w/ airblast application</p> <p>High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 68 at current REI of 24 hours MOE = 100 at 5 days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Reduce maximum application rate to 2.5 lbs./ai/A</p> <p>Require all wettable powders to be packaged in water soluble bags</p> <p>Cancel aerial application using the WP formulation</p> <p>Require closed mixing/loading systems for aerial application using the EC formulation</p> <p>Require closed cabs for airblast applications</p> <p>4-day REI for WP (high exposure hand harvesting, pruning, thinning etc.: MOE &gt; 100 at 2.5 rate)</p> <p>Reduce maximum seasonal application rate from 3 lbs./ai/A to 2.5 lbs./ai/A</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
<p><b>Rationale for Worker Risk Mitigation:</b> For peaches, apricots, nectarines, plums, prunes, cherries and non-bearing citrus, handler risks are not of concern at the 2.5 lb. rate provided that aerial application using WP products is canceled and engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products and closed cabs are used for airblast applications (designed to provide dermal protection).</p> <p>For peaches, apricots, nectarines, plums, prunes, cherries and non-bearing citrus, post-application risks are not of concern at the 2.5 lb. rate provided that the REI for the WP formulation is 4 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate and the maximum single application rate by 17%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Bark Treatments (0.4 lbs/ai/gal)  Greenhouse Uses (0.1 lbs/ai/gal)	Application with Rights-of-Way sprayer Mixing/Loading/Applying with a high pressure handwand	Reduce maximum application rate to 0.005 lbs./ai/gal for high pressure handwand and Rights-of-Way sprayers.
<b>Rationale for Worker Risk Mitigation:</b> For bark treatment and greenhouse uses, handler risks are not of concern at the 0.005 lb/ai/gal. rate.		
Tomatoes (1 lb./ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 6 per season to 4 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<b>Rationale for Worker Risk Mitigation:</b> For tomatoes, handler risks are not of concern at the 1 lb. rate provided that the wettable powder formulation is canceled.		
<b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and reducing the maximum number of applications per season to four. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.		
Sweet Corn (1.5 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting ): MOE = 10 at current REI of 24 hours MOE = 100 at 21days  High exposure activities for EC (hand harvesting ): MOE = 22 at current REI of 24 hours MOE = 100 at 17days  Risks to non-target aquatic organisms for WP and EC	Cancel WP Use  Require closed mixing/loading systems for aerial application using the EC formulation  17 day REI for EC (hand harvesting: MOE > 100)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A  Reduce maximum number of applications from 3 per season to 1 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b> For sweet corn, handler risks are not of concern at the 1.5 lb. rate provided that the wettable powder formulation is canceled and provided engineering controls are employed; that is closed mixing/loading systems are used for aerial applications of EC products.</p> <p>For sweet corn, post-application risks are not of concern at the 1.5 lb. rate provided the WP formulations are canceled and that the REI for the EC formulation is 17 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 50% and reducing the maximum number of applications per season to one. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Sweet Potatoes (2.0 lbs/ai/A)	<p>Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for ground application</p> <p>High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 32 at current REI of 24 hours MOE = 100 at 9 days</p> <p>Medium exposure activities for WP (scouting and irrigating): MOE = 54 at current REI of 24 hours MOE = 100 at 5 days</p> <p>High exposure activities for EC (hand harvesting, pruning, thinning etc.): MOE = 75 at current REI of 24 hours MOE = 100 at 3days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Cancel WP Use</p> <p>Require closed mixing/loading systems for aerial application using the EC formulation</p> <p>3 day REI for EC (high exposure activities: MOE &gt; 100)</p> <p>Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A</p> <p>Reduce maximum number of applications from 3 per season to 2 per season</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
<p><b>Rationale for Worker Risk Mitigation:</b> For sweet potatoes, handler risks are not of concern at the 2.0 lb. rate provided that the wettable powder formulation is canceled and provided engineering controls are employed; that is closed mixing/loading systems are used for aerial applications of EC products.</p> <p>For sweet potatoes, post-application risks are not of concern at the 2.0 lb. rate provided the WP formulations are canceled and that the REI for the EC formulation is 3 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and reducing the maximum number of applications per season to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Collard Greens (for seed) (2.0 lbs/ai/A)	Mixing/Loading Liquid for aerial application	<p>Require all wettable powders to be packaged in water soluble bags</p> <p>Require closed mixing/loading systems for aerial application using the EC formulation</p> <p>Cancel aerial application using the WP formulation</p> <p>5-day REI for WP (scouting and irrigating: MOE &gt; 100)</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
Kale (for seed) (2.0 lbs/ai/A)	Mixing/Loading WP for aerial application	
Mustard Greens (for seed) (2.0 lbs/ai/A)	Mixing/Loading WP for ground application	
	High exposure activities for WP (hand harvesting, pruning, thinning etc.):	
	MOE = 32 at current REI of 24 hours	
	MOE = 100 at 9 days	
	Medium exposure activities for WP (scouting and irrigating):	
Radish (for seed) (2.0 lbs/ai/A)	MOE = 54 at current REI of 24 hours	
	MOE = 100 at 5 days	
Turnip (for seed) (2.0 lbs/ai/A)	High exposure activities for EC (hand harvesting, pruning, thinning etc.):	
	MOE = 75 at current REI of 24 hours	
	MOE = 100 at 3days	
Rutabaga (for seed) (2.0 lbs/ai/A)	Risks to non-target aquatic organisms for WP and EC	
<p><b>Rationale for Worker Risk Mitigation:</b></p> <p>For collard greens, kale, mustard greens, radish, rutabaga and turnip (all for seed) handler risks are not of concern at the 2.0 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products, and aerial application using WP products are canceled.</p> <p>For collard greens, kale, mustard greens, radish, rutabaga and turnip (all for seed), post-application risks are not of concern at the 2.0 lb. rate provided that the REI for the WP formulation is 5 days. Endosulfan is generally applied to these seed crops at bloom/post bloom. Intensive hand activities such as thinning are expected to have occurred prior to the time of application and, therefore, high exposure activities are not expected to be relevant for these crops.</p> <p><b>Rationale for Ecological Risk Mitigation:</b></p> <p>The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Collard Greens (1.0 lbs/ai/A)	Mixing/Loading WP for aerial application	Reduce maximum application rate for kale to 0.75 lbs/ai/A
Kale (1.0 lbs/ai/A)	Mixing/Loading WP for ground application	Require all wettable powders to be packaged in water soluble bags
Mustard Greens (1.0 lbs/ai/A)	High exposure activities for WP (hand harvesting, pruning, thinning etc.):	4-day REI for WP (hand harvesting, pruning, thinning: MOE > 100)
Radish (1.0 lbs/ai/A)	MOE = 64 at current REI of 24 hours	100 ft. spray buffer for ground applications between a treated area and water bodies
	MOE = 100 at 4 days	
Turnip (1.0 lbs/ai/A)	Risks to non-target aquatic organisms for WP and EC	30 ft. maintained vegetative buffer strip between a treated area and water bodies
Rutabaga (1.0 lbs/ai/A)		

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b>  For collard greens, mustard greens, radish, rutabaga and turnip, handler risks are not of concern at the 1.0 lb. rate and kale at the 0.75 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.</p> <p>For collard greens, kale, mustard greens, radish, rutabaga and turnip, post-application risks are not of concern at the 1.0 lb. rate provided that the REI for the WP formulation is 4 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>  The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
<p>Broccoli (for seed) (2.0 lbs/ai/A)</p> <p>Cabbage (for seed) (2.0 lbs/ai/A)</p> <p>Kohlrabi (for seed) (2.0 lbs/ai/A)</p>	<p>Mixing/Loading Liquid for aerial application  Mixing/Loading WP for aerial application  Mixing/Loading WP for ground application</p> <p>High exposure activities for WP (hand harvesting, pruning, thinning etc.):  MOE = 16 at current REI of 24 hours  MOE = 100 at 14 days</p> <p>Medium exposure activities for WP (scouting and irrigating):  MOE = 20 at current REI of 24 hours  MOE = 100 at 12 days</p> <p>High exposure activities for EC (hand harvesting, pruning, thinning etc.):  MOE = 38 at current REI of 24 hours  MOE = 100 at 9 days</p> <p>Medium exposure activities for EC (scouting and irrigating):  MOE = 47 at current REI of 24 hours  MOE = 100 at 7 days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Require all wettable powders to be packaged in water soluble bags</p> <p>Require closed mixing/loading systems for aerial application using the EC formulation</p> <p>Cancel aerial application using the WP formulation</p> <p>12-day REI for WP (scouting and irrigating: MOE &gt; 100)</p> <p>7-day REI for EC (scouting and irrigating: MOE &gt; 100)</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
<p><b>Rationale for Worker Risk Mitigation:</b>  For broccoli, cabbage and kohlrabi (all for seed) handler risks are not of concern at the 2.0 lb. rate provided that aerial application using WP products are canceled and engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products, and aerial application using WP products are canceled.</p> <p>For broccoli, cabbage and kohlrabi (all for seed), post-application risks are not of concern at the 2.0 lb. rate provided that the REI for the WP formulation is 12 days and for the EC formulations is 7 days. Endosulfan is generally applied to these seed crops at bloom/post bloom. Intensive hand activities such as thinning are expected to have occurred prior to the time of application and, therefore, high exposure activities are not expected to be relevant for these crops.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>  The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Broccoli (2 lbs/ai/A)  Brussels Sprouts (1 lbs/ai/A)  Cauliflower (1 lbs/ai/A)  Cabbage (2 lbs/ai/A)  Kohlrabi (2 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for ground application	Reduce maximum application rate for broccoli, cabbage and kohlrabi to 1 lbs/ai/A
	High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 32 at current REI of 24 hours MOE = 100 at 9 days (1 lb. rate)	Require all wettable powders to be packaged in water soluble bags  9-day REI for WP (hand harvesting, pruning, thinning etc: MOE > 100)
	Medium exposure activities for WP (scouting and irrigating): MOE = 40 at current REI of 24 hours MOE = 100 at 7 days (1 lb. rate)	4-day REI for EC (hand harvesting, pruning, thinning etc: MOE > 100)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A
	High exposure activities for EC (hand harvesting, pruning, thinning etc.): MOE = 76 at current REI of 24 hours MOE = 100 at 4 days (1 lb. rate)	Reduce maximum number of applications from 4 per season to 2 per season (CA remains at 2)  100 ft. spray buffer for ground applications between a treated area and water bodies
	Medium exposure activities for EC (scouting and irrigating): MOE = 94 at current REI of 24 hours MOE = 100 at 2 days (1 lb. rate)	30 ft. maintained vegetative buffer strip between a treated area and water bodies
	Risks to non-target aquatic organisms for WP and EC	
<p><b>Rationale for Worker Risk Mitigation:</b>            For broccoli, brussels sprout, cauliflower, cabbage and kohlrabi, handler risks are not of concern at the 1.0 lb. rate provided engineering controls are employed; that is water soluble bags for wettable powder formulations.</p> <p>For broccoli, brussels sprout, cauliflower, cabbage and kohlrabi, post-application risks are not of concern at the 1.0 lb. rate provided that the REI for the WP formulation is 9 days and for the EC formulation is 4 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum application rate by 50% for broccoli, cabbage and kohlrabi, the maximum seasonal rate by 33% for each commodity and reducing the maximum number of applications per season to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Cotton (2 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Application with aerial equipment  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 16 at current REI of 24 hours MOE = 100 at 14 days  Medium exposure activities for WP (scouting and irrigating): MOE = 20 at current REI of 24 hours MOE = 100 at 12 days  High exposure activities for EC (hand harvesting, pruning, thinning etc.): MOE = 38 at current REI of 24 hours MOE = 100 at 9 days  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  Reduce rate for ground application to 1.5 lbs/a/A  Reduce rate for aerial application to 0.75 lbs/ai/A  Require closed mixing/loading systems for aerial application using the EC formulation  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A (ground)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A (aerial)  Reduce maximum number of applications from 6 per season to 2 per season  Restrict use on cotton to the following states: AZ, CA, NM, OK, and TX.  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>            For cotton, handler risks are not of concern at the 1.5 lb. rate (ground) and the 0.75 lb. rate (aerial) provided engineering controls are employed; that is closed mixing/loading systems are used for aerial applications of EC products.</p> <p>Post harvest risks are not of concern provided that labels state that only mechanical harvesting is allowed and hand thinning/pruning is prohibited.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum application rate by 25% for ground applications and 63% for aerial applications, the maximum seasonal rate by 33% (ground) and 50% (aerial), and reducing the maximum number of applications per season to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p> <p>By restricting the use on cotton to AZ, CA, NM, OK and TX exposures to aquatic organisms are expected to be reduced. These restrictions remove use in areas of the country where water resources are more abundant and potentially vulnerable.</p>		



Crop*	Risks of Concern	Mitigation
Blueberries (2 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 16 at current REI of 24 hours MOE = 100 at 14 days  Medium exposure activities for WP (scouting and irrigating): MOE = 81 at current REI of 24 hours MOE = 100 at 3 days  High exposure activities for EC (hand harvesting, pruning, thinning etc.): MOE = 38 at current REI of 24 hours MOE = 100 at 9 days  Risks to non-target aquatic organisms for WP and EC	Reduce the maximum application rate to 1.5 lbs/ai/A  Require all wettable powders to be packaged in water soluble bags  Require closed mixing/loading systems for aerial application using the EC formulation  Cancel aerial application using the WP formulation  9 day REI for WP (high exposure activities, hand harvesting , pruning, thinning etc.: MOE > 100)  6 day REI for EC (high exposure activities, hand harvesting , pruning, thinning etc.: MOE > 100)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>            For blueberry, handler risks are not of concern at the 1.5 lb. rate provided that aerial application using WP products is canceled and engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products and aerial application using WP products are canceled.</p> <p>For blueberry, post-application risks are not of concern at the 1.5 lb. rate provided that the REI for the WP formulation is 9 days and the REI for the EC formulation is 6 days. Since this use is primarily a post-harvest use increasing the REI is not expected to have an impact on use.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum application rate by 25% and reducing the maximum seasonal rate by 50%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Strawberry (2.0 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 54 at current REI of 24 hours MOE = 100 at 5 days  Risks to non-target aquatic organisms for WP and EC	Reduce the maximum application rate to 1 lbs/ai/A  Require all wettable powders to be packaged in water soluble bags  Require closed mixing/loading systems for aerial application using the EC formulation  Cancel aerial application using the WP formulation  5 day REI for WP (high exposure activities, hand harvesting , pruning, thinning etc.: MOE > 100)  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 3 per season to 2 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b>  For strawberry, handler risks are not of concern at the 1 lb. rate provided that aerial application using WP products is canceled and engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products and aerial application using WP products are canceled.</p> <p>For strawberry, post-application risks are not of concern at the 1 lb. rate provided the REI for the WP formulation is 5 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>  Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum application rate by 50%, reducing the maximum seasonal rate by 33% and reducing the maximum number of applications per season to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Alfalfa (seed) (1 lb/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Application with aerial equipment  Risks to non-target aquatic organisms for WP and EC	Cancel WP Use  Reduced application rate to 1lb/ai/A  Require closed mixing/loading systems for aerial application  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>  For alfalfa (seed), handler risks are of concern at the 1.0 lb. rate even provided that wettable powder formulations are canceled and provided engineering controls are employed; that is closed mixing/loading systems are used for aerial applications of EC products (MOE = 82).</p> <p>In California, the seed alfalfa acreage has decreased significantly to approximately 20,000 to 35,000 acres. Endosulfan use in seed alfalfa is part of an integrated management approach that also benefits cotton producers. The use of endosulfan, when combined with a pyrethroid, is important in the control of <i>Lygus</i> bugs. Since seed alfalfa is harvested earlier than cotton, there is potential for <i>Lygus</i> bugs to migrate into cotton fields later in the season. Use of sublethal doses of pyrethroid alone could result in resistance and the lower endosulfan rate may be insufficient to guarantee good coverage, especially under heavy infestations or over time. Resistance, which has been observed in other crops, hinders control with another pyrethroid application, the usual method of treatment, and would require use of potentially harsher alternatives. Relatively few other alternatives are available to alfalfa growers. Compared to those that are registered, including the organophosphates, malathion and dimethoate, endosulfan is less toxic to honey bees, which are crucial to the pollination of the alfalfa crop. <i>Lygus</i> bugs can also migrate to other crops, including dry beans. The Agency considers this use to be beneficial to both seed alfalfa and cotton growers in California, and minimizes resistance issues that would arise from sole reliance on pyrethroids.</p> <p>In Washington, Oregon, Idaho, and Nevada, the Agency believes that it is unlikely that 1200 acres would be treated in a given day. For instance, in eastern Oregon and southwest Idaho, seed alfalfa fields are usually about 5 to 20 acres in size, while the average farm size in Oregon was 114 acres in 1997. The spotted alfalfa aphid is the main pest treated. Endosulfan applications are generally needed only once per season when there is an outbreak, which may not occur simultaneously on all fields. Endosulfan is used at a range of rates, with lower rates being used at night during bloom to protect bees and at higher rates if the outbreak occurs later in the season. There are concerns that using lower rates of endosulfan for the spotted alfalfa aphid would not result in adequate control and would lead to resistance problems in the future. Given relatively few registered alternatives on alfalfa for seed, this is a plausible scenario.</p> <p>Given the benefits and the characterization of likely acres treated per day presented above, the Agency believes no further mitigation is necessary at this time for alfalfa (seed).</p>		

