

**Rotterdam Convention on the Prior
Informed Consent Procedure for
Certain Hazardous Chemicals and
Pesticides in International Trade**Distr.: General
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**Conference of the Parties to the Rotterdam Convention
on the Prior Informed Consent Procedure for Certain
Hazardous Chemicals and Pesticides in International Trade
Eighth meeting**

Geneva, 24 April–5 May 2017

Item 5 (b) (i) of the provisional agenda*

**Matters related to the implementation of the
Convention: listing of chemicals in Annex III
to the Convention: consideration of chemicals
for inclusion in Annex III****Inclusion of liquid formulations (emulsifiable concentrate and
soluble concentrate) containing paraquat dichloride at or above
276 g/L, corresponding to paraquat ion at or above 200 g/L, in
Annex III to the Rotterdam Convention****Addendum****Draft decision guidance document****Note by the Secretariat**

As referred to in document UNEP/FAO/RC/COP.8/10, at its eighth meeting, in its decision CRC-8/7, the Chemical Review Committee adopted a draft decision guidance document on liquid formulations (emulsifiable concentrate and soluble concentrate) containing paraquat dichloride at or above 276 g/L. The draft decision guidance document is set out in the annex to the present note for the consideration of the Conference of the Parties. It has not been formally edited.

* UNEP/FAO/RC/COP.8/1.

Annex

Rotterdam Convention

**Operation of the prior informed consent procedure for severely
hazardous pesticide formulations**

Draft

Decision Guidance Document

**Liquid formulations (EC and SL) containing
paraquat dichloride at or above 276 g/L,
corresponding to paraquat ion
at or above 200 g/L**



**Secretariat of the Rotterdam Convention
on the Prior Informed Consent
Procedure for
Certain Hazardous Chemicals and
Pesticides in International Trade**



Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals for the Rotterdam Convention include severely hazardous pesticide formulations. For the Rotterdam Convention, severely hazardous pesticide formulations are those that have been proposed by a developing country or country with economy in transition that is experiencing problems with such formulations under the conditions of use in its territory. Inclusion of a severely hazardous pesticide formulation in the Convention is based on a proposal submitted by a developing country or country with economy in transition as well as additional information collected by the Secretariat in line with parts 1 and 2 of Annex IV of the Convention. For each chemical included in the Rotterdam Convention, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its [...] meeting, held in [...] on [...], the Conference of the Parties agreed to list [chemical name] in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on [...], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals and severely hazardous pesticide formulations for possible inclusion in Annex III of the Convention. The decision guidance document for a severely hazardous pesticide formulation reflects the information provided in a proposal submitted by a developing country or country with economy in transition as well as additional information collected by the Secretariat in line with parts 1 and 2 of Annex IV of the Convention. It is not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have experienced problems with these chemicals or taken regulatory actions to ban or severely restrict the chemical and others that have not experienced problems nor banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
ACGIH	American Conference of Governmental Industrial Hygienists
add.	addendum
ARfD	Acute Reference Dose
a.i.	active ingredient
ADI	Acceptable Daily Intake
AOEL	Acceptable Operator Exposure Level
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CILSS	Permanent Interstate Committee for Drought Control in the Sahel / Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel
corr.	corrigendum
cm	centimetre
CRC	Chemical Review Committee
CSP	Sahelian Pesticides Committee
d	day
DT ₅₀	Degradation time, 50 %
EC	Emulsifiable Concentrate
E.C.	European Community
EC ₅₀	Effect Concentration, 50%
ED ₅₀	Effect Dose, 50%
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	Kilo- (x 1000)
kg	kilogram
Koc	organic carbon-water partition coefficient
KPa	Kilo Pascal
L	Litre
LC ₅₀	Lethal Concentration, 50%
LD ₅₀	Lethal Dose, 50%
LOAEL	Lowest Observed adverse Effect Level
LOEL	Lowest Observed Effect Level

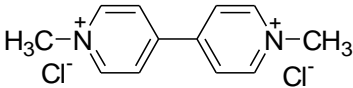
STANDARD CORE SET OF ABBREVIATIONS	
Log P _{ow}	log octanol/water partition coefficient
m	metre
m.p.	melting point
mg	milligram
ml	Millilitre
MRL	Maximum Residue Limit
NOAEC	No-Observed-adverse-Effect Concentration
NOAEL	No-Observed-Adverse-Effect Level
NOEC	No-Observed-Effect Concentration
NOEL	No-Observed-Effect Level
OECD	Organisation for Economic Co-operation and Development
Pow	octanol-water partition coefficient
PPE	Personal Protective Equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RC	Rotterdam Convention
RfD	Reference Dose for chronic oral exposure (comparable to ADI)
SL	Soluble Concentrate
T.L.V.	Threshold Limit Value
UK	United Kingdom
UNEP	United Nations Environment Programme
USA	United States of America
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization
w/w	Weight/weight (percent)
wt.	weight

Decision guidance document for a severely hazardous pesticide formulation causing human health problems

***LIQUID FORMULATIONS (EC AND SL) CONTAINING
PARAQUAT DICHLORIDE AT OR ABOVE 276 G/L,
CORRESPONDING TO PARAQUAT ION AT OR ABOVE 200
G/L***

Published:

1. Identification and uses (see Annex 1 for further details)

Name or trade name of the hazardous pesticide formulation	Gramoxone® Super
Name of the active ingredient or ingredients in the formulation	Paraquat dichloride
Relative amount of each active ingredient in the formulation	276 g paraquat dichloride/L, corresponding to 200 g paraquat ion/L or above
Type of formulation	Liquid formulations (EC - Emulsifiable Concentrate, SL - Soluble Concentrate)
Name(s) of the producer(s), if available	Syngenta
Molecular formula	C ₁₂ H ₁₄ Cl ₂ N ₂
Chemical structure	
CAS-No.(s)	Paraquat-dichloride 1910-42-5 Paraquat ion 4685-14-7

2. Reasons for inclusion in the PIC procedure

Liquid formulations (EC and SL) containing paraquat dichloride at or above 276 g/L corresponding to paraquat ion at or above 200 g/L are listed in Annex III of the Rotterdam Convention in the category of severely hazardous pesticide formulations, and, accordingly subject to the PIC procedure.

These pesticide formulations were found to cause human health problems to the applicators under conditions of use in Burkina Faso, consistent with the provisions of Article 6 and Annex IV to the Convention.

The rationale developed by the Chemical Review Committee at its seventh session in support of their recommendation to include such formulations in the PIC procedure can be found in Annex I to this document.

3. Description of common and recognized pattern of use of the formulation in the reporting country

3.1 Permitted uses of the formulation

In the CILSS (Permanent Interstate Committee for Drought Control in the Sahel) countries, Gramoxone® Super had been granted a provisional sale authorization (APV) valid for three years, delivered in May 2000 and renewed in January 2004. Gramoxone® Super was authorized as a herbicide (pre-emergence of crops and post emergence of weeds) for use on bananas, citrus, cacao, coconut trees, coffee tree, oil palm, plantain, rubber tree, tea shrubs, avocado trees, cashews, mango trees, papaya trees, sugar cane, cotton, maize, rice, sorghum, non-cultivated land, industrial land, railroads and roadsides for the controls of weeds such as grass and dicotyledonous plants. The product was applied by backpack sprayers with a dosage of 1.5-3 L/ha according to the weed situation in a spray solution of 200 - 300 L of water.

The nine CILSS member states Burkina Faso, Cape Verde, Chad, Gambia, Guinea-Bissau, Mali, Mauritania, Niger and Senegal share a common pesticide registration body, the Sahelian Pesticides Committee (CSP).

The CSP had decided not to register any formulation containing paraquat in 2006 and cancelled previous authorizations. Hence, the registration of paraquat containing products expired in 2006.

3.2 Restrictions in handling or use

There were no handling or applicator restrictions specified as a condition of registration.

The label included the following precautionary statements on use, partly illustrated by pictograms (see also section 3.3):

Personal Protection

- Avoid any contact with the spray mixture.
- Wear gloves and protect the eyes during preparation.
- Protect your eyes (wear glasses).
- Wear synthetic rubber gloves.
- Do not drink, eat or smoke during application.
- Wash working clothes after spraying.
- Wash gloves and hands after mixing.
- Wash after spraying.
- Avoid entering the treated plot (people, animals) during the 24 hours following the treatment.

Equipment:

- Do not use Gramoxone® Super with a mist blower, use it only with a sprayer (backpack or draw sprayer).
- Do not use damaged sprayers.
- Fill the sprayer with care, do not fill it too much.
- Do not treat when there is a lot of wind.

Storage:

- Keep the product under lock and key and out of reach of children.
- Keep the product in its original packaging. Avoid decanting.
- Do not put in a drinking bottle.
- Store the product away from heat and humidity in aerated premises, avoid temperatures above 35° C.

Disposal

- Cut the packaging into small pieces and bury it after spraying.

3.3 Availability/applicability of protective clothing

The label included the following precautionary statements on use, illustrated by pictograms (see also section 3.2):

Wear gloves and protect the eyes during preparation.
Protect your eyes (wear glasses).
Wear synthetic rubber gloves.