Crop*	Risks of Concern	Mitigation
<b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum application rate by 25%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.		
Small Grains (0.75 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Application with aerial equipment  Risks to non-target aquatic organisms for WP and EC	Cancel WP Use  Require closed mixing/loading systems for aerial application using the EC formulation  Reduce maximum number of applications from 2 per season to 1 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<b>Rationale for Worker Risk Mitigation:</b> For small grains, handler risks are not of concern at the 0.75 lb. rate provided that wettable powder formulations are canceled and provided engineering controls are employed; that closed mixing/loading systems are used for aerial applications of EC products..		
<b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum number of applications rate by 50%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.		
Filberts (2 lbs/ai/A)  Walnuts (2 lbs/ai/A)  Almonds (2 lbs/ai/A)  Macadamia Nuts (2 lbs/ai/A)	Mixing/Loading Liquid for aerial application Mixing/Loading WP for aerial application Mixing/Loading WP for airblast application Application w/ airblast application  Risks to non-target aquatic organisms for WP and EC	Require all wettable powders to be packaged in water soluble bags  Cancel aerial application using the WP formulation  Require closed mixing/loading systems for aerial application using the EC formulation  Require closed cabs for airblast applications  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 2 per season to 1 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b> For filberts and walnuts, handler risks are not of concern at the 2 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations, closed mixing/loading systems are used for aerial applications of EC products, aerial application using WP products are canceled and closed cabs are used for airblast applications (designed to provide dermal protection).</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and the maximum number of applications to one. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Peppers (1 lbs/ai/A)  Eggplant (1 lbs/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for airblast application  Risks to non-target aquatic organisms for WP and EC	Require all wettable powders to be packaged in water soluble bags  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b> For eggplant and peppers, handler risks are not of concern at the 1 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Potatoes (1 lbs/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for airblast application  Risks to non-target aquatic organisms for WP and EC	Require all wettable powders to be packaged in water soluble bags  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 6 per season to 4 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b> For potatoes, handler risks are not of concern at the 1 lb. rate provided engineering controls are employed; that is, water soluble bags for wettable powder formulations.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and the maximum number of applications to 4. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Carrots (1 lbs/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 54 at current REI of 24 hours MOE = 100 at 5 days  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>            For carrots, handler risks are not of concern at the 1 lb. rate provided that the wettable powder use is canceled.</p> <p>For carrots, post-application risks are not of concern at the 1 lb. rate provided the WP formulations are canceled.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Dry Beans (1 lbs/ai/A)  Dry Peas (1 lbs/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 65 at current REI of 24 hours MOE = 100 at 4 days  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 3 per season to 2 per season  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>            For dry beans and dry peas, handler risks are not of concern at the 1 lb. rate provided that the wettable powder use is canceled.</p> <p>For dry beans and dry peas, post-application risks are not of concern at the 1 lb. rate provided the WP formulations are canceled.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and the maximum number of applications to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

Crop*	Risks of Concern	Mitigation
Tobacco (1 lb/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 54 at current REI of 24 hours MOE = 100 at 4 days  Medium exposure activities for WP (scouting and irrigating): MOE = 83 at current REI of 24 hours MOE = 100 at 2 days  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A  Reduce maximum number of applications from 6 per season to 2 per season  Restrict use on tobacco to the following states: IN, KY, OH, PA, TN and WV.  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies
<p><b>Rationale for Worker Risk Mitigation:</b>            For tobacco, handler risks are not of concern at the 1 lb. rate provided that the wettable powder use is canceled.</p> <p>For tobacco, post-application risks are not of concern at the 1 lb. rate provided the WP formulations are canceled.</p> <p><b>Rationale for Ecological Risk Mitigation:</b>            Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum seasonal rate by 33% and the maximum number of applications to two. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p> <p>By restricting the use on tobacco to IN, KY, OH, PA, TN and WV exposures to aquatic organisms are expected to be reduced. These restrictions remove use in areas of the country where water resources are more abundant and potentially vulnerable.</p>		
Pineapple (2 lbs/ai/A)	Mixing/Loading WP for aerial application Mixing/Loading WP for ground application  High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 81 at current REI of 24 hours MOE = 100 at 3 days  Risks to non-target aquatic organisms for WP and EC	Cancel WP use  100 ft. spray buffer for ground applications between a treated area and water bodies  30 ft. maintained vegetative buffer strip between a treated area and water bodies

Crop*	Risks of Concern	Mitigation
<p><b>Rationale for Worker Risk Mitigation:</b> For pineapple, handler risks are not of concern at the 2 lb. rate provided that the wettable powder use is canceled.</p> <p>For pineapple, post-application risks are not of concern at the 2 lb. rate provided the WP formulations are canceled.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		
Ornamental Trees/Shrubs (3 lbs/ai/A)	<p>High exposure activities for WP (hand harvesting, pruning, thinning etc.): MOE = 68 at current REI of 24 hours MOE = 100 at 5 days</p> <p>Risks to non-target aquatic organisms for WP and EC</p>	<p>Require all wettable powders to be packaged in water soluble bags</p> <p>Reduce maximum application rate to 2.5 lbs/ai/A</p> <p>4-day REI (high exposure hand harvesting, pruning, thinning etc.: MOE &gt; 100)</p> <p>100 ft. spray buffer for ground applications between a treated area and water bodies</p> <p>30 ft. maintained vegetative buffer strip between a treated area and water bodies</p>
<p><b>Rationale for Worker Risk Mitigation:</b> For ornamental trees and shrubs, post-application risks are not of concern at the 2.5 lb. rate provided that the REI for the WP formulation is 4 days.</p> <p><b>Rationale for Ecological Risk Mitigation:</b> Overall environmental loading and, therefore, exposure to non-target organisms will be reduced by reducing the maximum single application rate by 17%. The vegetative buffer is designed to reduce the potential for endosulfan to contaminate water through runoff from treated fields. The 100 ft. spray buffer will also reduce the potential for contamination through spray drift during ground applications.</p>		

\* Rates in parentheses are the rates used in the risk assessment. Unless otherwise noted, these correspond to the maximum application rate to be allowed on labels.

## 2. Environmental Risk Mitigation

The Agency has ecological risk concerns regarding the acute and chronic risks to terrestrial birds and mammals, freshwater fish, freshwater invertebrates, estuarine/marine fish and estuarine/marine invertebrates. The ecological risk assessments exhibit RQ values which exceed the various target levels of concern (LOCs). As outlined in Section III above, risks are much higher, as evidenced by higher RQ values, for aquatic organisms, and especially for estuarine/marine organisms.

### *Birds and Mammals*

The Agency's assessment suggests the potential for the liquid formulation to cause acute and chronic effects to birds and mammals for broadcast applications. The avian acute RQs range from 0.02 to 0.53. The avian chronic RQs range from 0.03 to 2.7. For the same use patterns, mammalian acute RQs range from 0.06 to 40 while mammalian chronic RQs range from 0.3 to 5.4. The highest avian and mammalian RQs result from two 1.5 lb ai/A ground or aerial

applications to several crops. Most use patterns are of concern to the Agency for acute and chronic effects to birds and mammals.

Because of the toxicity of endosulfan, to help protect terrestrial birds and mammals, it is very important to minimize their potential exposure. To minimize risk to birds and mammals, several mitigation measures are needed as outlined in Table 20 above. These measures include reductions in single maximum application rates, reductions in maximum seasonal application rates, reductions in maximum numbers of applications allowed in a single growing season and the deletion of use on pecans, succulent beans, succulent peas, grapes and spinach.

### ***Aquatic Organisms***

At the current maximum application rates used on the major crops where endosulfan is employed, coupled with a 300-ft spray drift buffer, acute high risk, restricted use and endangered species levels of concern are exceeded for both freshwater and estuarine/marine organisms. Acute RQ values ranged from 1.04 to 34.8 for freshwater fish and from 0.15 to 5 for freshwater invertebrates. Estuarine/marine fish and invertebrates were roughly an order of magnitude more sensitive to the effects of endosulfan, with acute RQ values ranging from 8.7 to 289 for fish and 1.9 to 64.2 for invertebrates. Chronic RQ values ranged from 1.5 to 64 for freshwater fish and from 3.6 to 135.3 for freshwater invertebrates. Chronic RQ values for estuarine/marine fish ranged from 16 to 704 and 1 to 39.5 for estuarine/marine invertebrates. The highest aquatic RQs result from three 1.0 lb ai/A applications to tomatoes. All use patterns are of concern to the Agency for acute and chronic effects to aquatic organisms.

Because of the toxicity of endosulfan, to help protect aquatic organisms, it is very important to minimize their potential exposure to endosulfan products that have been applied. To reduce risk to aquatic organisms, several mitigation measures are needed as outlined in Table 20 above. These measures include deletion of use on pecans, succulent beans, succulent peas, grapes and spinach, reductions in single maximum application rates, maximum seasonal application rates and maximum numbers of applications allowed in a single growing season. They also include implementing a 100 foot setback from water bodies for ground applications and a 30 foot maintained vegetative buffer between treated fields and water bodies.

### **3. Public Comment and Stakeholder Process to Address Aquatic Risks and Long Range Transport**

Given the toxicity and persistence of endosulfan and potential risks to aquatic organisms, the Agency has developed a number of mitigation measures to reduce the risks to aquatic organisms outlined in this document. While the Agency believes that these measures will reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan, it also believes that in specific geographical areas where conditions exist that make aquatic organisms especially vulnerable (e.g. shallow, leaky aquifers, highly erodible lands, the presence of especially sensitive organisms and high use of endosulfan) additional measures may be identified. In order to more fully evaluate the risks in these vulnerable areas; the risk



management strategies that may be in place or could potentially be implemented in such areas (e.g. use of retention ponds) to reduce exposure; and the benefits of the use of endosulfan in those areas, the Agency is planning to conduct a public comment and stakeholder process.

During the public comment period, commencing with the publishing of a Federal Register Notice, comments and suggestions will be collected and reviewed concerning risks to aquatic organisms in vulnerable areas, risk management strategies for addressing those risks and the benefits of use of endosulfan in vulnerable areas. Further, a stakeholder meeting(s) will be held within 3 months for the issuance of this RED at a location(s) to be determined. For this meeting(s) to be most efficient and successful, all interested parties and viewpoints will be welcomed and considered.

Endosulfan is a semivolatile and persistent cyclodiene pesticide that can migrate over a long distance through various environmental media such as air, water, and sediment. Once endosulfan is applied to crops, it can either persist in soil as a sorbed phase or be removed through several physical, chemical, and biological processes. Recent studies suggest that secondary emissions of residual endosulfan continue to recycle in the global system while they slowly migrated and are redeposited via wet deposition in the Northern Hemisphere. The occurrence of endosulfan in remote regions like the Great Lakes, the Arctic, and mountainous areas is well documented. Endosulfan can also enter the air as adsorbed phase onto suspended particulate matter, but this process does not appear to be a major contributor long range transport like volatilization.

The presence of endosulfan in the remote areas like the Arctic and the Great Lakes requires further understanding of the transport mechanisms from the atmosphere. The potential impact of atmospheric deposition of endosulfan into surface water and its potential effect on water quality and aquatic organisms in the non-use areas is not well documented. Despite the progress made in recent years in estimating the persistence and long-ranged transport of chemicals using models, a validated global model has not been published because of uncertainties involved in the source inventories, chemical fate data, degradative pathways and exposure analyses. Future work will be aimed at developing a comprehensive screening tool that can be used reliably in risk assessments for regulatory purposes. Part of the stakeholder process will include an evaluation of to what extent data related to long range transport may be necessary.

## **E. Other Labeling**

Other use and safety information needs to be placed on the labeling of all end-use products containing endosulfan. For the specific labeling statements, refer to Section V of this document

### **1. Endangered Species Statement**

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to

implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at this time.

The Agency will begin an endangered species effects determination process for all uses of endosulfan that remain registered following completion of the RED. Through this effects determination the Agency will develop use limitations and/or consult with the Fish and Wildlife Service and/or the National Marine Fisheries Service where appropriate.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at <http://www.epa.gov/espp>. A final Endangered Species Protection Program, which may be altered from the interim program, will soon be proposed for public comment in the Federal Register.

## **2. Spray Drift Management**

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force and is developing policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, or ground hydraulic spray. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial application or other application methods associated with drift, where appropriate.

Based on these analyses, the Agency is in the process of developing more appropriate label statements for spray, and dust drift control to ensure that public health, and the environment are protected from unreasonable adverse effects. In August 2001, EPA published draft guidance for label statements in a pesticide registration (PR) notice ("Draft PR Notice 2001-X" [http://www.epa.gov/PR\\_Notices/#2001](http://www.epa.gov/PR_Notices/#2001)). A *Federal Register* notice was published on August 22, 2001 (<http://www.epa.gov/fedrgstr>) announcing the availability of this draft guidance for a 90-day public comment period. After review of the comments, the Agency will publish final guidance in a PR notice for registrants to use when labeling their products.

In the interim, registrants may choose to use the proposed statements. Registrants should read and refer to the draft PR notice to obtain a full understanding of the proposed guidance and its intended applicability, exemptions for certain products, and the Agency's willingness to consider other versions of the statements.

Registrants may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling for the purpose of complying with the deadlines for label submission outlined in this document. The proposed label language is as follows:

For products applied outdoors as liquids:

“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”

“For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use \_\_\_\_\_ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”

“For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. Use \_\_\_\_\_ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.”

For overhead chemigation:

“Apply only when wind speed is 10 mph or less.”

On all product labels:

“The applicator also must use all other measures necessary to control drift.”

“For ground rig applications, apply product no more than 4 feet above the ground or the crop canopy, and only when wind speed is 10 mph or less at the application site as measured by an anemometer.”

“For aerial applications, use upwind swath displacement, and apply only when wind speed is 3 - 10 mph as measured by an anemometer. If application includes a no-spray

zone, do not release dust at a height greater than 10 feet above the ground or the crop canopy.”

*Or*

“The applicator also must use all other measures necessary to control drift.”

For hand-applied products to be applied as sprays:

“Do not allow spray or dust to drift from the application site, and contact people, structures people occupy at any time, and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals. Apply only when wind speed is not more than 10 mph. For sprays, apply largest size droplets possible.”

Alternatively, registrants may elect to use the following language, which is the current Agency policy on drift labeling:

For products that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method, the following must be added to the labels:

“Do not allow this product to drift.”

The Agency recognizes that the above option does not address other application types. Registrants may therefore wish to adapt some variation of the old, and proposed new language for their particular products, depending on their application methods.

## **V. What Registrants Need to Do**

The Agency has determined that agricultural use of endosulfan, based on the currently approved labeling, pose occupational and ecological risks that constitute unreasonable adverse effects on the environment. However, the Agency believes that these risks can likely be acceptably mitigated through routine changes to pesticide labeling and formulations. Accordingly, the Agency has determined that endosulfan is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision for occupational exposures associated with the application of dip treatment to roots or whole plants and ecological risks; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section E below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

**A. Data Call-In Responses**

For endosulfan technical grade active ingredient products, registrants need to submit the following items.

**Within 90 days from receipt of the generic data call-in (DCI):**

- (1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
- (2) submit any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:**

- (1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Stacey Milan at (703) 305-2505 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:

Document Processing Desk (DCI/SRRD)  
Stacey Milan  
US EPA (7508C)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)  
Stacey Milan  
Office of Pesticide Programs (7508C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**B. For products containing the active ingredient endosulfan**, registrants need to submit the following items for each product.

**Within 90 days from the receipt of the product-specific data call-in (PDCI):**

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. Submit any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:**

- a. two copies of the confidential statement of formula (EPA Form 570-4);
- b. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an “application for reregistration”;
- c. five copies of the draft label incorporating all label amendments outlined in Table 21 of this document;
- d. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
- e. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- f. the product-specific data responding to the PDCI.

Please contact Karen Jones at (703) 308 - 8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:

Document Processing Desk (PDCI/PRB)  
Karen Jones  
US EPA (7508C)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)  
Karen Jones  
Office of Pesticide Programs (7508C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

## **B. Manufacturing Use Products**

### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of endosulfan for the above uses has been reviewed and determined to be substantially complete with the exception of the following studies. The following data requirements are necessary to confirm the reregistration eligibility decision documented in this RED.

Studies on endosulfan sulfate

- 1. OPPTS 850.2100: Avian acute oral toxicity of bobwhite quail and mallard duck.
- 2. OPPTS 850.2200: Avian subchronic oral toxicity of bobwhite quail and mallard duck.
- 3. OPPTS 850.2300: Avian reproduction study of bobwhite quail and mallard duck

4. OPPTS 850.1075: Freshwater fish acute toxicity study of bluegill sunfish.
5. OPPTS 850.1500: Freshwater fish full life cycle using rainbow trout.
6. OPPTS 850.1075: Estuarine/marine fish acute toxicity study.
7. OPPTS 850.1035: Estuarine/marine invertebrate acute toxicity study of mysid shrimp
8. OPPTS 850.1300: Early life stage fish
9. OPPTS 850.1350: Life cycle invertebrate

#### Other Studies

1. OPPTS 850.1735: Whole sediment acute toxicity testing using a freshwater invertebrate.
2. OPPTS 850.1740: Whole sediment acute toxicity testing using a estuarine/marine invertebrate.
3. OPPTS 850.1735S: Whole sediment chronic toxicity testing using a freshwater invertebrate.
4. OPPTS 850.1740S: Whole sediment chronic toxicity testing using an estuarine/marine invertebrate.
5. 164 -2 (Special Study): Vegetative buffer effectiveness study
6. OPPTS 835.7100: Groundwater monitoring study
7. OPPTS 835.7200: Surface drinking water monitoring study
8. OPPTS 870.6200: Subchronic Neurotoxicity - Rat
9. OPPTS 870.6300: Developmental Neurotoxicity Toxicity Study - Rat
10. OPPTS 860.1380: Storage stability (oils seed, non-oily grain and processed commodities)
11. OPPTS 860.1900: Field rotational crop study
12. OPPTS 860.1500: Crop field trials for the following raw agricultural commodities: barley hay, and pearled barley; oat forage, hay, and rolled oats; rye forage; wheat forage, and hay.
13. OPPTS 860.1500: Crop field trials for tobacco and a pyrolysis.
14. OPPTS 860.1520: Magnitude of residue in processed food/feed commodities
15. OPPTS 875.1100: Dermal outdoor exposure for applying dip treatments to trees and roots or whole plants.
16. OPPTS 875.1700: Product use information for applying dip treatments to trees and roots or whole plants.