The Pilot study on Agricultural Pesticide Poisoning in Burkina Faso (Toé, 2010) describes the common practices as regards pesticide application in the field in Burkina Faso:

Limited protective clothing was worn: the most frequently used items were dust masks (39% of cases) followed by boots (28.8%), whereas suits were the least used (4.5%) during application. The most frequently used combination of protective gear was masks & boots, which were worn by 12.6% of the farmers. The combination of chemical cartridge respirator, gloves, boots, suit and glasses was used in only 0.31% of cases.

Reasons for not using PPE include:

- No financial means to buy them;
- PPE is considered too expensive by farmers;
- Farmers do not know PPE exists;
- The equipment is not available on local markets;

- PPE is inappropriate to the local climate conditions. Some farmers for example feel they suffocate if they wear PPE while spraying;
- Underestimation of pesticide hazard;
- Lack of education or instruction of the right use of pesticides and illiteracy
- Lack of knowledge and training of pesticide distributors and vendors who are unable to provide proper advice to their customers

3.4 Actual uses

In the surveyed regions of Burkina Faso, Gramoxone® Super was used on cotton, rice and maize to control weeds. The formulation was applied using a pressure backpack sprayer. Treatment of 2 to 3 L/ha was carried out once at the beginning of the season.

The average duration of the operator's exposure during agricultural use as reported by Burkina Faso was 3½ hours/ha on an average area of 2 ha/farm, for a total of 7 hours of exposure during an average of 1½ to 2 days of treatment.

4. Description of the incident(s), including adverse effects and way in which the formulation was used

4.1 Description of the incident(s)

During a pilot study carried out in Burkina Faso in June-July 2010 through retrospective and prospective surveys conducted among different relevant stakeholders, i.e., agricultural producers, pesticide distributors and retailers, as well as health officers, 296 cases of intoxication that occurred during the application of pesticides have been reported among 650 farmers. A total of 153 different pesticide formulations have been identified among the surveyed distributors and retailers.

53 of these incidents had been caused by the formulation Gramoxone® Super and were related to 53 males between 20 and 70 years old who had applied the product in the field. The incidents occurred from 1996-2010 in three regions of Burkina Faso (Boucle du Mouhoun, Cascades and Hauts Bassins) (No date of intoxication was reported for some of the incidents). The product was used for cotton, rice and maize. The treatments were done one time only at the beginning of the season with a dosage of 2 to 3 L/ha. The average duration of exposure was 3½ hours/ha on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ to 2 days of treatment.

The product was applied using backpack sprayers. When applying pesticide preparations by means of that application technology, it is recommended to use a combination of chemical cartridge respirator, gloves, boots, suit and glasses, even in hot countries. A study carried out in Burkina Faso (Toé, 2010) showed that in many cases, little or no personal protective equipment (PPE) was worn due to various factors such as lack of financial means to acquire it, inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides (see 3.3. above): the most frequently used were dust masks (39% of cases) followed by boots (28.8%), whereas suits were the least used (4.5%) during spraying. The combination of chemical cartridge respirator, gloves, boots, suit and glasses was used in 0.31% of cases. The fact that this PPE combination was very little used (0.31% of cases) explains the fact that farmers applying the product were highly exposed to it.

The adverse effects appeared immediately to several hours after the application of the pesticide. Symptoms reported included headache, excessive sweating, itching, tingling, burning of the skin, skin rashes and sores, complete destruction of the contaminated area, fever, dizziness, bone pains, loss of consciousness, breathing difficulties, cough, vision troubles, eye pains, ringing in the ears, abdominal pain, nausea, vomiting and locked jaw. In 16 cases, the treatment was unknown, whereas treatment was administered in 26 cases, and in an additional 11 cases, hospitalization was required.

4.2 Description of the adverse effects

Adverse effects comprised: headache, excessive sweating, itching, tingling, skin burn, rashes and sores, total destruction of contaminated areas, fever, dizziness, bone pains, fainting, breathing problems, cough, blurred vision, eye pain, buzzing, stomach ache, nausea, vomiting and locked jawbones. For further information see incident report forms in Annex II.

4.3 Relationship of the adverse effects observed to recognized acute toxicological effects of the active ingredient(s)

Paraquat has been classified by WHO as class II (moderately hazardous). Certain formulations are classified in class Ib (as for Gramoxone® Plus, which is classified as highly toxic by inhalation).

Paraquat has serious delayed effects if absorbed. It is of relatively low hazard in normal use but may be fatal if the concentrated product is taken by mouth or spread on the skin (WHO 2010).

The minimum lethal dose of paraquat in humans is approximately 35 mg paraquat/kg bw. Acute intoxication can lead to respiratory distress and affect the nervous system and kidneys. Contamination by ingestion can lead to the following signs and symptoms within a few hours: burning pains in the mouth, throat, chest and upper abdomen, pulmonary oedema, pancreas inflammation, effects on the central nervous system and the kidneys. Dermal contact can lead to dry and cracked hands, loss or horizontal protuberances of nails, ulceration and abrasion. A phase of hepatic cytolysis and acute kidney failure may appear 12 hours after contamination. Death is usually ascribed to progressive pulmonary fibrosis and to pulmonary epithelial proliferation between the 4th and 10th day after exposure. In case of respiratory failure, survival is exceptional. The treatment of intoxication is symptomatic and no antidote exists to date.

The effects observed in the pesticide applicators (Toé, 2010) are representative of dermal exposure to paraquat (itching, tingling, skin burn, rashes and sores, total destruction of contaminated areas), respiratory distress (fainting, breathing problems, cough), nervous system effects (headache, excessive sweating, dizziness, blurred vision, locked jawbones) as well as symptoms indicative of adverse response in the digestive system (stomach ache, nausea, vomiting).

4.4 Extent of incident (e.g. number of people affected for human health incidents)

During the study carried out, fifty-three males aged between 20 and 70 years, who had applied Gramoxone® Super in the field, were reported as affected over a 14 year period. Detailed information on the reported incidents is contained in chapter 4.1.

5. Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents

A detailed report of a survey carried out in three regions of the proposing Party Burkina Faso (Boule du Moulhoun, Cascades and Hauts Bassins) on intoxication cases caused by agricultural pesticides is available: Pilot Study on Agricultural Pesticide Poisoning in Burkina Faso. Final Report (Toé, 2010). The following actions have been undertaken by Burkina Faso in response to the incidents reported:

- The distribution of the report of the survey to all relevant parties,
- A workshop to present and validate the results of the survey was organized to increase awareness among the key stakeholders,

The CSP had decided not to register any formulation containing paraquat in 2006 and cancelled previous authorizations.

The decision to ban paraquat was taken on 5 August 2011 by the Coordination Minister of the Permanent Interstate Committee for Drought Control in the Sahel (CILSS).

6. WHO hazard classification of the formulation

Route	Species	LD50 (mg/kg bw)	WHO toxicity class
Oral	Rat	612 (Gramoxone® Super)	II Moderately hazardous
Dermal	Rat	590 (Gramoxone® Super)	II Moderately hazardous

7. Alternative pest-control practices

General

There are a number of alternative methods available, involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration, the national circumstances and local conditions of use. Countries should consider promoting, as appropriate, integrated pest management (IPM) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, International Federation of Organic Movements (IFOAM), and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to Gramoxone® Super may be found on the Rotterdam Convention website www.pic.int.

Burkina Faso

As an alternative there are herbicide formulations based on glyphosate registered and authorized for sale in CILSS countries.

Annexes

Annex I	Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure
Annex II	Information on reported incident from incident report
Annex III	Safety data sheet(s) on pesticide active ingredient(s)
Annex IV	Further information on the pesticide active ingredient
Annex V	References

Annex I Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure

Rationale for the recommendation by the Chemical Review Committee to list paraquat dichloride (formulated as emulsifiable concentrate¹ of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L) in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation, based on a proposal from Burkina Faso

1. The proposal submitted by Burkina Faso referred to the formulation Gramoxone® Super (200 g/L EC). This is an emulsifiable concentrate of 276 g paraquat dichloride/L (CAS 1910-42-5), corresponding to paraquat ion at 200 g/L (CAS 4685-14-7).
2. The proposal and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.7/11, Corr.1 and Add. 1 to 6.
3. Gramoxone® Super (200 g/L EC) was used in Burkina Faso as a total herbicide in cotton, rice and maize once at the beginning of the season with a dosage of 2 to 3 liters/hectare.
4. Incidents were reported (survey among farmers) involving 53 males between 20 and 70² years old who had applied the product in the field. The incidents occurred from 1996 to 2010 in three provinces of Burkina Faso (Boucle du Mouhoun, Cascades and Hauts Bassins).
5. The product was applied using backpack sprayers. In many cases, little or no personal protective equipment (PPE) was worn due to various factors, such as lack of financial means to acquire it, inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides.
6. The adverse effects appeared immediately to several hours after the application of the pesticide. Symptoms reported included headache, excessive sweating, itching, tingling, burning of the skin, skin rashes and sores, complete destruction of the contaminated area, fever, dizziness, bone pains, loss of consciousness, breathing difficulties, cough, vision troubles, eye pains, ringing in the ears, abdominal pain, nausea, vomiting and locked jaw. In 15 cases, the treatment was unknown, whereas treatment was administered in 26 cases, and in an additional 11 cases, hospitalization was required. A detailed report of a survey undertaken in three regions of Burkina Faso on intoxications due to agricultural pesticides is available.
7. The documentation required according to part 1 of Annex IV to the Convention was submitted by Burkina Faso in its proposal and published in PIC Circular XXXII (12, Dec. 2010).
8. The information collected by the Secretariat according to part 2 of Annex IV to the Convention was submitted by parties and observers and was made available to the Committee in documents UNEP/FAO/RC/CRC7/11/Add.1 to 6.