## **2. Labeling for Manufacturing Use Products**

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 21 at the end of this section.

### **C. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if

not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, accompanies this RED.

## **2. Labeling for End-Use Products**

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 21 at the end of this section.

### **D. Existing Stocks**

The Agency has determined that registrant may distribute and sell endosulfan products bearing old labels/labeling for 9 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 18 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

### **E. Labeling Changes Summary Table**

In order to mitigate the risks identified in this document, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.



**Table 21. Summary of Labeling Changes for Endosulfan**

Description	Labeling	Placement on Label
<b>Manufacturing-Use Products</b>		
Formulation instructions required for all MUP labels.	"Only for formulation into an <b>insecticide</b> for the following use(s)" [fill blank only with those uses that are being supported by MP registrant].	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	<p>"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p> <p>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p><b>"Environmental Hazards"</b></p> <p>"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Water Board or Regional Office of the EPA."</p> <p>"This product is extremely toxic to fish and aquatic invertebrates and toxic to birds and mammals. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. See Spray drift management instructions under "Directions for use. Do not contaminate water when disposing of equipment wash waters or rinsate."</p>	Precautionary Statements
<b>End-Use Products Intended for Occupational Use</b>		
Handler PPE Guidelines (all formulations)	<p>Note the following information when preparing labeling for all end use products:</p> <p>For <b>sole-active-ingredient</b> end-use products that contain Endosulfan, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For <b>multiple-active-ingredient</b> end-use products that contain Endosulfan, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that will be established on the basis of Acute Toxicity testing on end-use products undergoing product reregistration must be compared with the active ingredient PPE specified below by the RED. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	Handler PPE Statements

Description	Labeling	Placement on Label
RUP Statement Required for All Formulations	<p>“RESTRICTED USE PESTICIDE”</p> <p>“Due to acute toxicity to humans, aquatic organisms, and avian species.”</p> <p>“For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification.”</p>	
PPE Established by the RED for liquid formulations.	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>).</p> <p>“If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“<b>All</b> handlers except those using engineering controls must wear:</p> <ul style="list-style-type: none"> <li>- Respirator with <ul style="list-style-type: none"> <li>- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or</li> <li>- a NIOSH approved respirator with an (OV) cartridge or a canister with any N,R,P or HE filter.</li> </ul> </li> </ul> <p><b>IN ADDITION:</b></p> <p>Mixers and loaders supporting aerial applications who are not using engineering controls (see engineering requirements below), handlers supporting or using high pressure handwand equipment and flaggers must wear:</p> <ul style="list-style-type: none"> <li>- Coveralls over long-sleeved shirt and long pants</li> <li>- Chemical resistant footwear plus socks</li> <li>- Chemical resistant gloves (except when flagging)</li> <li>- Chemical resistant head gear when exposed overhead</li> <li>- Chemical resistant apron when mixing and loading</li> </ul> <p>All other mixers, loaders applicators and handlers must wear:</p> <ul style="list-style-type: none"> <li>- Long-sleeved shirt and long pants;</li> <li>- Socks and shoes;</li> <li>- Chemical resistant gloves except, for applicators using enclosed cabs or cockpits,</li> <li>- Chemical resistant apron when mixing and loading, applying dips cleaning up spills or cleaning/repairing equipment.</li> <li>- A respirator of the type specified above for all handlers except for those using engineering controls.”</li> </ul>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Labeling	Placement on Label
<p>PPE Established by the RED for Wettable Powder Formulation (wetable powder formulations need to be marketed in water soluble packaging.)</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” <i>(registrant inserts correct chemical-resistant material)</i>.          “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“<b>All</b> handlers except for those using engineering controls must wear:</p> <ul style="list-style-type: none"> <li>- Respirator with             <ul style="list-style-type: none"> <li>- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or</li> <li>- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or</li> <li>- a NIOSH approved respirator with an (OV) cartridge or a canister with any N,R,P or HE filter.</li> </ul> </li> </ul> <p><b>In addition:</b></p> <p>“Handlers supporting or using high pressure handwand equipment and flaggers must wear:</p> <ul style="list-style-type: none"> <li>- Coveralls over long-sleeved shirt and long pants</li> <li>- Chemical resistant footwear plus socks</li> <li>- Chemical resistant gloves (except when flagging)</li> <li>- Chemical resistant head gear when exposed overhead</li> <li>- Chemical resistant apron when mixing and loading</li> </ul> <p>All other mixers, loaders applicators and handlers must wear:</p> <ul style="list-style-type: none"> <li>- Long-sleeved shirt and long pants;</li> <li>- Socks and shoes;</li> <li>- Chemical resistant gloves except, for applicators using enclosed cabs or cockpits,</li> <li>- Chemical resistant apron when mixing and loading, applying dips cleaning up spills or cleaning/repairing equipment.</li> <li>- A respirator of the type specified above for all handlers except for those using engineering controls.</li> </ul>	<p>Precautionary Statements:          Immediately following/below Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	<p>Precautionary Statements:          Immediately following the PPE requirements</p>

Description	Labeling	Placement on Label
Engineering Controls for Liquid Formulations	<p>“Engineering Controls”</p> <p>“Mixers and loaders supporting aerial applications at the rate of more than 1.5 lbs/ai per acre or supporting applications to alfalfa, cotton, barley, rye oats and wheat and must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal and inhalation protection , and must:</p> <ul style="list-style-type: none"> <li>-- wear long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves and chemical apron,</li> <li>-- wear long-sleeved shirt, long pants, shoes, socks,, and</li> <li>-- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown coveralls, chemical resistant footwear and the type of respirator specified in the PPE.”</li> </ul> <p>“Applicators using airblast equipment on all crops except ornamental trees and shrubs must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling ,</li> <li>-- <i>either</i> wear the type of respirator specified in the PPE section of this labeling <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,</li> <li>-- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,</li> <li>-- take off any PPE that was worn in the treated area before reentering the cab, and</li> <li>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.”</li> </ul> <p>“Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];”</p> <p>“When handlers use closed systems and enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p>	Precautionary Statements: Immediately following the User Safety Requirements

Description	Labeling	Placement on Label
Engineering Controls for Wettable Powder Formulations	<p>“Engineering Controls”</p> <p>“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :</p> <ul style="list-style-type: none"> <li>-- wear long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves and chemical apron,, and</li> <li>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown coveralls, and the type of respirator specified in the PPE.”</li> </ul> <p>“Applicators using airblast equipment on all crops except ornamental trees and shrubs must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> <li>-- wear long-sleeved shirt, long pants, shoes, socks,</li> <li>-- <i>either</i> wear the type of respirator specified in the PPE section of this labeling <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,</li> <li>-- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,</li> <li>-- take off any PPE that was worn in the treated area before reentering the cab, and</li> <li>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.”</li> </ul> <p>“Pilots must use an enclosed cockpit in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)];”</p> <p>“When handlers use enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p>	
User Safety Recommendations	<p>“<b>User Safety Recommendations</b>”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements: Immediately following Engineering Controls)</p> <p>Must be placed in a box</p>

Description	Labeling	Placement on Label
Environmental Hazards	<p>“Environmental Hazards”</p> <p>“This product is extremely toxic to fish and aquatic invertebrates and toxic to birds and mammals. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. See Spray drift management instructions under “Directions for use. Do not contaminate water when disposing of equipment wash waters or rinsate.”</p>	Precautionary Statements: Immediately following the User Safety Recommendations
Restricted Entry Interval (REI).	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI).”	Directions for Use in the Agricultural Use Requirements Box.
Restricted Entry Intervals (REI) for EC Formulations.	<p>All crops except for the crops listed below have an REI of 48 hours.</p> <p><u>The following crop has an REI of 3 days:</u> sweet potato.</p> <p><u>The following crops grown for seed have an REI of 3 days:</u> collard greens, kale, mustard greens, radish, rutabaga, and turnip.</p> <p><u>The following crops NOT grown for seed have an REI of 4 days:</u> kohlrabi, broccoli and cabbage.</p> <p><u>The following crops also have an REI of 4 days:</u> brussels sprouts and cauliflower.</p> <p><u>The following crops have an REI of 6 days:</u> blueberries.</p> <p><u>The following crops grown for seed have an REI of 7 days:</u> kohlrabi, broccoli and cabbage</p> <p><u>The following crops have an REI of 17 days:</u> sweet/fresh corn</p>	Directions for Use next to the application instructions for each crop

Description	Labeling	Placement on Label
restricted Entry Intervals (REI) for wettable powder formulations.	<p>All crops except for the crops listed below have an REI of 48 hours.</p> <p><u>The following crops have an REI of 3 days:</u> cucumbers, melons, pumpkins, and squash.</p> <p><u>The following crops have an REI of 4 days:</u> celery, lettuce, apple, apricot, cherry, nectarines, peach, pear, plum, and prune, Christmas trees, ornamental trees and shrubs, and non-bearing citrus trees.</p> <p><u>The following crops NOT grown for seed have an REI of 4 days:</u> collard greens, kale, mustard greens, radish, rutabaga, and turnip.</p> <p><u>The following crops grown for seed have an REI of 5 days:</u> collard greens, kale, mustard greens, radish, rutabaga, and turnip.</p> <p><u>The following crops have an REI of 9 days:</u> brussels sprouts, cauliflower</p> <p><u>The following crops NOT grown for seed have an REI of 9 days:</u> kohlrabi, broccoli, cabbage.</p> <p><u>The following crops for seed have an REI of 12 days:</u> kohlrabi, broccoli, cabbage.</p>	Directions for Use next to the application instructions for each crop
Early Entry PPE	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>* coveralls,</li> <li>* chemical-resistant gloves made of any waterproof material,</li> <li>* shoes plus socks,</li> <li>* protective eyewear”</li> </ul>	Directions for Use in the Agricultural Use Requirements Box.
Double Notification	“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.”	Directions for Use in the Agricultural Use Requirements Box.
Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Directions for Use

Description	Labeling	Placement on Label
Other Risk Mitigation	<p><b>Reduced Application Rates (maximum a.i. per acre or per gallon per application)</b></p> <p><u>Tree bark application:</u> 0.005 lb/ai gallon</p> <p><u>Cotton (aerial applications), alfalfa grown for seed, and kale:</u> 0.75 lb ai/acre</p> <p><u>Broccoli, kohlrabi, cabbage and cauliflower not grown not for seed:</u> 1.0 lb ai/acre</p> <p><u>Strawberries:</u> 1.0 lb ai/acre</p> <p><u>Cotton (ground applications) and blueberries:</u> 1.5 lb ai/acre</p> <p><u>Macadamia nuts:</u> 2.0 lbs ai/acre</p> <p><u>Pome fruit, stone fruit, nonbearing citrus, pecans and ornamental trees and shrubs:</u> 2.5 ai/acre</p> <p><b>Reduce Seasonal Application Rate (maximum amount a.i./acre that can be applied in a single season)</b></p> <p><u>Celery:</u> Reduce to 1.0 lbs ai/acre per season</p> <p><u>Sweet/fresh corn, cotton (aerial application) and blueberries:</u> Reduce to 1.5 lbs ai/acre per season</p> <p><u>Melons, cucumbers, squash, pumpkins, lettuce, tomatoes, sweet potato, cotton (ground applications), broccoli, cauliflower, cabbage, kohlrabi, brussels sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, egg plant, potatoes, carrots, dried beans, dried peas and tobacco:</u> Reduce to 2.0 lbs ai/acre per season.</p> <p><u>Pome fruit, stone fruit, nonbearing citrus and pecans:</u> Reduce to 2.5 lbs ai/acre per season.</p> <p><b>Reduce Number of Applications/Season (max. # of applications that can be made in one season)</b></p> <p><u>Almonds, filberts, macadamia nuts, walnuts, sweet corn, barley, oats, wheat, and rye:</u> Reduce to 1 application per season.</p> <p><u>Broccoli, brussels sprouts, cauliflower, cabbage, cotton, dry deans, dry peas, kohlrabi, lettuce, strawberry, sweet potatoes, tobacco:</u> Reduce to 2 applications per season.</p> <p><u>Melons, cucumber, squash and pumpkins:</u> Reduce to 4 applications per season except for CA where the maximum number of applications per season is 3.</p> <p><u>Potatoes, tomatoes:</u> Reduce to 4 applications per season.</p>	Directions for Use under application instructions and/or restrictions



Description	Labeling	Placement on Label																					
Other Risk Mitigation (continued)	<p><b>Site/Crop Deletions (remove the following sites or crops from the label)</b></p> <p><u>All formulations:</u></p> <p>Grapes (all types)</p> <p>Spinach</p> <p>Succulent Beans</p> <p>Succulent Peas</p> <p>Pecans</p> <p><u>Wettable Powders:</u></p> <p>Alfalfa (grown for seed only) Pineapple</p> <p>Blueberries Strawberries</p> <p>Carrots Small Grains (barley, oats, rye, and wheat)</p> <p>Cotton Sweet Corn</p> <p>Dry Beans Sweet Potatoes</p> <p>Dry Peas Tobacco</p> <p>Tomato</p> <p><b>Application Equipment/Method Deletions:</b></p> <p>Revise applications instructions for the below crops to remove and prohibit aerial applications:</p> <p><u>Wettable powder formulations only:</u></p> <table border="0"> <tr> <td>Apricots</td><td>Radish (grown for seed only)</td><td>Almonds</td></tr> <tr> <td>Peaches</td><td>Turnip (grown for seed only)</td><td>Macadamia Nuts</td></tr> <tr> <td>Nectarines</td><td>Rutabaga (grown for seed only)</td><td>Filberts</td></tr> <tr> <td>Plum/Prune</td><td>Broccoli (grown for seed only)</td><td>Walnuts</td></tr> <tr> <td>Cherries</td><td>Cabbage (grown for seed only)</td><td>Kale (grown for seed only)</td></tr> <tr> <td>Non-bearing Citrus</td><td>Kohlrabi (grown for seed only)</td><td>Collard Greens (grown for seed only)</td></tr> <tr> <td>Mustard Greens (grown for seed only)</td><td></td><td></td></tr> </table> <p>For all formulations, prohibit use of high pressure hand wand on all sites except to bark treatment or tobacco drench.</p>	Apricots	Radish (grown for seed only)	Almonds	Peaches	Turnip (grown for seed only)	Macadamia Nuts	Nectarines	Rutabaga (grown for seed only)	Filberts	Plum/Prune	Broccoli (grown for seed only)	Walnuts	Cherries	Cabbage (grown for seed only)	Kale (grown for seed only)	Non-bearing Citrus	Kohlrabi (grown for seed only)	Collard Greens (grown for seed only)	Mustard Greens (grown for seed only)			Directions for Use under application instructions and/or restrictions
Apricots	Radish (grown for seed only)	Almonds																					
Peaches	Turnip (grown for seed only)	Macadamia Nuts																					
Nectarines	Rutabaga (grown for seed only)	Filberts																					
Plum/Prune	Broccoli (grown for seed only)	Walnuts																					
Cherries	Cabbage (grown for seed only)	Kale (grown for seed only)																					
Non-bearing Citrus	Kohlrabi (grown for seed only)	Collard Greens (grown for seed only)																					
Mustard Greens (grown for seed only)																							

Description	Labeling	Placement on Label
Spray Drift Labeling	<p>“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”</p> <p>“A 30 ft. vegetative buffer strip must be maintained between all areas treated with this product and rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds.”</p> <p>“For ground boom applications, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”</p> <p>“For orchard/vineyard airblast applications, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 –10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side.”</p> <p>“For aerial applications, do not apply within 300 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. The boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.”</p> <p>“For overhead chemigation, do not apply within 100 feet of rivers, natural ponds, lakes, streams, reservoirs, marshes, estuaries and commercial fish ponds. Apply only when wind speed is 10 mph or less.”</p> <p>“The applicator also must use all other measures necessary to control drift.”</p>	Directions for Use under General application instructions and/or restrictions