Criterion Annex IV, part 3 (a)

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

9. The Pilot study on Agricultural Pesticide Poisoning in Burkina Faso clearly describes the common and recognized practices as regards pesticide application in the field in Burkina Faso. In Burkina Faso, Gramoxone® Super is reported to be used in the field in cotton, rice and maize once at the beginning of the season and it is applied by means of backpack sprayer at rates of 2 to 3 L/ha. The average duration of the operator's exposure during agricultural use as found in the Pilot study was 3½ hours/hectare on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ to 2 days of treatment.
10. The common practices regarding use of PPE (personal protective equipment) in Burkina Faso were as follows: Only 20 per cent of pesticide distributors also sell protective equipment (dust masks, boots and gloves in particular) to the farmers; limited use of PPE by farmers: dust masks (39 per cent), boots (29 per cent), suits (5 per cent). Around 13 per cent use both dust masks and boots, whereas around 1 per cent use gloves, boots, suits, dust masks and glasses at the same time. The combination of chemical cartridge respirator, gloves, boots, suit and glasses was used in 0.3 per cent of cases.

¹ Due to information from industry and Burkina Faso received after finalization of the rationale it became evident that liquid concentrates of the types EC and SL should be covered in the definition of the SHPF.

² In the original rationale by mistake 29 - 65 years is given.

11. Most farmers in Burkina Faso are illiterate and not able to read label instructions. In addition, pesticide distributors and vendors lack the necessary knowledge and training and are therefore unable to provide proper advice to customers. There is also a lack of financial means to buy PPE. PPE is often not available on local markets and is generally not adapted to local weather conditions.

12. With regard to Gramoxone® Super, incidents were reported involving 53 farmers who had applied the product in the field using backpack sprayers. In many cases, little or no PPE was worn as a result of various factors explained above, such as lack of financial means to acquire it, the inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides.

13. The Committee concluded that evidence indicating that the use of Gramoxone® Super, in accordance with common and recognized practices within Burkina Faso, resulted in the reported incidents was reliable and, taking into account this criterion, concluded that it was met.

Criterion Annex IV, part 3 (b)

The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

14. Abundant documentation was available to the Committee demonstrating that the above listed conditions for Burkina Faso were similar to the conditions prevailing in other States and regions. For example, a study was reported from Senegal presenting information on chemical pesticide poisoning incidents. Data were analysed from 166 poisoning incidents, 59 per cent of which were related to pesticide applications in the field. Inappropriate application practices (lack of PPE) were identified as the main reason for those incidents. A report from the Niger identified the following operator exposure risks with respect to pesticide use in that country (among others): lack of use of PPE, illiteracy, attitude, application under inappropriate conditions such as excessive wind. The conditions of pesticide use and the climate in neighbouring countries the Niger and Senegal can be considered to be similar to those of Burkina Faso. Documentation is available from other regions, including on intoxications from occupational exposure in Costa Rica, attributable to leaking backpack sprayers among other causes. Especially in Costa Rica's banana plantations, Gramoxone® is reported as a frequent cause of occupational accidents. In a contribution from Chile, 43 acute occupational poisoning incidents with paraquat formulations from 2004 to 2009 were reported, although full PPE is mandatory in that country. In El Salvador between 289 and 402 (average 344) intoxications due to Gramoxone® are reported per year from 2005–2010. Further examples are provided in documents UNEP/FAO/RC/CRC.7/11/Add.2 and 3.

15. The Committee concluded that there was convincing evidence that the incidents reported by Burkina Faso were relevant to other States with similar climate, conditions and patterns of use of the formulation, and therefore that the criterion was met.

Criterion Annex IV, part 3 (c)

The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

16. Handling or applicator restrictions for the use of paraquat products have been provided by various parties (UNEP/FAO/RC/CRC.7/11/Add.2 and 3). They include, for example, such instructions as “Wear coveralls over a long-sleeved shirt and long pants during application with a backpack sprayer” and “Do not use damaged sprayers”. The product label contains precautionary advice to keep the product under lock and key, not to use mist blowers, to use only backpack or draw sprayers, not to smoke, eat or drink during use of the product, to wear glasses, boots and synthetic rubber gloves, to avoid entering a treated plot within 24 hours after application of the product and to avoid any contact with spray mixture.

17. Evidence is provided by Burkina Faso and other parties that the majority of farmers in many developing countries do not use PPE (see also paragraphs 8–10), are illiterate and are unaware of the risks posed by pesticides. Reports are available about defective sprayers; more than half of the sprayers in use in Cameroon, for example, were damaged. In Brazil 80 per cent of sprayers were reported to have deficiencies, while in Costa Rica it is reported to be 58 per cent. Frequently leaking sprayers were also reported from China. A survey in Cameroon revealed that 85 per cent of the farmers there do not use PPE, and in particular, 80 per cent of operators wear no boots. In Zimbabwe, the use of PPE was reported to be low, partly because the benefits of such equipment did not seem overwhelming and use of the equipment was associated with discomfort, high cost and maintenance. In Nicaragua, field workers usually get no appropriate instructions (UNEP/FAO/RC/CRC.7/11/Add.3).

18. Taking into account the information available, the Committee concluded that the criterion was met.

Criterion Annex IV, part 3 (d)

The significance of reported effects in relation to the quantity of the formulation used;

19. In Burkina Faso Gramoxone® Super is reported to be used in the field on cotton, rice and corn once at the beginning of the season at rates of 2 to 3 L/hectare. The average duration of exposure was 3½ hours/hectare on an average area of 2 hectares/farm, for a total of 7 hours of exposure during an average of 1½ –2 days of treatment. With regard to incident frequency rate, Gramoxone® Super alone has been implicated in 53 intoxication incidents and is the product that has caused the greatest number of health problems among agricultural producers in Burkina Faso. Of 153 pesticide formulations identified in the survey and 296 poisoning incidents from field application, Gramoxone® Super was responsible for 20 per cent of intoxications. This is due to the high toxicity of paraquat. Exposure through dermal or ocular contact, inhalation or ingestion may readily lead to systemic intoxication. Exposure to small amounts of paraquat, for example through ingestion of inhaled spray droplets, eating food that has been in contact with contaminated hands, or absorption through damaged skin when insufficient PPE is used, can cause systemic intoxication. In case of intoxication, no antidote or cure exists.

20. In a study performed in Costa Rica, eleven knapsack spray operators using Gramoxone® at four banana plantations were studied. Between 22 litres with a concentration of 0.2 per cent and 42 litres with a concentration of 0.1 per cent spray solution were sprayed per working hour. Of the 11 spray operators under study, seven reported having had one or more health problems in the preceding 12 months that were thought to have been related to paraquat exposure. Dermal and respiratory exposure was measured with skin pads and personal air sampling, and internal exposure by urine sampling. In Costa Rica in 2001, paraquat was identified as causal agent in 127 cases out of 544 notified pesticide poisonings. Seventeen of the cases were attributable to occupational exposure (24 unknown). Paraquat was also the leading active ingredient for severe and moderate poisonings. In Costa Rica, total actual dermal exposure of applicators to paraquat in banana plantations, assessed by skin pads in 1995, varied between 35–1130 mg/kg or 2–57 mg/h. The number of pesticide poisonings and incidents per million inhabitants are reported for several countries in document UNEP/FAO/RC/CRC.7/11/Add.3. In El Salvador, approximately 2 million litres of paraquat formulations are imported each year and between 289 and 402 (average 344) incidents were reported each year from 2005–2010. This corresponds to 172 incidents per 1 million litres.

21. Taking into account the information available, the Committee concluded that the criterion was met.

Criterion Annex IV, part 3 (e)

That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

22. The reason for the proposal to list Gramoxone® Super in Annex III was the occurrence of a number of poisoning incidents during the agricultural use of Gramoxone® Super (operator exposure) in the field under conditions of use that are reported to be common in Burkina Faso. Intentional misuse was not reported to be a reason for the proposal.

23. Taking into account the information available, the Committee concluded that the criterion was met.

24. The Committee concluded at its seventh session that the proposal from Burkina Faso to list Gramoxone® Super (paraquat dichloride formulated as emulsifiable concentrate of 276 g active ingredient/L, corresponding to paraquat ion at 200 g/L) in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of part 1 of Annex IV and all criteria set out in part 3 of Annex IV to the Convention, considering the information collected by the Secretariat in accordance with part 2 of Annex IV.

25. The Committee therefore recommends that paraquat dichloride formulated as emulsifiable concentrate of 276 g active ingredient/L or above, corresponding to paraquat ion at or above 200 g/L (CAS Nos.1910-42-5, 4685-14-7), be included in Annex III of the Rotterdam Convention as a severely hazardous pesticide formulation.