## **VI. APPENDICES**

**Appendix A. Endosulfan Table of Use Patterns Reflecting Label Changes Based on Mitigation Measures**

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Alfalfa (grown for seed)</b>						
Foliar treatment Ground or aerial	3 lb/gal EC [CA860035]	1.0 lb/A	2	1.0 lb/A	21	Require closed mixing/loading systems for aerial application. Reduce application rate to 1b./ai/A. WP formulation canceled. Use limited to CA. Applications may be made in a minimum of 10 gal/A by ground or 5 gal/A by air. The feeding or grazing of treated foliage, crop residues, or seed millings and the use of treated seed for livestock food or feed are prohibited.
	3 lb/gal EC [NV860005]	1.0 lb/A	2	(NS)	(NS)	Use limited to NV. Applications may be made in a minimum of 10 gal/A by ground or 2 gal/A by air. The feeding or grazing of treated foliage, crop residues, or seed millings and the use of treated seed for livestock food or feed are prohibited.
	3 lb/gal EC [WA880012]	0.5 lb/A	2	NS	21	Use limited to WA. Applications may be made in a minimum of 25 gal/A by ground or 10 gal/A by air. The feeding or grazing of treated foliage, crop residues, or seed screening is prohibited.
<b>Almond</b>						
Delayed dormant or foliar (during popcorn, pink, or petal fall) Ground or aerial	2 lb/gal EC [279-2659]	2.0 lb/A	1	2.0 lb/A	NS	Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial application using the WP formulation. Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast applications. Reduce application rate from 3lbs./ai/A to 21bs./ai/A. Reduce maximum number of applications per season from 2 to 1. Application may be made in a minimum of 200 gal of water/A (dilute) or 40 gal of water/A (concentrate). The grazing of livestock on orchard crops or grasses in treated areas is prohibited*. Treated hulls may be fed to livestock and dairy animals.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Apple</b>						
Delayed dormant and/or foliar (during pink and/or petal fall) Ground or aerial	50% WP [279-1380] [279-3129] [45639-194] [66222-2]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.5 lb/100 gal or 2.5 lb/A	3 (2 per fruiting period)	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications. A second application may be made 10 days later. The feeding of pomace from treated apples to livestock, the feeding of cull fruits to animals, or allowing livestock to graze in treated orchards is prohibited.*
Foliar treatment Ground or aerial	50% WP [45639-198]	0.5 lb/100 gal or 2.5 lb/A	3 (2 per fruiting period)	2.5 lb/A	30	Use limited to CA. Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. For EC formulation require closed mixing/loading systems for aerial applications. Require closed cabs for airblast applications. The feeding of pomace from treated apples to livestock, the feeding of cull fruits to animals, or allowing livestock to graze in treated orchards is prohibited.*
	3 lb/gal EC [45639-197]	0.5 lb/100 gal or 2.5 lb/A	2	2.5 lb/A	30	
	3 lb/gal EC [WA880012]	0.5 lb/A	2	2.5 lb/A	21	Use limited to WA. Reduce maximum application rate to 2.5lbs./ai/A. For EC formulation require closed mixing/loading systems for aerial applications. Require closed cabs for airblast applications. Applications may be made in a minimum of 25 gal/A by ground or 10 gal/A by air. The feeding or grazing of treated foliage, crop residues, or seed screening is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Foliar treatment Aerial	50% WP [WA780033]	1.5 lb/A	NS	2.5 lb/A	NS	Use limited to WA. Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP Applications may be made in a minimum of 3 gal of water/A using aerial equipment.
<b>Apricot</b>						
Bark treatment Postharvest Ground	50% WP [279-1380] [279-3129] [45639-194]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.75 lb/100 gal (Pacific Northwest)  2.5 lb/100 gal (Southeastern states)	2	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.  The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*
	50% WP [66222-2]	0.75 lb/100 gal (West coast)  2.5 lb/100 gal (Southeastern states)	2	2.5 lb/A	21	
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	30	Reduce maximum application rate to 2.5lbs./ai/A. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited. * Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Barley</b>						
Foliar treatment Ground or aerial	50% WP [279-1380] [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822] 3 lb/gal EC [279-2924] [45639-169]	0.5 lb/A	2	1.0 lb/A	NS	Require all wettable powder formulations to be packaged in water soluble bags. Applications may be made in a minimum of 10 gal of water/A using ground equipment. For control of army cutworm, aerial applications may be made in a minimum of 2 gal of crop oil, diesel oil, or water/A. Use limited to IL, IN, MI, and OH for control of cereal leaf beetle, aerial applications may be made in a minimum of 1 gal of water/A. The feeding of treated forage to livestock and application after heads begin to form are prohibited. *
	50% WP [279-1380] [279-3129] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.75 lb/A	2	1.0 lb/A	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial applications of the EC formulation. Require closed cabs for airblast applications. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The feeding of treated forage to livestock and application after heads begin to form are prohibited.* Use of the 3 lb/gal EC (EPA Reg. No. 45639-197) formulation is limited to CA.
<b>Bean, succulent</b>						
Foliar treatment Ground or aerial	50% WP [279-1380] [279-3129] [45639-194] [45639-198] [66222-22]	Succulent Green Beans Canceled	Succulent Green Beans Canceled	Succulent Green Beans Canceled	Succulent Green Beans Canceled	Endosulfan use on succulent green beans canceled.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Bean, dry						
Foliar treatment Ground or aerial	2 lb/gal EC [279-2659] [279-2735] [279-2822]	Dry Beans	Dry Beans	Dry Beans	Dry Beans	For dry beans, cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs.ai/A. Reduce maximum number of applications per season from 3 to 2.
	3 lb/gal EC [279-2924] [45639-169] [45639-197]	1bs./ai/A	2	2.0 lb/A		
	3 lb/gal EC [279-3222]	1.0 lb/A	3	3.0 lb/A	21	Endosulfan use on succulent green beans canceled
Blueberry						
Postharvest treatment Ground or aerial	50% WP  [279-3129] [45639-194] [66222-22]	1.5 lb/A	2	1.5 lb/A	NS	Reduce maximum seasonal application rate from 3lbs./ai/A to 1.5 lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial applications using the EC formulation. Cancel aerial application using the WP formulation. Applications may be made after harvest in 3 lbs./ai/300 gal of water with a 6- to 8-week pretreatment interval. Application after buds are well formed is prohibited.*
	2 lb/gal EC [279-2659] [279-2822]					
	3 lb/gal EC [279-2924] [45639-169]					



Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Broccoli</b>						
Foliar treatment Ground or aerial	50% WP  [45639-194] [66222-22]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	2	2.0 lb/A	7	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications from 4 per season to 2 per season. Applications may be made in a minimum of 10 gal/A by ground or 1-3 gal/A by air.
Foliar treatment Ground or aerial	50% WP [279-3129]  50% WP [45639-198]	1.0 lb/A	3	2.0 lb/A	7	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications from 4 per season to 2 per season. For use on broccoli, including Chinese broccoli. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
	3 lb/gal EC [45639-197]	1.0 lb/A	2	2.0 lb/A	7	Use limited to CA. Require all wettable powders to be packaged in water soluble bags. Number of applications per season remains at 2. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Brussels sprouts</b>						
Foliar treatment Ground or aerial	50% WP [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	2	2.0 lb/A	14	Require all wettable powders to be packaged in water soluble bags. Reduce maximum application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications from 4 per season to 2 per season. Applications may be made in a minimum of 10-25 gal/A by ground or 1-3 gal/A by air.
	50% WP [279-3129]	1.0 lb/A	2	2.0 lb/A	14	Require all wettable powders to be packaged in water soluble bags. Reduce maximum application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications per season from 4 per season to 2 per season. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
Foliar treatment Ground or aerial	50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	2	2.0 lb/A	14	Use limited to CA. Require all wettable powders to be packaged in water soluble bags. Number of applications per season remains at 2. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Cabbage</b>						
Foliar treatment Ground or aerial	50% WP [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	4	2.0 lb/A	7	Require all wettable powders to be packaged in water soluble bags. Reduce maximum application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications from 4 per season to 2 per season. Applications may be made in a minimum of 10-25 gal/A by ground or 1-3 gal/A by air.
	50% WP [279-3129]	1.0 lb/A	3	2.0 lb/A	7	For use on cabbage, including Chinese cabbage or Napa. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
	50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	2	2.0 lb/A	7	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2.0 lbs./ai/A. Reduce maximum number of applications from 4 per season to 2 per season. Applications may be made in a minimum of 10-25 gal/A by ground or 1-3 gal/A by air.
	3 lb/gal EC [279-3222]	0.75 lb/A	3	2.0	14	Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Cabbage (grown for seed)</b>						
Foliar treatment Ground or aerial	3 lb/gal EC [WA760012]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial applications using the EC formulation. Cancel aerial application using the WP formulation. Use limited to WA. Applications may be made in a minimum of 20 gal/A by ground or 5 gal/A by air. The grazing of livestock in treated areas and the use of treated crop or crop residue or screening for food or feed are prohibited.*
	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial applications using the EC formulation. Cancel aerial application using the WP formulation. Use limited to OR and WA on cabbage including Chinese cabbage. Applications may be made in a minimum of 20 gal/A by ground or 5 gal/A by air. Use of treated crops or crop residue or sweepings for food or feed and the grazing of livestock on treated areas are prohibited.*
<b>Carrot</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	1	2.0 lb/A	7	Cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Applications may be made in a minimum of 10-25 gal/A by ground or 1 gal/A by air. Use of tops for food or feed is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Carrot, continued</b>						
Foliar treatment Ground or aerial	3 lb/gal EC [279-2149]	1.0 lb/A	1	2.0 lb/A	15	Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of tops for food or feed is prohibited.
<b>Cauliflower</b>						
Foliar treatment Ground or aerial	50% WP [45639-194] [66222-22]  2 lb/gal EC  [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	4	2.0 lb/A	14	See "Brussels sprouts".
	50% WP [279-3129]	1.0 lb/A	3	2.0 lb/A	14	See "Brussels sprouts".
	3 lb/gal EC [279-2149]	0.75 lb/A	2	2.0 lb/A	14	See "Brussels sprouts".
	50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	2	2.0 lb/A	14	See "Brussels sprouts".

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Celery</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	1	1.0 lb/A	4	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 1lbs./ai/A. Application may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	2	1.0 lb/A	7	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 1lbs./ai/A. Application may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Cherry</b>						
Bark treatment Ground	50% WP [279-3129]  3 lb/gal EC [279-2924]	0.75 lb/100 gal	2	.0005 lbs./ai/gal	21	Reduce maximum application rate to 0.005 lbs./ai/gal for high pressure handwands and rights-of-way sprayer. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*
Bark treatment Postharvest Ground	50% WP [45639-194] [66222-22]	0.75 lb/100 gal	2	2.5 lb/A	21	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Cancel aerial application using WP formulation..

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Cherry, continued</b>						
Bark treatment Postharvest Ground	3 lb/gal EC [45639-169]	0.75 lb/100 gal	2	2.5 lb/A	21	Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast applications. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*
Delayed dormant (popcorn or prepink stage) Ground or aerial	50% WP  [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal     2.5 lb/A	2	2.5 lb/A	21	Use limited to Pacific Northwest. Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Cancel aerial application using WP formulation. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Delayed dormant Ground or aerial	50% WP  [279-3129] [45639-194] [66222-22]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/100 gal	2	3.0 lb/A	21	Use limited to MI. Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Cancel aerial application using WP formulation.  Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast applications. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*
Foliar treatment Ground or aerial	50% WP  [279-3129] [45639-194] [45639-198] [66222-22]	0.5 lb/100 gal	2	3.0 lb/A	21	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Cancel aerial application using WP formulation..

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Cherry (continued)</b>						
Foliar treatment Ground or aerial	3 lb/gal EC [279-2924] [45639-169] [45639-197]	2.5 lb/A	2	3.0 lb/A	21	Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast applications. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited. * Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Nursery stock dip	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	2 lb/40 gal	NS	NS	Not applicable (NA)	Immerse trees so that the roots and crowns are covered well above the grafting bud scar; plant immediately or dry before returning to storage. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Citrus (nonbearing trees and nursery stock)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]	0.25 lb/100  2.5 lb/A	2	2.5 lb/A	NS	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Cancel aerial application using WP formulation. Require closed mixing/loading systems for aerial application using the EC formulation. Application to bearing trees or trees that will bear fruit within 12 months is prohibited. Use of the 50% WP (EPA Reg. No. 45639-198) formulation is limited to CA.



Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Citrus (nonbearing trees and nursery stock), continued						
Foliar treatment Ground or aerial	3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100  2.5 lb/A	2	2.5 lb/A	NS	Application to bearing trees or trees that will bear fruit within 12 months is prohibited. Use of the 3 lb/gal EC (EPA Reg. No. 45639-197) formulation is limited to CA.
Collards						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]	1.0 lb/A	1	1.0 lb/A	21	Require all wettable powders to be packaged in water soluble bags. Application may be made in a minimum of 10-25 gal/A by ground or 1 gal/A by air.
	2 lb/gal EC [279-2659] [279-2735] [279-2822]					
	3 lb/gal EC [279-2924] [45639-169]					
	50% WP [45639-198]  3 lb/gal EC [45639-197]	0.75 lb/A	1	0.75 lb/A	21	Use limited to CA. Require all wettable powders to be packaged in water soluble bags. Application may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
Collards (grown for seed)						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powders to be packaged in water soluble bags. Require closed mixing/loading systems for aerial applications using the EC formulation. Cancel aerial application using the WP formulation.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Corn, sweet</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.5 lb/A	1	1.5 lb/A	1	Cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 1.5lbs./ai/A. Require closed mixing/loading systems for aerial application using the EC formulation. Use limited to fresh vegetable; application to sweet corn to be processed is prohibited.* Applications may be made in a minimum of 10 gal/A by ground or 1-5 gal/A by air with a 5-day pretreatment interval. The feeding of treated forage or ensilage to livestock or the grazing of livestock in treated fields is prohibited.* Use of the 3 lb/gal EC (EPA Reg. No. 45639-197) is limited to CA.
<b>Cotton</b>						
Foliar treatment (until bolls open) Ground or aerial	50% WP [279-3129] [45639-194] [66222-22] 2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.5 lb/A	2	1.5 lb/A (aerial)  2.0 lb/A (ground)	NS	Cancel WP use. Reduce rate for ground application to 1.5 lbs./ai/A. Reduce rate for aerial application to 0.75 lbs./ai/A. Require closed mixing/loading systems for aerial application using EC formulation. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A (ground) and reduce maximum seasonal application rate from 3lbs./ai/A to 1.5 lbs./ai/A (aerial). Reduce maximum number of applications per season from 6 to 2. Restrict use on cotton to the following states: AZ, CA, NM, OK, and TX. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The grazing of dairy or meat animals in treated fields and application after bolls open are prohibited.* Use of the 3 lb/gal EC (EPA Reg. No. 45639-197) is limited to CA.
	3 lb/gal EC [279-2149] [279-3222]	1.5 lb/A	2	1.5.0 lb/A (aerial)  2.0 lb/A (ground)	NS	Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The grazing of dairy or meat animals in treated fields and application after bolls open are prohibited.*

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Cotton (continued)</b>						
Foliar treatment (after bolls open) Ground or aerial	2 lb/gal EC [AZ930014] [AZ930016]	0.75 lb/A	NS	1.5.0 lb/A (aerial) 2.0 lb/A (ground)	14	Use limited to AZ. Applications may be made in a minimum of 10 gal/A using ground or aerial equipment.
<b>Cucumber</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	4	2.0 lb/A	2	Require all wettable powders be packaged in water soluble bags. Reduce maximum number of applications per season from 6 to 4. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
	50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	3	2.0 lb/A	2	Use limited to CA. Require all wettable powders be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Maintain maximum number of applications per season at 3. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Eggplant</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] 3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	2	2.0 lb/A	1	Require all wettable powders be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
<b>Eggplant, continued</b>						
Foliar treatment Ground or aerial	3 lb/gal EC [45639-197]	0.5 lb/A	2	2.0 lb/A	1	Use limited to CA. Require all wettable powders be packaged in water soluble bags. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
	50% WP [45639-198]	0.5 lb/A	1	2.0 lb/A	1	Use limited to CA. Require all wettable powders be packaged in water soluble bags Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
<b>Filbert</b>						
Foliar treatment Ground or aerial	50% WP [279-1380] [279-3129] [45639-194] [45639-198] [66222-22]	0.5 lb/100 gal  2.0 lb/A	1	2.0 lb/A	1	Require all wettable powders to be packaged in water soluble bags. Cancel aerial application using the WP formulation. Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast application. Reduce maximum seasonal application rate from 2 per season to 1. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. The grazing of livestock on orchard crops or grasses in treated areas is prohibited. * Use of the 50% WP (EPA Reg. No. 45639-198) formulation is limited to CA.
	50% WP [OR780020]	0.5 lb/100 gal (300 gal/A; dilute)  1.5 lb/A (25 gal/A; concentrate)	NS	NS	NS	Use limited to OR. Application may be made in a minimum of 300 gal of water/A (dilute) or in 25 gal of water/A (concentrate). The grazing of livestock in treated groves is prohibited.* No PHI has been established.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Grape</b>						
Foliar treatment Ground (preferred)	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Endosulfan use on grapes canceled
Foliar treatment Ground	3 lb/gal EC [CA760115]	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Endosulfan use on grapes canceled
<b>Kale</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.75 lb/A	1	0.75 lb/A	21	Reduce maximum application rate to 0.75 lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Application Type Application Timing Application Equipment						
<b>Kale (grown for seed)</b>						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using EC formulation. Cancel aerial application using the WP formulation.
<b>Kohlrabi (grown for seed)</b>						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using EC formulation. Cancel aerial application using the WP formulation.
<b>Lettuce, head</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	2	2.0 lb/A	14	Require all wettable powder formulations to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce number of applications per season from 3 to 2. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The feeding of crop refuse to livestock is prohibited. * Remove wrapper leaves at harvest.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Lettuce, leaf</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	2	2.0 lb/A	14	Require all wettable powder formulations to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Number of applications per season will remain at 2 in CA. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The feeding of crop refuse to livestock is prohibited. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Macadamia nut</b>						
Foliar treatment Ground or aerial	2 lb/gal EC [279-2659] [279-2822]	1.0 lb/100 gal	2	2.0 lb/A	1	Require all wettable powders to be packaged in water soluble bags. Cancel aerial application using the WP formulation. Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast application. Reduce maximum seasonal application rate from 2 per season to 1. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. The grazing of livestock on orchard crops or grasses in treated areas is prohibited.
Foliar treatment Ground	50% WP [HI880008]	1.0 lb/100 gal	2	2.0 lb/A	2	Use limited to HI. The grazing of livestock on orchard crops or grasses in treated areas.* Application by aircraft is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Melons						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]	1.0 lb/A	4	2.0 lb/A	2	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 4 (except in CA where the application per season will remain at 3.
	2 lb/gal EC [279-2659]					
	3 lb/gal EC [279-2924] [45639-169]					
	50% WP [45639-198]					
	3 lb/gal EC [45639-197]	1.0 lb/A	3	2.0 lb/A	2	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 4 (except in CA where the application per season will remain at 3.
Mustard greens						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]	0.75 lb/A	1	0.75 lb/A	21	Reduce maximum application rate to 0.75 lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags Application may be made in a minimum of 10 gal/A by ground or 1 gal/A by air.
	2 lb/gal EC [279-2659] [279-2822]					
	3 lb/gal EC [279-2924] [45639-169]					



Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Mustard greens (continued)</b>						
Foliar treatment Ground or aerial	50% WP [45639-198]  3 lb/gal EC [45639-197]	0.75 lb/A	1	0.75 lb/A	21	Reduce maximum application rate to 0.75 lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Application may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
	50% WP [WA780029]  3 lb/gal EC [OR770043]	0.75 lb/A	1	0.75 lb/A	NS	Reduce maximum application rate to 0.75 lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags.
<b>Nectarine</b>						
Bark treatment Postharvest Ground	50% WP [279-3129] [45639-194]  2 lb/gal EC [279-2659] [279-2822] 3 lb/gal EC [279-2924] [45639-169]	0.75 lb/100 gal (Pacific Northwest)  2.5 lb/100 gal (Southeastern states)	2	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.
	50% WP [279-1380]	0.75 lb/100 gal (West coast)	2	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Nectarine (Continued)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	30	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.
<b>Oats</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924]	0.5 lb ai/A	1	1.0 lb/A	NS	Cancel WP use. Require closed mixing/loading systems for aerial application using EC formulation. Reduce maximum number of applications from 2 per season to 1.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Oats (continued)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.75 lb/A	1	1.0 lb/A	NS	Cancel WP use. Require closed mixing/loading systems for aerial application using EC formulation. Reduce maximum number of applications from 2 per season to 1.
<b>Peach</b>						
Bark treatment Postharvest Ground	50% WP [279-3129] [45639-194]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.75 lb/100 gal (Pacific Northwest)  2.5 lb/100 gal (Southeastern states)	2	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.
	50% WP [279-1380] [66222-22]	0.75 lb/100 gal (West coast)  2.5 lb/100 gal (Southeastern states)	2	2.5 lb/A	21	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Peach (continued)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	30	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications.
Nursery stock dip	50% WP [27-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.005 lbs./ai/ gal	NS	NS	NA	Reduce maximum application rate to 0.005 lbs lbs.ai/A from 0.4 lbs/ai/gal for high pressure handwand and rights-of way sprayers.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Pear</b>						
Delayed dormant and foliar (during white bud or petal fall) Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	2.5 lb/A	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Application may be made in a minimum of 10-20 gal of water/A by air, in 40 gal (semi-concentrate), or in 300 gal (dilute). The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited. * Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
	2 lb/gal EC [279-2822]	0.75 lb/100 gal [300 gal of finished spray/A]	2	2.5 lb/A	7	The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.*

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Pear (continued)</b>						
Soil treatment Prebloom Ground	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  [200-400 gal of finished spray/A]	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Applications may be made to the orchard floor. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited. * Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Postharvest or dormant Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. The feeding of cull fruits to animals or allowing livestock to graze in treated orchards is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Peas, succulent, Dry Peas</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	Succulent Green Peas Canceled  Dry Peas  1.0 lb/A	Succulent Green Peas Canceled  Dry Peas  2	Succulent Green Peas Canceled  Dry Peas  2.0 lb/A	Succulent Green Peas Canceled  Dry Peas  3	See "Bean, succulent and dry".
	2 lb/gal EC [279-2659] [279-2822]	1.0 lb/A	2	2.0 lb/A	1	Use limited to the Northwest (EPA Reg. No. 279-2659). Use limited on peas to be harvested by combine only. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The feeding of treated vines or threshing to livestock or allowing livestock to graze in treated fields is prohibited.*
<b>Dry Peas</b>						
	3 lb/gal EC [279-2924]	1.0 lb/A	2 per fruiting period	2.0 lb/A	5	Use limited on peas to be harvested by combine only. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The feeding of treated vines or threshing to livestock or allowing livestock to graze in treated fields is prohibited.*
	3 lb/gal EC [W1920007]	1.0 lb/A	2 per fruiting period	2.0 lb/A	NS	Use limited to WI on peas to be harvested by combine only. Applications may be made in a minimum of 10 gal/A by ground or 2 gal/A by air. The grazing of treated fields or the feeding of treated forage or threshing to livestock is prohibited.*

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Pecan</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	Canceled	Canceled	Canceled	Canceled	Endosulfan use on pecans is canceled
<b>Pepper</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	2	2.0 lb/A	4	Require all wettable powders to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A.



Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Pepper (continued)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	2	2.0 lb/A	4	Require all wettable powder formulations to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Pineapple</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-197]	2.0 lb/A	2	3.0 lb/A	7	Cancel use of WP formulation. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air with a 7- to 10-day pretreatment interval. The feeding of treated forage or pineapple byproducts to livestock is prohibited.* Use of the 3 lb/gal EC (EPA Reg. No. 45639-197) is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Plum</b>						
Delayed dormant (during pre-pink stage) Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications. Use limited to the Pacific Northwest. The grazing of livestock on treated orchard crops or grasses in treated areas is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Prebloom or foliar (petal fall) Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	Reduce maximum application rate to 2.5lbs./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Cancel aerial applications using WP formulation. Require closed mixing/loading systems for aerial applications using the EC formulation. Require closed cabs for airblast applications The grazing of livestock on treated orchard crops or grasses in treated areas is prohibited. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639- 197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Plum (continued)</b>						
Foliar treatment Ground or aerial	50% WP [45639-194] [45639-198]	0.75 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	The grazing of livestock on treated orchard crops or grasses in treated areas is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) formulation is limited to CA.
Bark treatment Postharvest Ground	50% WP [279-3129] [45639-194] [45639-198]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [45639-169] [45639-197]	0.75 lb/100 gal  2.5 lb/A	2	0.005 lbs/ai/gal	7	Reduce maximum application rate to 0.005 lbs./ai/gal for high pressure handwand and rights-of-way sprayer scenarios. The grazing of livestock on treated orchard crops or grasses in treated areas is prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Bark treatment Ground	50% WP [66222-22]  3 lb/gal EC [279-2924]	0.75 lb/100 gal  2.5 lb/A	2	0.005 lbs/ai/gal	7	Reduce maximum application rate to 0.005 lbs./ai/gal for high pressure handwand and rights-of-way sprayer scenarios. The grazing of livestock on treated orchard crops or grasses in treated areas is prohibited.*

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Plum (continued)</b>						
Nursery stock dip	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	2 lb/40 gal	NS	NS	NA	Reduce maximum application rate of 0.005 lbs./ai/A from high pressure handwand and rights-of-way sprayer scenarios.
<b>Potato</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	4	2.0 lb/A	1	Require all wettable powder formulations to be packaged in water soluble bags. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Reduce maximum number of applications per season from 6 to 4. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
Chemigation Sprinkler irrigation	3 lb/gal EC [WA900023]	1.0 lb/A	NS	2.0 lb/A	1	Use limited to WA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Prune</b>						
Delayed dormant (during pre-pink stage) Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	See "Plum".
Prebloom or foliar (petal fall) Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.5 lb/100 gal  2.5 lb/A	2	2.5 lb/A	7	See "Plum".

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Prune (continued)</b>						
Bark treatment Postharvest Ground	50% WP [279-3129] [45639-194] [45639-198]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [45639-169] [45639-197]	0.75 lb/100 gal  2.5 lb/A	2	0.005 lbs./ai/gal	7	Reduce maximum seasonal application rate to 0.005 lbs./ai/gal for high pressure handwand and rights-of-way sprayer scenarios.
Bark treatment Ground	50% WP [66222-22]  3 lb/gal EC [279-2924]	0.75 lb/100 gal  2.5 lb/A	2	0.005 lbs./ai/gal	7	Reduce maximum seasonal application rate to 0.005 lbs./ai/gal for high pressure handwand and rights-of-way sprayer scenarios.
<b>Pumpkin</b>						
Foliar treatment Ground or aerial	50% WP  [279-3129] [45639-194] 2 lb/gal EC [279-2659] 3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	4	2.0 lb/A	2	See "Cucumber".
	3 lb/gal EC [45639-197]	1.0 lb/A	4	2.0 lb/A	2	See "Cucumber".

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Radish (grown for seed)</b>						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using the EC formulation. Cancel aerial application using the WP formulation.
<b>Rutabaga (grown for seed)</b>						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using the EC formulation. Cancel aerial application using the WP formulation.
<b>Rye</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924]	0.75 lb/A	1	1.0 lb/A	NS	Cancel WP use. Require closed mixing/loading systems for aerial application using EC formulation. Reduce maximum number of applications from 2 per season to 1.

Site	Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
		50% WP [279-3129] [66222-22]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	0.75 lb/A	2	1.0 lb/A	NS	Cancel WP use. Require closed mixing/loading systems for aerial application using EC formulation. Reduce maximum number of applications from 2 per season to 1.
<b>Spinach</b>							
Foliar treatment Ground or aerial		50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	Canceled	Canceled	Canceled	Canceled	Endosulfan use on spinach is canceled
		50% WP [45639-198]  3 lb/gal EC [45639-197]	Canceled	Canceled	Canceled	Canceled	Endosulfan use on spinach is canceled



Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Squash, summer and winter</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	4	2.0 lb/A	2	Require all wettable powder formulations to be packaged in water soluble bags. Reduce the maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Reduce maximum number of applications per season from 6 to 4.
	50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	4	2.0 lb/A	2	Require all wettable powder formulations to be packaged in water soluble bags. Reduce the maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Reduce maximum number of applications per season from 6 to 4.
<b>Strawberry</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A	3	2.0 lb/A	4	Reduce maximum application rate to 1 lb./ai/A. Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using EC formulation. Cancel aerial application using WP formulation. Reduce maximum seasonal application rate from 3lbs./ai/A to 2lbs./ai/A. Reduce maximum number of applications from 3 per season to 2 per season. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Do not reapply within 15 days or more than twice during a 35 day period when fruit is present. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
		1.0 lb/A	3	2.0 lb/A	4	Applications may be made in 400 gal. Do not apply at intervals less than 35 days when fruit is present. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site	Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
	Dip treatment	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822] 3 lb/gal EC [279-2924]	1.0 lb/100 gal	NS	NS	NA	Use limited to Northwest. Immerse bundles of plants; drain and allow plants to dry before setting them out in the field. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Sweet potato</b>							
	Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [66222-22]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A	32	1.0 lb/A	1	Cancel WP use. Require closed mixing/loading systems for aerial application using the EC formulation. Reduce maximum seasonal applications rate from 3lbs./ai/A to 2lbs./ai/A. Reduce maximum number of applications per season from 3 to 2. The feeding of cull potatoes to livestock or the grazing of livestock in treated fields is prohibited.*
		50% WP [45639-198]  3 lb/gal EC [45639-197]	1.0 lb/A	2	1.0 lb/A	1	Use limited to CA. The feeding of cull potatoes to livestock or the grazing of livestock in treated fields is prohibited.*
		50% WP [MS810036]  3 lb/gal EC [MS810035]	0.5 lb/A	NS	NS	NS	Use limited to MS. The feeding of treated potatoes to livestock is prohibited. *

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Sweet potato (continued)						
Soil band or broadcast Ground or aerial	50% WP [279-3129] [66222-22]  3 lb/gal EC [279-2924] [45636-169]	2.0 lb/A (broadcast)  0.67-0.75 lb/A based on a 16 inch band with a 48 inch row spacing	2	2.0 lb/A	1	Use limited to South central states and PR. The feeding of cull potatoes to livestock or the grazing of livestock in treated fields is prohibited.*
Soil treatment Ground or aerial	50% WP [MS8100036]	2.0 lb/A	NS	NS	NS	Use limited to MS. The feeding of treated potatoes to livestock is prohibited.*
	3 lb/gal EC [MS810035]	1.5 lb/A	NS	NS	NS	
Tobacco						
Foliar treatment Seed bed Ground	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.5 lb/100 gal [6 gal of finished spray/100 sq. yd]	2	2.0 lb/A	5	Cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 2. Restrict use on tobacco to the following states: IN, KY, OH, PA, and WV.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
Drench treatment Plant bed Ground	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	0.25 lb/100 gal [1 gal of finished spray/sq. yd]	2	2.0 lb/A	5	Cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 2. Restrict use on tobacco to the following states: IN, KY, OH, PA, and WV.
<b>Tobacco (continued)</b>						
Foliar treatment Field Ground	50% WP [279-3129] [45639-194] [66222-22]  2 lb/gal EC [279-2659] [279-2822]  3 lb/gal EC [279-2924] [45639-169]	1.0 lb/A  1.5 lb/100 gal  1.0 lb/A  0.5 lb/100 gal	2  2	2.0 lb/A  1.0 lb/A	5  5	Cancel WP use. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 2. Restrict use on tobacco to the following states: IN, KY, OH, PA, and WV.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Tomato (field)</b>						
Foliar treatment Ground or aerial	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A  0.5 lb/100-200 gal	2	2.0 lb/A	2	Cancel WP use. Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A. Reduce maximum number of applications per season from 6 to 4. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.
<b>Tomato (greenhouse)</b>						
Foliar treatment Ground	50% WP [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2735] [279-2822]  3 lb/gal EC [279-2924] [45639-169] [45639-197]	1.0 lb/A  0.5 lb/100-200 gal	4	0.005 lbs/ai/gal	2	Reduce maximum application rate to 0.005 lbs./ai/gal for high pressure handwand and rights-of-way sprayers. Applications may be made in a minimum of 10-25 gal/A by ground. Use of the 50% WP (EPA Reg. No. 45639-198) and the 3 lb/gal EC (EPA Reg. No. 45639-197) formulations is limited to CA.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Turnip</b>						
Foliar treatment Ground or aerial	2 lb/gal EC [279-2659] [279-2822]	0.75 lb/A	1	0.75 lb/A	21	Reduce maximum application rate to 0.75 lbs/ai/A. Require all wettable powders to be packaged in water soluble bags. Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. Application to turnips grown for roots is prohibited.*
<b>Turnip (grown for seed)</b>						
Foliar treatment Ground or aerial	50% WP [WA780029]  3 lb/gal EC [OR770043] [WA770016]	2.0 lb/A	2	NS	NS	Require all wettable powder formulations to be packaged in water soluble bags. Require closed mixing/loading systems for aerial application using the EC formulation. Cancel aerial application using the WP formulation.
<b>Walnut</b>						
Foliar treatment Ground or aerial	50% WP  [279-3129] [45639-194] [45639-198] [66222-22]  2 lb/gal EC [279-2659] [279-2822]	2.0 lb/A	2	2.0 lb/A	NS	Require all wettable powders to be packaged in water soluble bags. Cancel aerial application using the WP formulation. Require closed mixing/loading systems for aerial application using the EC formulation. Require closed cabs for airblast application. Reduce maximum seasonal application rate from 2 per season to 1. Reduce maximum seasonal application rate from 3lbs./ai/A to 2 lbs./ai/A Applications may be made in a minimum of 10 gal/A by ground or 1 gal/A by air. The grazing of livestock on orchard crops or grasses in treated areas and application after husk split are prohibited.* Use of the 50% WP (EPA Reg. No. 45639-198) formulation is limited to CA.
	3 lb/gal EC [279-2924] [45639-169]	2.0 lb/A	2	2.0 lb/A	NS	

NS = Not Specified

## Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

### GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0014 (endosulfan) covered by this RED. It contains generic data requirements that apply to endosulfan in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  - A. Terrestrial food
  - B. Terrestrial feed
  - C. Terrestrial non-food
  - D. Aquatic food
  - E. Aquatic non-food outdoor
  - F. Aquatic non-food industrial
  - G. Aquatic non-food residential
  - H. Greenhouse food
  - I. Greenhouse non-food
  - J. Forestry
  - K. Residential
  - L. Indoor food
  - M. Indoor non-food
  - N. Indoor medical
  - O. Indoor residential
3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
<b>PRODUCT CHEMISTRY</b>				
830.1550	61-1	Product Identity and Composition	A,B,C,H	00128650, 42932001, 42932002, 42932003, 42932004, 42932005, 42932006, 42932007
830.1600	61-2A	Start. Mat. & Mfg. Process	A,B,C,H	00128650, 42932001, 42932002, 42932003, 42932004, 42932005, 42932006, 42932007
830.1670	61-2B	Formation of Impurities	A,B,C,H	00128650, 42932001, 42932002, 42932003, 42932004, 42932005, 42932006, 42932007
830.1700	62-1	Preliminary Analysis	A,B,C,H	00128662, 42919102
830.1750	62-2	Certification of limits	A,B,C,H	00128650, 42932001, 42932002, 42932003, 42932004, 42932005, 42932006, 42932007
830.1800	62-3	Analytical Method	A,B,C,H	00128662, 42932001, 42932002, 42932003, 42932004, 42932005, 42932006, 42932007
830.6302	63-2	Color	A,B,C,H	00128650, 00128657
830.6303	63-3	Physical State	A,B,C,H	00128650, 00128657
830.6304	63-4	Odor	A,B,C,H	00128650, 00128657
830.7200	63-5	Melting Point	A,B,C,H	00128657
830.7220	63-6	Boiling Point	A,B,C,H	00128657
830.7300	63-7	Density	A,B,C,H	00128657
830.7840 830.7860	63-8	Solubility	A,B,C,H	00128657
830.7950	63-9	Vapor Pressure	A,B,C,H	00128657
830.7370	63-10	Dissociation Constant		Not Applicable
830.7550	63-11	Octanol/Water Partition Coefficient	A,B,C,H	00128657
830.7000	63-12	pH	A,B,C,H	00128657
830.6313	63-13	Stability	A,B,C,H	00128657
830.6314	63-14	Oxidizing/Reducing Action	A,B,C,H	00128650
830.6314	63-15	Flammability	A,B,C,H	00128650
830.6316	63-16	Explosibility	A,B,C,H	00128650
830.6316	63-17	Storage Stability	A,B,C,H	00128650
830.7100	63-18	Viscosity	A,B,C,H	00128650
830.6319	63-19	Miscibility	A,B,C,H	00128650
830.6320	63-20	Corrosion Characteristics	A,B,C,H	00128650
830.7050	None	UV/Visible Absorption		Not Applicable
<b>ECOLOGICAL EFFECTS</b>				
850.2100	71-1 A	Avian Acute Oral Toxicity (Quail or Duck)	A,B,C	137189, 00136998, 00137189
850.2100	None	Avian Acute Oral Toxicity of Bobwhite Quail and Mallard Duck (Endosulfan Sulfate)	A,B,C	DATA GAP



## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.2200	71-2A	Avian Dietary Toxicity - Quail	A,B,C	22923
850.2200	None	Avian Subchronic Oral Toxicity of Bobwhite Quail and Mallard Duck (Endosulfan Sulfate)	A,B,C	DATA GAP
850.2200	71-2B	Avian Dietary Toxicity - Duck	A,B,C	22923
850.2400	71-3	Wild Mammal Toxicity	A,B,C	00038307, 00148264
850.2300	71-4A	Avian Reproduction - Quail	A,B,C	40261303
850.2300	71-4B	Avian Reproduction - Duck	A,B,C	40261302, 40335001, 40335002, 146843
850.2300	71-4 (A)	Avian Reproduction - Quail (Endosulfan Sulfate)	A,B,C	DATA GAP
850.2300	71-4 (B)	Avian Reproduction - Duck (Endosulfan Sulfate)	A,B,C	DATA GAP
850.1075	72-1A	Fish Toxicity Bluegill	A,B,C	38806, 40094602,
850.1075	None	Freshwater Fish Acute Toxicity Bluegill Sunfish (Endosulfan Sulfate)	A,B,C	DATA GAP
850.1075	72-1C	Fish Toxicity Rainbow Trout	A,B,C	40098001, 00136998
850.1010	72-2A	Invertebrate Toxicity	A,B,C	5008271, 40098001, 40094602
NONE	72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	40228401
850.1075	None	Estuarine /Marine Fish Acute Toxicity Study (Endosulfan Sulfate)	A,B,C	DATA GAP
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C	40228401, 128688
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C	40228401, 128688
850.1300	72-4A	Fish- Early Life Stage	A,B,C	DATA GAP
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A,B,C	DATA GAP
850.1035	None	Estuarine/Marine Invertebrate Acute Toxicity Study of Mysid Shrimp (Endosulfan Sulfate)	A,B,C	DATA GAP
850.1500	72-5	Life Cycle Fish	A,B,C	DATA GAP

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
850.1500	None	Freshwater Fish Full Life Cycle Using Rainbow Trout (Endosulfan Sulfate)	A,B,C	DATA GAP
850.1735	None	Whole Sediment Acute Toxicity Testing Using Freshwater Invertebrate	A,B,C	DATA GAP
850.1740	None	Whole Sediment Acute Toxicity Testing Using Estuarine/Marine Invertebrate	A,B,C	DATA GAP
850..1735S	None	Whole Sediment Chronic Toxicity Testing Using Freshwater Invertebrate	A,B,C	DATA GAP
850.1740S	None	Whole Sediment Chronic Toxicity Testing Using Estuarine/Marine Invertebrate	A,B,C	DATA GAP
Special Study	None	Tissue Residue Toxicity Study in Fish	A,B,C	RESERVE
Special Study	None	Tissue Residue Toxicity Study in Amphibians	A,B,C	RESERVE
164-2SS	None	Vegetative Buffer Effectiveness Study	A,B,C	DATA GAP
835.7100	None	Groundwater Monitoring	A,B,C	DATA GAP
835.7200	None	Surfacewater Monitoring	A,B,C	DATA GAP
850.4230	123-1	Non-target Terrestrial Plant Phytotoxicity	A,B,C	Not Applicable
850.4400	123-2	Aquatic Plant Growth	A,B,C	Not applicable
<b>OCCUPATIONAL/RESIDUE EXPOSURE</b>				
875.2100	132-1(a)	Foliar Residue Dissipation	A,B,C	44403102
875.2200	132-1B	Soil Residue Dissipation	A,B,C	Not Applicable
875.2400	133-3	Dermal Passive Dosimet	A,B,C	Not Applicable
NONE	133-4	Inhalation Passive Dosimet		WAIVED
NONE	201-1	Droplet Size Spectrum	A,B,C	Not Applicable
NONE	202-1	Drift Field Evaluation	A,B,C	Not applicable
NONE	231	Estimation of Dermal Exposure	A,B,C	41715201, 44939101
NONE	232	Estimation of Inhalation Exposure	A,B,C	41715201
NONE	85-3	Dermal Absorption	A,B,C	40223601, 41048503, 41048504

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
875.1100	None	Dermal Outdoor Exposure For Applying Dip Treatments to Trees, Roots, and Whole Plants	A,B,C	DATA GAP
875.1700	None	Product Use Information for Applying Dip Treatments to Trees, Roots, and Whole Plants	A,B,C	DATA GAP
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral Toxicity-Rat	A,B,C,H	00038307, 41183502
870.1100	81-1	Acute Oral Toxicity-Rat	A,B,C,H	00038307, 41183502
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A,B,C,H	41183503
870.1300	81-3	Acute Inhalation Toxicity-Rat	A,B,C,H	41183504
870.2400	81-4	Primary Eye Irritation-Rabbit	A,B,C,H	255157, 41183505
870.2500	81-5	Primary Skin Irritation	A,B,C,H	00038309, 00128649, 41183506
870.2600	81-6	Dermal Sensitization	A,B,C,H	00136994, 41183507
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A,B,C,H	00147181, 44403101, 44560701, 44560702
870.6200	81-8	Acute Neurotoxicity Screen	A,B,C,H	44403101
870.6200	82-7	Subchronic Neurotoxicity - Rat	A,B,C,H	DATA GAP
870.6300	83-6	Developmental Neurotoxicity Study - Rat	A,B,C,H	DATA GAP
870.3100	82-1A	90-Day Feeding - Rodent	A,B,C,H	00257932, 00257727, 00147299, 40767601, 41775501
870.3150	82-1B	90-Day Feeding - Non-rodent	A,B,C,H	00147182, 40648801
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A,B,C,H	00146841, 00147744, 41048505, 41048506
NONE	82-4	90 Day Inhalation-Rat	A,B,C,H	00147183, 41667501, 41667502, 41667503
NONE	82-5A	90 Day Neurotox -Hen		RESERVED
NONE	82-5B	90 Day Neurotox - Mammal		RESERVED
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	A,B,C,H	41099502
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B,C,H	41099501
870.4200	83-2A	Oncogenicity - Rat	A,B,C,H	41099501, 41099502
870.4200	83-2B	Oncogenicity - Mouse	A,B,C,H	40792401
870.3700	83-3A	Developmental Toxicity - Rat	A,B,C,H	43129101

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
870.3700	83-3B	Developmental Toxicity - Rabbit	A,B,C,H	00094837
870.3800	83-4	2-Generation Reproduction - Rat	A,B,C,H	00256126, 00256127, 00257727, 00148264
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A,B,C,H	41099502
870.5140	84-2A	Gene Mutation (Ames Test)	A,B,C,H	00147199, 00148266
870.5375	84-2B	Structural Chromosomal Aberration	A,B,C,H	00147197, 00148265
	84-4	Other Genotoxic Effects	A,B,C,H	00147198
870.7485	85-1	General Metabolism	A,B,C,H	00004257
<b>ENVIRONMENTAL FATE</b>				
835.2120	161-1	Hydrolysis	A,C,H	00150714, 00142649, 00128661, 00128557, 00128659, 41412901
835.2240	161-2	Photodegradation - Water	A,C,H	00253395, 41415701, 41490101
835.2410	161-3	Photodegradation - Soil	A,C,H	00128660, 00142640, 00150714, 41430701
835.2370	161-4	Photodegradation - Air	A,C,H	WAIVED
835.4100	162-1	Aerobic Soil Metabolism	A,C,H	00148993, 41412902, 43812801
835.4200	162-2	Anaerobic Soil Metabolism	A,C,H	00136884, 41412903, 41412904
835.1240	163-1	Leaching/Adsorption/Desorption	A,C,H	00137002, 00137162, 00137446, 41412905, 44346901
NONE	163-2	Volatility-Lab	A,C,H	00252043, 40060601
835.6100	164-1	Terrestrial Field Dissipation	A,C,H	00137003, 00137161, 41309701, 41309702, 41468601, 43069701
860.1850	165-1	Confined Rotational Crop	A,C,H	44393001
860.1900	165-2	Field Rotational Crop	A,C,H	DATA GAP
NONE	165-4	Bioaccumulation in Fish	A,C,H	41421503
<b>RESIDUE CHEMISTRY</b>				
NONE	171-2	Chemical Identity		Not Applicable
860.1300	171-4A	Nature of Residue - Plants	A,B	00003600, 00003642, 00003654, 05002565, 05003004, 05003085, 05003336, 05003801, 05004385, 05004620, 05018169, 44082701, 44082702, 44099101
860.1300	171-4B	Nature of Residue - Livestock	A,B	00003742, 00003743, 00003838, 00003840, 05003222, 05003877, 44082703, 44099101, 440099102, 44427601
860.1340	171-4C	Residue Analytical Method -plants	A,B	00003588, 00003612, 00003795, 00003959, 05003395, GS014024, 00146842, 00157147, 00157148, 44346902
860.1340	171-4D	Residue Analytical Method-Animal	A,B	00003703, 00003840, 44427601
860.1360	171-4M	Multiresidue Methods	A,B	44427601
860.1380	171-4E	Storage Stability	A,B	44396301, 44599600, 44599601, 44637800

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1380	171-4E	Storage Stability	A,B	DATA GAP - oils seed, non-oily grain and processed commodities
860.1480	171-4J	Meat, Milk, Poultry, Eggs  Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses and Sheep  Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A,B	44843702  00003742, 00003743, 00003838, 05003222, 05003877, 05013696  00003840, 44843702
860.1500	171-4K	Crop Field Trials (Carrot)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Potato)	A,B	00003709
860.1500	171-4K	Crop Field Trials (Sweet Potato)	A,B	00003642, 00003669, 44346912
Leaves of Root and Tuber Vegetables Group				
860.1500	171-4K	Turnip, Tops	A,B	00003796
Leafy Vegetables (except Brassica) Vegetables Group				
860.1500	171-4K	Crop Field Trials (Celery)	A,B	00003796, 44346906, 44701201
860.1500	171-4K	Crop Field Trials (Lettuce, Leaf)	A,B	00003722, 00003790, 44346904, 44701202
860.1500	171-4K	Crop Field Trials (Spinach)	A,B	00003796
Brassica (Cole) Vegetables Group				
860.1500	171-4K	Crop Field Trials (Broccoli)	A,B	00003796, 44346908
860.1500	171-4K	Crop Field Trials (Brussels Sprouts)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Cabbage)	A,B	00003790
860.1500	171-4K	Crop Field Trials (Cauliflower)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Collards)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Collards, Grown for Seed)	A,B	Not Applicable
860.1500	171-4K	Crop Field Trials (Kale)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Mustard Greens)	A,B	00003796
Legume Vegetables Group				
860.1500	171-4K	Crop Field Trials (Bean, Dry and Succulent)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Eggplant)	A,B	00003796
860.1500	171-4K	Crop Field Trials (Pea, Succulent)	A,B	00003917, 00003949

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1500	171-4K	Crop Field Trials (Pea, Grown for Seed)	A,B	00003917, 00003949
860.1500	171-4K	Crop Field Trials (Pepper)	A,B	00003864
860.1500	171-4K	Crop Field Trials (Tomatoes)	A,B	00003783, 00146842, 44346905
Cucurbit Vegetables Group				
860.1500	171-4K	Crop Field Trials (Cucumber)	A,B	00146842, 44346909
860.1500	171-4K	Crop Field Trials (Melons, Cantaloupe)	A,B	00146842, 44346903
860.1500	171-4K	Crop Field Trials (Melons, Musk)	A,B	00146842, 44346903
860.1500	171-4K	Crop Field Trials (Melons, Water)	A,B	00146842, 44346903
860.1500	171-4K	Crop Field Trials (Pumpkin)	A,B	00146842, 44346909, 44346903, 44346907
860.1500	171-4K	Crop Field Trials (Squash, Summer)	A,B	00146842, 44346907
860.1500	171-4K	Crop Field Trials (Squash, Winter)	A,B	00146842, 44346907
Pome Fruits Group				
860.1500	171-4K	Crop Field Trials (Apple)	A,B	00003787
860.1500	171-4K	Crop Field Trials (Pear)	A,B	00003862
Stone Fruits Group				
860.1500	171-4K	Crop Field Trials (Cherry)	A,B	00003782, 44346910, 44346911
860.1500	171-4K	Crop Field Trials (Peach)	A,B	00003784, 00003789
860.1500	171-4K	Crop Field Trials (Plume, Fresh Prune)	A,B	00003786, 00003791
Berries Group				
860.1500	171-4K	Crop Field Trials (Blueberry)	A,B	00003587, 00003843
Tree Nuts Group				
860.1500	171-4K	Crop Field Trials (Almond, Nutmeat and Hulls)	A,B	00003713, 00004254
860.1500	171-4K	Crop Field Trials (Filbert)	A,B	00004254
860.1500	171-4K	Crop Field Trials (Macadamia Nut)	A,B	00004254
860.1500	171-4K	Crop Field Trials (Pecan)	A,B	00004254
860.1500	171-4K	Crop Field Trials (Walnut)	A,B	00004254
Cereal Grains Group				
860.1500	171-4K	Crop Field Trials (Barley, Grain)	A,B	00003710

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1500	171-4K	Crop Field Trials (Corn, Sweet, K + CWHR)	A,B	00003634, 00003760, 44457001
860.1500	171-4K	Crop Field Trials (Oats, Grain)	A,B	00003710
860.1500	171-4K	Crop Field Trials (Rye, Grain)	A,B	00003710
860.1500	171-4K	Crop Field Trials (Wheat, Grain and Aspirated Grain Fractions)	A,B	00003710
Forage, Fodder, and Straw of Cereal Grains Group				
860.1500	171-4K	Crop Field Trials Barley, Hay and Straw	A,B	00003710, DATA GAP
860.1500	171-4K	Crop Field Trials (Corn, Sweet, Forage and Stover)	A,B	44457001
860.1500	171-4K	Crop Field Trials (Oats, Forage, Hay and Straw)	A,B	00003710
860.1500	171-4K	Crop Field Trials (Rye, Forage and Straw)	A,B	00003710, DATA GAP
860.1500	171-4K	Crop Field Trials (Wheat, Forage, Hay, and Straw)	A,B	00003710, 44762901
Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay) Group				
860.1500	171-4K	Crop Field Trials (Alfalfa, Forage and Hay)	A,B	00003834, 00003835, 00003836, 00003841, 00004258, 00157148
Miscellaneous Commodities				
860.1500	171-4K	Crop Field Trials (Cotton, Seed and Gin Byproducts)	A,B	00003725, 00003777, 44854101, 44854102, 44854103
860.1500	171-4K	Crop Field Trials (Grape)	A,B	00003788
860.1500	171-4K	Crop Field Trials (Pineapple)	A,B	00003797, 00003798, 00003799
860.1500	171-4K	Crop Field Trials (Rape, Seed and Forage)	A,B	00003724
860.1500	171-4K	Crop Field Trials (Strawberry)	A,B	00003785
860.1500	171-4K	Crop Field Trials (Tobacco)	A,B	05003004, 05003801, DATA GAP
Processed Food/Feed				
860.1520	171-4L	Processed Food (Apple)	A,B	00156259, 44933001
860.1520	171-4L	Processed Food (Barley)	A,B	DATA GAP
860.1520	171-4L	Processed Food (Cotton Seed)	A,B	00003726

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of Endosulfan

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
860.1520	171-4L	Processed Food (Grapes)	A,B	00156259, 44346915
860.1520	171-4L	Processed Food (Oats)	A,B	DATA GAP
860.1520	171-4L	Processed Food (Pineapple)	A,B	00146997, 00156259, 00157147
860.1520	171-4L	Processed Food (Potato)	A,B	44346913
860.1520	171-4L	Processed Food (Rye)	A,B	DATA GAP
860.1520	171-4L	Processed Food (Tomato)	A,B	00146842, 44346914
860.1520	171-4L	Processed Food (Wheat)	A,B	44762901
<b>OTHER</b>				
860.1850	NONE	Confined Rotational Crops	A,B,C	44933001
860.1900	NONE	Field Rotational Crops	A,B,C	44972301



## Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP Public Regulatory Docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202-4501. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4 PM.