Annex II Information on reported incident from incident report**Country Name: Burkina Faso**

Address of Designated National Authority

Burkina Faso**Pesticides**

Directeur de la Protection des Végétaux
 Direction de la Protection des Végétaux
 Ministère de la Agriculture de l'Hydraulique et des Ressources
 Halieutiques
 01BP5362
 Ouagadougou 01
 Burkina Faso

Phone: +226 50 36 1915**Fax:** +226 50 36 1865**Email:** dpvcagriculture@yahoo.fr**PART B - PESTICIDE INCIDENT REPORT FORM****I. Product identity: What formulation was used when the incident took place**

1. Name of the formulation: **GRAMOXONE SUPER**.....
2. Type of formulation (check one of the following):
☒ **Emulsifiable Conc. (EC)** ☐ *Wettable Powder (WP)* ☐ *Dustable powder (DP)*
☐ *Water Soluble Powder (SP)* ☐ *Ultra Low Volume (ULV)* ☐ *Tablet (TB)*
☐ *Granular (GR)* ☐ *other, please specify:*
3. Trade name and name of producer, if available: **GRAMOXONE, Syngenta**

4. Name of the active ingredient(s) in the formulation: **Paraquat**

5. Relative amount of each active ingredient in the formulation (% concentration, g/l, etc.): **200g/l**

6. Attach copy of the label(s), if available. **Label attached**

II. Description of the incident: How the formulation was used.

7. Date of incident: **20/06/2010, 2005 (2), 2009 (2), 2004 (2), 2008, 2006, 1996, 2000, 2003, 2007**
8. Location of incident: village/city: **Bama, Zegnedougou, Wétina, Baguéra, Ouafirmadougou, Moundasso, N'Dorola, Foukoura, Tagouassi, Tansila**
 province/state/region: **Cascades/Hauts Bassins/Boucle Mouhoun**
 country: **Burkina Faso**
9. Person exposed (identity should be checked and recorded before submission of the form)
 Sex: **53 males (see annex)** ☐ female X age: **between 20 and 70³ yrs**
 If age unknown: ☐ child (<14 yrs) ☐ adolescent (14-19 yrs) ☐ adult (>19 yrs)

³ In the original Part B document by mistake 65 years is given.

10. Main activity at time of exposure (check one or more of the following):

- ☒ **application in field** ☐ *mixing/loading* ☐ *veterinary therapy*
☐ *household application* ☐ *vector control application* ☐ *human therapy*
☐ *re-entry to treated field* ☐ *other, please specify:*

11. Was protective clothing used during application? ☐ no ☐ yes

The most used are dust masks (in 39,08% of cases) followed by boots (28,8%), whereas suits are the least used (4.5%) during plant treatment. The combination of chemical cartridge respirator, gloves, boots, suit and glasses is used in 0.31% of cases. This combination of PPE (personal protective equipment) is however recommended during the application of pesticide preparations (especially paraquat-based preparations) in hot countries. The fact that this PPE combination is very little used (0.31% of cases) explains the fact that farmers applying the product are highly exposed to it.

The reasons for not using adapted PPE are the following:

- no financial means to buy them ;
- conventional EPPs are considered too expensive by farmers;
- farmers do not know that they exist;
- farmers hope they will get them for free;
- these equipments are not available on local markets;
- PPEs are inappropriate to the local climate conditions. Some farmers for example feel they suffocate if they wear PPEs while spraying;
- under-estimation of pesticides hazard.

If no, please explain why:.....

If yes, briefly describe (check one or more of the following):

- ☐ *gloves* ☐ *overalls* ☐ *eye glasses* ☐ *respirator*
☐ *face mask* ☐ *boots/shoes* ☐ *long-sleeve shirt* ☐ *long pants*
☐ *other, please specify:*.....

12. Information on how product was being used:

(a) Location of exposure/incident (*field, garden, greenhouse, house, etc.*): **Fields**.....

(b) List the animals/crop(s)/stored products treated if relevant: **Cotton, rice, corn**.....

(c) Application method: (*How product was used e.g. hand, bucket & brush, soil injection, spray(backpack, tractor mounted,etc), drip irrigation, aerial (helicopter, plane etc.)*):

The product is applied by means of backpack sprayer and treatment is carried out only once at the beginning of the season.

(d) Dose applied/concentration (*or amount of pesticide applied*): **2 to 3 l/ha**.....