The docket initially contained preliminary human health & ecological effects risk assessments and related documents as of 09/13/2001. The public comment period closed sixty (60) days later on 11/13/2001. The EPA then considered comments, reevaluated the retention of the FQPA 10x Safety Factor and revised the occupational risk assessment. The Agency also reevaluated the toxicological endpoint selection for dermal and inhalation risk assessments and the 3x safety factor for bioaccumulation. The following documents were added to the docket and posted to the webpage on 3/15/2002. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded/viewed via the Agency's website at <http://www.epa.gov/pesticides/reregistration/endosulfan/>. These documents include:

### Health Effects Risk Assessment Documents:

1. Re-Evaluation of Toxicology Endpoint Selection for Dermal and Inhalation Risk Assessments and 3X Safety Factor for Bioaccumulation, February 7, 2002.
2. Revised Residue Chemistry Chapter For The Endosulfan Reregistration Eligibility Decision (RED) Document, February 14, 2002.
3. Report of the FQPA Safety Factor Committee, February 14, 2002.
4. Third Revision of Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document, February 26, 2002.
5. Anticipated Residues and Revised Chronic Dietary Exposure Analyses, February 28, 2002.
6. New FQPA and PDP Data, Anticipated Residues, and Revised Acute and Chronic Dietary Exposure Analyses, April 22, 2002.
7. Response to Registrant Comments on the Data Supporting the FQPA Safety Factor Rationale for Endosulfan

### Health Effects Risk Assessment Documents Added to the Endosulfan Docket on 09/30/2002:

8. Response to Comments. Response to comments on EPA's Human Health Risk Assessment of Endosulfan dated 01/31/2001.
9. Endosulfan. Agency Response to the 60-Day Response by the Endosulfan Task Force to the Revised Residue Chemistry Chapter dated January 31, 2002.
10. Revised Residue Chemistry Chapter for the Endosulfan Reregistration Eligibility Decision (RED) Document, 2/14/2002.

11. Supporting documentation for findings of FQPA Safety Committee on February 11, 2002, May 9, 2002
12. Endosulfan. Review of Endosulfan Task Force Response to the Health Effects Division February 28, 2002 Dietary Exposure Assessment dated, 6/14/2002
13. New FQPA, PDP, and Processing Data, Anticipated Residues, and Revised Acute and Chronic Dietary Exposure Analyses, July 19, 2002
14. Response to Registrant Comments on the Data Supporting the FQPA 10x Safety Factor Rationale for Endosulfan, August 12, 2002.

### **Environmental Fate and Ecological Effects**

15. Final EFED Risk Assessment for the Reregistration Eligibility Decision on Endosulfan, February 26, 2002.
16. Endosulfan and Endosulfan Sulfate: Drinking Water EECs in Surface Water for Use in the Human Health Risk Assessment, July 3, 2002.
17. EFED Response to the ETF “60-Day Response by the Endosulfan Task Force to the Environmental Fate and Effects Drafted Risk Assessment for the Reregistration Eligibility Decision on Endosulfan (EFED Memorandum dated July 12, 2001)”
18. EFED Response to Comments by the World Wildlife Federation on the Environmental Fate and Ecological Risk assessment for the Reregistration Eligibility Decision on Endosulfan
19. EFED Response to Comments by the National Resource Defense Council Environmental Fate and Ecological Risk assessment for the Reregistration Eligibility Decision on Endosulfan

### **Biological and Economic Analysis of Endosulfan Benefits Assessments**

20. Benefits Assessment for Endosulfan Use in Sweet Potato, 4/15/2002
21. Biological And Economic analysis of Endosulfan on Pears: Impacts from Changes in the Re-entry Interval, 4/18/2002
22. Benefits Assessment for Endosulfan Use on Broccoli: Impacts from Changes in the Re-entry Interval, 4/18/2002
23. Biological and Economic Analysis of Endosulfan on Peaches: Impacts from Changes in the Re-entry Interval, 4/24/2002
24. Biological and Economic Analysis of Endosulfan on Grapes: Impacts from Changes in the Re-entry Interval, 5/30/2002
25. Biological and Economic Analysis of Endosulfan on Blueberries: Impacts from Changes in the Re-entry Interval, 5/23/2002
26. Biological and Economic Analysis of Endosulfan on Fresh Sweet Corn: Impacts from Changes in the Re-entry Interval, 6/27/2002

27. Biological and Economic Analysis of Endosulfan Benefits on Selected Crops: Impacts of Cancellation, 7/12/2002
28. Assessment of Endosulfan Use in Seed Alfalfa: Application Rate Reduction to Reduce Risks to Mixers/Loaders, 7/26/2002
29. Biological and Economic Analysis of Endosulfan on Cabbage: Impacts from Changes in the Re-entry Interval, 8/8/2002

## **Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)**

### **GUIDE TO APPENDIX D**

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

- b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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| 00003586 | Brogdon, J.E.; Marvel, M.E. (1959) Commercial Vegetable Insect and Disease Control Guide. Gainesville, Fla.: Agricultural Extension Service. (Circular 193; also~In~unpublished submission received Sep 25, 1959 under 279-1182; submitted by FMC Corp., Philadelphia, Pa.; CDL:224560-A)        |
| 00003587 | Shuttleworth, J.M. (1971) Determination of Endosulfan I, Endosulfan II, and Endosulfan Sulfate Residues in or on Blueberries. Method M-2908 dated Aug 17, 1971. (Unpublished study received Aug 27, 1971 under 1F1034; submitted by FMC Corp., Philadelphia, Pa.; CDL:093343-A)                  |
| 00003588 | FMC Corporation (1969) Analytical Method and Residues: [Endosulfan]. (Unpublished study received Sep 3, 1970 under 1F1034; CDL:093343-D)   |
| 00003592 | Shuttleworth, J.M. (1970) Development of an Analytical Method for Determining Endosulfan and Endosulfan Sulfate Residues in or on Small Grains. Method M-2653 dated May 5, 1970. (Unpublished study received Aug 18, 1970 under 1F1028; submitted by FMC Corp., Philadelphia, Pa.; CDL:093338-C) |
| 00003600 | FMC Corporation (1958) Petition for the Establishment of a Tolerance for Thiodan on Strawberry and Peach...Including a Description of the Analytical Methods Used. (Unpublished study including supplement, received Feb 9, 1960 under PP0237; CDL: 090265-A)                                    |
| 00003634 | Stanovick, R.P. (1967) Determination of Thiodan I, II and Sulfate Residues in or on Sweet Corn (Husk, Cob and Kernels): M-2129. Includes undated method. (Unpublished study received Jun 14, 1967 under 279-1182; submitted by FMC Corp., Philadelphia, Pa.; CDL:008892-A)                       |

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00003654	Ware, G.W.; Myser, W.C.; Treece, R.E.; Carey, W.E.; Terranova, A.C. (1961) Final Report: The Determination of <sup>14</sup> C-tagged Thiodan Residues on Alfalfa: State Special Project #112. (Unpublished study received Jun 6, 1962 under PP0373; prepared in cooperation with Ohio Agricultural Experiment Station, submitted by FMC Corp., Philadelphia, Pa.; CDL:090402-D)
00003703	FMC Corporation (1970) Thiodan: Analytical Method for Milk and Tissues: Supplemental Information to Niagara Report M-1656. (Unpublished study received Aug 24, 1967 under 8F0632; CDL:092926-D)
00003709	FMC Corporation (1969) (Foliar Application of Endosulfan on Potatoes). (Unpublished study received May 30, 1970 under 0F0925; CDL:091579-B)
00003710	FMC Corporation (1970) Results of Tests of the Amount of Residues Remaining and Description of Analytical Method: (Endosulfan). (Unpublished study received Sep 6, 1971 under 1F1028; CDL:091905-B)
00003713	FMC Corporation (1971) Results of Tests of the Amount of Residues Remaining and Description of Analytical Method: (Endosulfan). (Unpublished study received Nov 17, 1972 under 3F1314; CDL: 092246-C)
00003721	Hinstridge, P.A. (1968) Project No. and Title: 015--Thiodan and Thiodan Sulphate Residues in Refined Soybean Oil: R-1086. Includes method dated Jan 29, 1968. (Unpublished study received Jan 17, 1969 under 8F0723; submitted by FMC Corp., Philadelphia, Pa.; CDL:091250-S)
00003722	Hinstridge, P.A. (1966) Project No. and Title: 015--Thiodan and Thiodan Sulphate Residues on Leaf Lettuce: R-993. Includes method dated Aug 9, 1966. (Unpublished study received Jan 17, 1969 under 8F0723; submitted by FMC Corp., Philadelphia, Pa.; CDL:091250-T)

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| 00003723 | IR-4 Project at Rutgers, the State University (19??) Summary: Crop--Dosages--Applications--Interval--Residue--Recovery: (Endosulfan and Parathion on Mustard Seed and Rape Seed.) Summary of study 092201-B. Includes undated method. (Unpublished study received Aug 11, 1972 under 3E1300; CDL:092201-A)  |
| 00003724 | Winterlin, W. (1968) Residues Found on Mustard and Rape Seed. Includes undated method. (Unpublished study received Aug 11, 1972 under 3E1300; prepared by Univ. of California--Davis, Dept. of Environmental Toxicology, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:092201-B)  |
| 00003725 | FMC Corporation (1966) [Residue Data of Endosulfan on Cotton]. (Unpublished study received Jun 8, 1970 under 0F0929; CDL:091584-B)  |
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| 00003727 | FMC Corporation (1967) [Residues of Endosulfan on Safflower Seed]. Includes undated method. (Unpublished study received Jun 8, 1970 under 0F0929; CDL:091584-E)   |
| 00003728 | Shuttleworth, J.M. (1971) Determination of Endosulfan and Endosulfan Sulfate Residues in Sugar Beet Roots and Sugar Beet Pulp: M-2866. Includes undated method. (Unpublished study including letter dated Sep 10, 1971 from P.J. Boughton to William H. Morgan, received Jul 2, 1971 under 1F1058; submitted by FMC Corp., Philadelphia, Pa.; CDL:093371-E)   |
| 00003741 | Baran, J. (1967) Report to Niagara Chemical Division, FMC Corporation: Two-Year Chronic Oral Toxicity of Thiodan Technical--Beagle Dogs: IBT No. C3758. (Unpublished study including letter dated Dec 5, 1967 from J.C. Calandra to John F. McCarthy, received Dec 7, 1967 under 7F0632; prepared by Industrial Bio-Test Laboratories, Inc., submitted by FMC Corp., Philadelphia, Pa.; CDL:091100-A) |



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| 00003743 | Gorbach, S (1965) Investigations on Thiodan in the Metabolism of Milk Sheep. Includes undated method. (Unpublished study including report, received Dec 7, 1967 under 7F0632; prepared by Farbwerke Hoechst AG, Germany, submitted by FMC Corp., Philadelphia, Pa.; CDL:091100-C)  |
| 00003744 | Gorbach, S. (1973) Extraction of Endosulfan from Tea-Leaves. Includes method dated Nov 4, 1973. (Unpublished study received on unknown date under 2H2667; prepared by Farbwerke Hoechst AG, Germany, submitted by American Hoechst Corp., North Hollywood, Calif.; CDL:225765-A)   |
| 00003760 | Hinstridge, P.A. (1968) Project No. and Title: 015--Endosulfan and Endosulfan Sulphate (Residues on Sweet Corn): R-1111. (Unpublished study received Oct 17, 1969 under 9F0845; prepared in cooperation with Washington State Univ., Irrigated Agriculture Research and Extension Center, submitted by FMC Corp., Philadelphia, Pa.; CDL:091461-B)                               |
| 00003777 | Stanovick, R.P. (1964) Determination of Thiodan Residues on or in Cottonseed: M-1339. Includes method dated Apr 3, 1964. (Unpublished study received Apr 9, 1964 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119688-A)  |
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| 00003782 | Stanovick, R.P. (1963) Determination of Thiodan Sulfate and Diol Residues on Strawberries, Sweet Cherries and Tart Cherries Using the MCGC Analytical Procedure: M-1246. (Unpublished study received Oct 8, 1968 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119621-B)  |

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00003784	Stanovick, R.P. (1965) Determination of Thiodan I, II and Sulfate Residues in or on Peaches: M-1692. Includes method dated Dec 13, 1965. (Unpublished study received Oct 8, 1968 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL: 119621-D)
00003785	Hinstridge, P.A. (1963) Project No. and Title: 15--Thiodan and Thiodan Sulphate (Residues on Strawberries): R-666. (Unpublished study received Oct 8, 1968 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119621-E)
00003786	Hinstridge, P.A. (1963) Project No. and Title: 15--Thiodan and Thiodan Sulphate (Residues on Fresh and Dry French Prunes): R-673. (Unpublished study received Oct 8, 1968 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL: 119621-F)
00003787	Hinstridge, P.A. (1963) Project No. and Title: 15--Thiodan and Thiodan Sulfate Residues on Apples: R-677. (Unpublished study received Oct 8, 1968 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119621-G)
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44972301	Brady, S. (1999) Magnitude of Endosulfan Residues in or on Rotational Crops from Two Applications of Phaser Insecticide USA, 1998: Lab Project Number: BJ98R002: B002616: AE F002671. Unpublished study prepared by AgrEvo USA Co. 225 p. {OPPTS 860.1900}

## **Appendix E. Generic Data Call-In**

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

## **Appendix F. Product Specific Data Call-In**

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

## **Appendix G. EPA'S Batching of Endosulfan Products for Meeting Acute Toxicity Data Requirements for Reregistration**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing ENDOSULFAN as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options:



Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Forty-two products were found which contain Endosulfan as the active ingredient. These products have been placed into eight batches in accordance with the active and inert ingredients and type of formulation.

#### Batching Instructions:

Batch 6: EPA Reg. No. 7401-317 may cite data from EPA Reg. No. 70-126 or EPA Reg. No. 3342-94.

Batch 7: EPA Reg. No. 7401-316 cite data from EPA Reg. No. 16-133.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	264-637	96.0%
	279-2306	95.0%
	10163-223	95.0%
	11678-05	95.0%
	19713-319	94.0%
	34704-799	95.0%

Batch 2	EPA Reg. No.	Percent Active Ingredient
	264-656	50.0%
	267-659	50.0%
	279-1380	50.4%
	279-3129	50.0%
	10163-98	50.0%
	10163-130	50.0%
	51036-91	50.8%
	51036-209	50.0%
	66222-02	51.3%

Batch 3	EPA Reg. No.	Percent Active Ingredient
	264-638	34.4%
	264-658	34.4%
	5905-418	33.3%
	10163-110	34.0%
	11678-25	35.6%
	19713-399	34.3%
	34704-21	33.3%
	34704-516	34.0%

Batch 4	EPA Reg. No.	Percent Active Ingredient
	279-2924	34.0%
	51036-92	34.0%

Batch 5	EPA Reg. No.	Percent Active Ingredient
	70-142	24.0%
	19713-99	24.6%

Batch 6	EPA Reg. No.	Percent Active Ingredient
	70-126	4.0%
	3342-94	4.0%
	7401-317	4.0%

Batch 7	EPA Reg. No.	Percent Active Ingredient
	16-133	3.0%
	7401-316	2.0%

No Batch	EPA Reg. No.	Percent Active Ingredient
	16-141	9.0%
	279-3222	Endosulfan ..... 31.25% Methyl Parathion ..... 20.88%
	802-516	9.2%
	1327-35	15.0%
	1386-338	23.8%
	3342-102	10.2%
	5481-278	26.0%
	5481-296	24.0%
	5481-316	Endosulfan ..... 1.5% Sevin ..... 1.5%
	9779-330	Endosulfan ..... 22.50% Pyrethrins ..... 4.75% Piperoyl Butoxide ..... 0.45%

**Appendix H. List of Registrants Sent this Data Call-In Notice**

<b>Case # and Name</b>				
<b>0014 Endosulfan</b>				
<b>Chemical # and Name</b>				
<b>079401 Hexachloro-1, 5, 5a, 6, 9, 9a - hexahydro - 6, 9 - methano - 2, 4</b>				
<b>Company Number</b>	<b>Company Name</b>	<b>Address</b>	<b>City &amp; State</b>	<b>Zip</b>
00254	BAYER CROPSCIENCE	2 T.W. ALEXANDER DRIVE, P.O. BOX 12014	RESEARCH TRIANGLE PARK, NC	27709
019713	DREXEL CHEMICAL COMPANY	P.O. BOX 13327	MEMPHIS , TN	38113
011678	MAKHTESHIM CHEMICAL WORKS, LTD C/O MAKHTESHIM- AGAN OF N. AMERICA, INC.	551 FIFTH AVENUE, SUITE 1100	NEW YORK, NY	10176

## Appendix I. List of Available Related Documents and Electronically Available Forms

**Pesticide Registration Forms are available at the following EPA internet site:**

[http://www.epa.gov/opprd001/forms/.](http://www.epa.gov/opprd001/forms/)

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

### Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at [williams.nicole@epamail.epa.gov](mailto:williams.nicole@epamail.epa.gov).

The following Agency Pesticide Registration Forms are currently available via the internet:  
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>
8570-27	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>

8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-35	Data Matrix (in PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>

Pesticide Registration Kit [www.epa.gov/pesticides/registrationkit/](http://www.epa.gov/pesticides/registrationkit/)

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
  - a. 83-3 Label Improvement Program--Storage and Disposal Statements
  - b. 84-1 Clarification of Label Improvement Program
  - c. 86-5 Standard Format for Data Submitted under FIFRA
  - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
  - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
  - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
  - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
  - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at [http://www.epa.gov/opppmsd1/PR\\_Notices](http://www.epa.gov/opppmsd1/PR_Notices).

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
  - a. Registration Division Personnel Contact List
  - B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - C. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)  
5285 Port Royal Road  
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: [ace.orst.edu/info/nptn](http://ace.orst.edu/info/nptn).

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt  
EPA identifying number  
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

### **Documents Associated with this RED**

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

- a. Health and Environmental Effects Science Chapters.
- b. Detailed Label Usage Information System (LUIS) Report.

**The NRA review of**

**ENDOSULFAN**

**August 1998**

**VOLUME 2**



**National  
Registration  
Authority**

for Agricultural and  
Veterinary Chemicals

**Existing Chemicals Review Program**



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ISBN 0 642 49013 9	volume 1
ISBN 0 642 49014 7	volume 2
ISBN 0 642 49016 3	set of both volumes

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For further information, see the NRA internet site at:

<http://www.dpie.gov.au/nra/welcome.html>

or contact:

Manager, Chemical Review  
National Registration Authority  
PO Box E240  
KINGSTON ACT 2604

Telephone: (02) 6272 3213  
Facsimile: (02) 6272 3551

## FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals.

The NRA's Existing Chemicals Review Program (ECRP) systematically examines agricultural and veterinary chemicals registered in the past to determine whether they continue to meet current standards for registration. Chemicals for review are chosen according to pre-determined, publicly available selection criteria. Public participation is a key aspect of this program.

In undertaking reviews, the NRA works in close cooperation with advisory agencies including the Department of Health and Family Services (Chemicals and Non-Prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Commission (Chemical Assessment Division) and relevant State Departments.

The NRA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of evaluation documents for all ECRP reviews is a part of that process.

The NRA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD *ad hoc* exchange program. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

The summary provides a brief overview of the review of endosulfan that has been conducted by the NRA and its advisory agencies. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public, questionnaires sent to key user/industry groups and government organisations, and literature searches.

The information and technical data required by the NRA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken. Details of required data are outlined in various NRA publications.

Other publications explaining the NRA's requirements for registration can also be purchased or obtained by contacting the NRA. Among these are: *Ag Manual: The Requirements Manual for Agricultural Chemicals*; *Vet Manual: The Requirements Manual for Veterinary Chemicals* and the *Agricultural Requirements Series*.



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## BRIEF OVERVIEW

Endosulfan is an insecticide which has been widely used in Australia for over 30 years. The agricultural industry and State agricultural authorities advise that endosulfan is extremely important to agriculture and for some crop/pest situations there are no alternatives at all or none which work as well.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it largely disappears from soil in 3 to 6 months and does not remain in the bodies of animals or humans. Numerous scientific studies have not found any evidence of involvement in cancer, birth defects, damage to genetic material, disruption of the endocrine hormone system or other long term affects due to chronic, low level exposure. However, endosulfan has a high acute or immediate toxicity to humans which is a matter of concern for agricultural workers. In addition, endosulfan is quite toxic to fish and other aquatic organisms.

Although endosulfan concentrations in surface waters in areas of intensive use routinely exceed ANZECC criteria recommended to protect aquatic ecosystems, there is not yet clear evidence that endosulfan is causing long term harm to the general environment or biological communities. However, it is known that during parts of each year in the rivers and creeks of these regions, endosulfan reaches concentrations which are lethal to important species of native fish and native macroinvertebrates when tested under laboratory conditions. Regular attainment of such concentrations of endosulfan in regional surface waters is not acceptable on an ongoing basis. Concern over this problem is increased by predictions of some authorities that acreage of cotton, the main user of endosulfan, is likely to increase significantly in the next few years in some regions.

A simple ban of endosulfan could lead to other problems. This is because endosulfan has relatively low toxicity to many species of beneficial insects, mites and spiders (that is, ones which prey upon or parasitise damaging insect pests). Other chemicals, necessarily substituted for endosulfan, would kill beneficial insects leading to population explosions of damaging pests which in turn would require more frequent sprays of harsher chemicals than if endosulfan had been used in the first place. In addition, because endosulfan is from a different chemical class than almost all other available insecticides, its use is very important for slowing the development of insecticide resistance to the other chemicals. Loss of endosulfan would, therefore, also lead to more insecticide use due to increasing resistance among insect pests. The net result is greater overall danger to agricultural workers and to the environment.

To address the above concerns, the National Registration Authority has taken steps to manage the use of endosulfan on an interim basis while more data on worker safety and commodity residues are developed to determine specific requirements in those areas necessary for ongoing use. In addition, the NRA has taken steps designed to reduce the inappropriate use of endosulfan and to reduce the amount of endosulfan which is carried off farms into creeks and rivers. The results of environmental monitoring and an assessment of use patterns over the next three years will be examined to determine whether endosulfan can continue to be used.

## ABBREVIATIONS AND ACRONYMS

<b>ac</b>	Active Constituent	<b>MOE</b>	Margin of Exposure
<b>ADI</b>	Acceptable Daily Intake (for humans)	<b>MRL</b>	Maximum Residue Limit
<b>ai</b>	Active Ingredient	<b>MSDS</b>	Material Safety Data Sheet
<b>ANZECC</b>	Australia and New Zealand Environment and Conservation Council	<b>NDPSC</b>	National Drugs and Poisons Schedule Committee
<b>Bt</b>	<i>Bacillus thuringiensis</i>	<b>NHMRC</b>	National Health and Medical Research Council
<b>ChE</b>	Cholinesterase	<b>NOEL</b>	No Observed Effect Level
<b>d</b>	Day	<b>NOHSC</b>	National Occupational Health and Safety Commission
<b>EC</b>	Emulsifiable Concentrate	<b>OP</b>	Organophosphate
<b>EC50</b>	Concentration at which 50% of the test population are affected.	<b>POEM</b>	Predictive Operator Exposure Model
<b>EEC</b>	Estimated Environmental Concentration	<b>ppb</b>	Parts per Billion
<b>GAP</b>	Good Agricultural Practice	<b>PPE</b>	Personal Protective Equipment
<b>h</b>	Hour	<b>ppm</b>	Parts per Million
<b>ha</b>	Hectare	<b>RBC</b>	Erythrocyte
<b>in vitro</b>	Outside the living body and in an artificial environment	<b>SUSDP</b>	Standard for the Uniform Scheduling of Drugs and Poisons
<b>in vivo</b>	Inside the living body of a plant or animal	<b>TGAC</b>	Technical Grade Active Constituent
<b>IPM</b>	Integrated Pest Management	<b>WHP</b>	Withholding Period
<b>kg</b>	Kilogram	<b>WSA</b>	Worksafe Australia
<b>L</b>	Litre		
<b>LC50</b>	Concentration that kills 50% of the test population of organisms		
<b>LD50</b>	Dosage of chemical that kills 50% of the test population of organisms		
<b>LOEL</b>	Lowest Observable Effect Level		
<b>m</b>	Metre		
<b>mg</b>	Milligram		
<b>µg</b>	Microgram		
<b>mL</b>	Millilitre		

## Section 3

### CHEMISTRY ASSESSMENT

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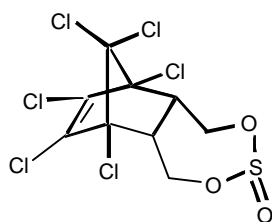


## 1. ACTIVE CONSTITUENT

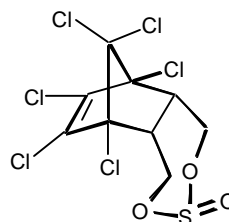
### 1.1 Chemical Identity

Endosulfan is an organochlorine insecticide. Technical endosulfan consists of a mixture of two stereoisomers, alpha-endosulfan stereochemistry  $3\alpha$ ,  $5a\beta$ ,  $6\alpha$ ,  $9\alpha$ ,  $9a\beta$ -, comprises 64 to 67% of the technical grade; beta-endosulfan stereochemistry  $3\alpha$ ,  $5a\alpha$ ,  $6\beta$ ,  $9\beta$ ,  $9a\alpha$ -, comprises 29-32% of the technical grade.

Common name :	Endosulfan (ISO, Standards Australia)
IUPAC name:	1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-en-2,3-ylenebismethylene) sulfite
CAS name:	6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide
CAS Registry numbers:	115-29-7 (endosulfan); Technical endosulfan is a mixture of $\alpha$ (959-98-8) and $\beta$ (33213-65-9) isomers in 2:1 ratio.
Development codes:	Hoe 02671, SHC-A-601, FMC 5462
Empirical formula:	$C_9H_6Cl_6O_3S$
Molecular weight:	406.9
Structural formula:	



$\alpha$ -endosulfan



$\beta$ -endosulfan

## 1.2 Physical and Chemical Properties

### Physical and chemical properties of pure active constituent

Color:	colourless crystalline solid
Odour:	odourless
Physical state;	pure alpha-isomer - crystalline solid pure beta-isomer - crystalline solid
Melting Point:	80 °C (TGAC); $\alpha$ 109.2°C, $\beta$ 213.3°C.
Density:	1.8 (TGAC).
Octanol/water partition coefficient:	$\alpha$ 4.74, $\beta$ 4.79 in <i>n</i> -Octanol/Water at pH 5 (Sarafin and Abhauer, 1987).
Henry's Law Constant:	$\alpha$ 1.48, $\beta$ 0.07 Pa.m <sup>3</sup> /mol at 22°C estimated from vapour pressure and water solubility (Weller, 1990). Estimated water/air partition coefficients based on these data are 1660 and 34500.
Dissociation Constant:	Endosulfan does not contain any readily dissociable groups (ie those that can readily gain or lose a proton over the pH range of 5 to 9).
Vapour pressure:	1 x 10 <sup>-5</sup> mm Hg at 25°C 9 x 10 <sup>-3</sup> mm Hg at 80°C 1.7 mPa (TGAC). The vapour pressures of the individual isomers ( $\alpha$ 1.9, $\beta$ 0.09 mPa at 25°C) differ by more than an order of magnitude (Sarafin, 1987a). At 20°C, the vapour pressures are 0.96 and 0.04 mPa. Vapour pressures for endosulfan sulfate at the two temperatures are 0.023 and 0.01 mPa (unsubmitted Hoechst document A50940, cited by Raupach <i>et al</i> , 1996).
Specific gravity:	1.745 at 20°C
Solubility in water:	$\alpha$ 0.33, $\beta$ 0.32 mg/L (22°C). Solubility was determined in double distilled water (pH < 7 due to dissolved CO <sub>2</sub> ). Solubility is considered to be independent of pH based on the structure (Görlitz, 1990). A column elution method was used for parent isomers (Sarafin, 1979), and for determining the solubility (0.5 mg/L) of the sulfate metabolite (Görlitz, 1986). Earlier measurements found solubilities of 0.15, 0.06 and 0.22 mg/L for $\alpha$ and $\beta$ isomers and sulfate, respectively (NRCC, 1975).
Solvent solubility:	200 g/L (ethyl acetate, dichloromethane, toluene) 65 g/L (ethanol) 24 g/L (hexane)
Stability:	Stable at ambient temperatures

Hydrolysis:	Hydrolysed very slowly in acidic media, more rapidly in alkaline media. In aqueous solution, it is hydrolysed with a half life of: At 22 <sup>0</sup> C alpha-isomer: pH 5 T <sub>1/2</sub> = >1 year pH 7 T <sub>1/2</sub> = 22 days pH 9 T <sub>1/2</sub> = 7 hr At 22 <sup>0</sup> C beta-isomer: pH 5 T <sub>1/2</sub> = >1 year pH 7 T <sub>1/2</sub> = 17 days pH 9 T <sub>1/2</sub> = 5.1 hr
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### Physical and chemical properties of TGAC

Color:	brown																
Odour:	terpene odour																
Physical state;	crystalline flakes																
Density:	1.8																
Melting point:	70-100 <sup>0</sup> C																
Vapor pressure:	1x10 <sup>-5</sup> mm Hg at 25 <sup>0</sup> C																
Specific gravity:	1.745 at 20 <sup>0</sup> C																
Solubility in water:	60-150 µg/litre																
Solubility in organic solvents: (per 100 g solvent at 20 <sup>0</sup> C)	<table> <tr> <td>chloroform</td><td>50 g</td></tr> <tr> <td>xylene</td><td>45 g</td></tr> <tr> <td>benzene</td><td>37 g</td></tr> <tr> <td>acetone</td><td>33 g</td></tr> <tr> <td>carbon tetrachloride</td><td>29 g</td></tr> <tr> <td>kerosene</td><td>20 g</td></tr> <tr> <td>methanol</td><td>11 g</td></tr> <tr> <td>ethanol</td><td>5 g</td></tr> </table>	chloroform	50 g	xylene	45 g	benzene	37 g	acetone	33 g	carbon tetrachloride	29 g	kerosene	20 g	methanol	11 g	ethanol	5 g
chloroform	50 g																
xylene	45 g																
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carbon tetrachloride	29 g																
kerosene	20 g																
methanol	11 g																
ethanol	5 g																

### 1.3 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results and analytical methods) of endosulfan TGACs were evaluated and found acceptable.

## 2. FORMULATION OF END-USE PRODUCT

Endosulfan is used in a formulated form as a broad spectrum contact and stomach insecticide in agriculture. It is available as emulsifiable concentrate and ultra-low-volume (ULV) formulations. The ULV formulation is almost exclusively used in cotton, and the EC formulation used predominantly in cotton but with significant use in tomatoes and vegetables and a broad range of minor uses.

### 3. DECLARATION OF COMPOSITION

The FAO monograph specifications for Technical endosulfan are listed below:

Endosulfan content:	not less than 940 g/kg
Isomer content:	alpha-isomer: 64 to 67%
	beta-isomer: 29-32%
Impurities:	endosulfan-ether: 10 g/kg maximum
	endosulfan-alcohol: 20 g/kg maximum
	endosulfan-sulfate: 2 g/kg maximum

The active content and impurities present in the technical material are determined by a gas chromatographic method with electron capture detection.

Endosulfan TGACs from 5 approved sources comply with the FAO specifications for endosulfan in respect of endosulfan content, endosulfan-ether and endosulfan-sulfate. However, in the majority of Declarations of Composition approved by the NRA, the limit for endosulfan-sulfate is not included. According to the literature, the toxicity of endosulfan-sulfate is similar to the parent compound.

#### 3.1 Microcontaminants

Other compounds of toxicological significance (sulfotep, N-nitrosamines, halogenated dibenzo-p-dioxins or halogenated dibenzofurans and PCBs) are not expected in endosulfan TGAC due to the raw materials and synthetic chemistry route used.

### 4. CONCLUSION

The NRA will introduce a compositional standard for all endosulfan TGACs which is based on the latest FAO specifications for this chemical. All Declarations of Composition will be required to demonstrate compliance with the standard by 30 June 1999.

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**ATTACHMENT 3: PRODUCTS AND TGACS AFFECTED BY THIS REVIEW***Registered products containing endosulfan*

<b>Product Name</b>	<b>Applicant</b>
Campbell Endosulfan 350 EC Insecticide	Colin Campbell (Chemicals) Pty Ltd
Endosan ULV Insecticide	Crop Care Australasia Pty Ltd
Endosan Emulsifiable Concentrate Insecticide	Crop Care Australasia Pty Ltd
Davison Endosulfan 350 EC Insecticide	Davison Industries Pty Ltd
Davison Endosulfan 250 ULV Insecticide	Davison Industries Pty Ltd
Farm-oz Endosulfan 240 ULV Insecticide	Farmoz Chemicals Pty Ltd
Farm-oz Endosulfan 350 EC Insecticide	Farmoz Chemicals Pty Ltd
Thiodan ULV Insecticide	Hoechst Schering AgrEvo Pty Ltd
Thiodan Insecticide	Hoechst Schering AgrEvo Pty Ltd
Thiodan EC Insecticide	Hoechst Schering AgrEvo Pty Ltd
Thionex 350 EC Insecticide Spray	Makhteshim-Agan (Aust) Pty Ltd
Nufarm Endosulfan ULV 240 Insecticide	Nufarm Ltd (Laverton)
Nufarm Endosulfan 350 EC Insecticide	Nufarm Ltd (Laverton)
350 EC Bar Insecticide by Sanonda	Sanonda (Australia) Pty Ltd
240 ULV Bar Insecticide by Sanonda	Sanonda (Australia) Pty Ltd

*Approved sources of endosulfan TGAC*

Endosulfan	Farmoz Pty Ltd	E.I.D. Parry (India) Limited Thane-Belapur Road Thane Maharashtra State INDIA	44288
Endosulfan	Hoechst Schering AgrEvo Pty Ltd	Hoechst Schering AgrEvo GmbH Werk Greisheim Stroofstrasse 27 D65933 Frankfurt am Main GERMANY	44305
Endosulfan	Makhteshim-Agan (Australia) Pty Ltd	Makhteshim Chemical Works Ltd New Industrial Estate Beer-Sheva 84100 ISRAEL	44093
Endosulfan	Pivot Limited	Excel Industries Ltd 6/2 Ruvapari Road Bhavnagar - 364001 Bombay 4000102 INDIA	44012

*Products included in the review that are no longer registered*

<b>Product Name</b>	<b>Applicant</b>
ICI Crop Care Endosan ULV Insecticide	Crop Care Australasia Pty Ltd
Crop King Endosulfan 240 ULV Insecticide	Crop Care Australasia Pty Ltd
Rhone-Poulenc Endosulfan Insecticide	Rhone-Poulenc Rural Aust Pty Ltd
Rhone-Poulenc Endosulfan ULV Insecticide	Rhone-Poulenc Rural Aust Pty Ltd
Velsicol Endosulfan 250 Emulsifiable Concentrate Insecticide	Velsicol Australia Ltd