(e) Duration of the exposure period:

- ☐ hours ☐ ½ day ☐ day ☐ other (specify): **3h 30 hours of spraying/ha on an average**

surface of 2h per farm, that is 7h of exposure in the whole during 1 day and a half to 2 days of treatment, considering that farmers can spray 1h to 1h½ per day by means of pressure backpack sprayers

13. If more than one pesticide formulation was used at the same time, please respond to points i) to iv) below for each formulation. (see also Part I Product Identity)

i) Was the pesticide in its original container? ☐ no ☒ **yes**

ii) Was the label available? ☐ no ☒ **yes**

If yes, was exposed individual able to read and understand label? ☐ no ☐ yes

Some farmers said they could get some advice on the use of pesticides but in general Farmers are illiterate

iii) Does the label include the reported use? ☐ no ☒ **yes**

If no, describe how the use reported above differs from that recommended on the label

(*use a separate page if necessary*):

iv) Is the reported incident typical of how the formulation is generally used? ☐ no ☒ **yes**

14. Climatic conditions under which the incident occurred (eg. temperature, relative humidity):

Wintering in the Sahel, characterized by hot and humid weather.

15. Were other individuals affected in the same incident? ☐ no ☒ **yes 53 cases**

16. Include any other details that may be useful in describing the incident and the way in which the formulation was used, in particular how the use reported here reflects common or recognized use patterns for this formulation (additional pages may be attached). See annex 1

III. Description of adverse effects:

17. Individual's reaction (check one or more of the following):

- ☐ dizziness **X** headache ☐ blurred vision **X** excessive sweating
☐ hand tremor ☐ convulsion ☐ staggering ☐ narrow pupils/miosis
☐ excessive salivation ☐ nausea/vomiting ☐ death

X other, please specify:

- itching
- tingling,
- skin burn,
- rashes and sores,
- total destruction of contaminated areas,
- fever,
- dizziness,
- bone pains,
- fainting,
- breathing problems,
- cough
- blurred vision,
- eyes pain,
- buzzing,
- stomach ache,
- Nausea,
- Vomiting
- blocked jawbones.

Most symptoms appeared immediately or a few hours after pesticide application.

18. Route of exposure (check main route or more than one if applicable)

- ☐ mouth **X** skin **X** eyes **X** inhalation
☐ other, please specify:

19. How soon after last use of the formulation were the adverse effects observed:

Most symptoms appeared immediately or a few hours after pesticide application.

.....

IV. Management:

20. Treatment given: **X** None in 1 case **X** Yes in 26 cases

X Unknown in 15 cases

Hospitalization: ☐ No **X** Yes in 11 cases ☐ Unknown

21. Include any other details/information regarding treatment including medical intervention/first aid/hospitalization/local practices, etc. (additional pages may be attached):

.....**In 25 cases, a treatment with medicinal plants has been administered to patients**

.....

V. Reporting/communication:

22. Date of data collection/consultation: June - July 2010

23. Name and address of investigator/data collector: See annex 3.....

.....

24. Category of investigator/data collector:

- ☐ medical ☐ paramedical **X** non-medical

If non-medical, then specify type of person (applicator, formulator, vendor, extension worker, manager, etc.):

25. Contact if further information is needed: **See annex 2**

Tel:

Fax: E.mail:

26. Has this incident been reported elsewhere? ☐ No ☒ Yes

If yes, where: **In several of the above mentioned villages, in 3 regions of Burkina Faso
(Cascades, Boucle du Mouhoun and Hauts bassins).**

Send the completed incident report form to the Designated National Authority.

(Name and address of the DNA)

Annex III Safety data sheet(s) on pesticide active ingredient(s)

Note: A safety data sheet on the product Gramoxone® Super by Syngenta from February 2007 can be found at:
http://cms.fideck.com/userfiles/duwest.com/webmaster/file/descargas_esp/agricola/Gramoxone+Super++Ing.pdf

WHO/FAO DATA SHEETS ON PESTICIDES No. 4 Rev.1 (8/78)

WORLD HEALTH ORGANIZATION

FOOD AND AGRICULTURE

ORGANISATION MONDIALE DE LA SANTE

ORGANIZATION

ORGANISATION POUR L'ALIMENTATION
ET L'AGRICULTURE

VBC/DS/75.4 (Rev.1)

ORIGINAL : ENGLISH

DATA SHEETS ON PESTICIDES No. 4 Rev.1**PARAQUAT**

CLASSIFICATION:

Primary use: Herbicide

Secondary use: None

Chemical group: Bipyridyl

Data sheet No. 4, Rev.1 (8/78)

It must be noted that the issue of a Data Sheet for a particular pesticide does not imply endorsement of the pesticide by WHO or FAO for any particular use, or exclude its use for other purposes not stated. While the information provided is believed to be accurate according to data available at the time when the sheet was compiled, neither WHO nor FAO are responsible for any errors or omissions, or any consequences therefrom.

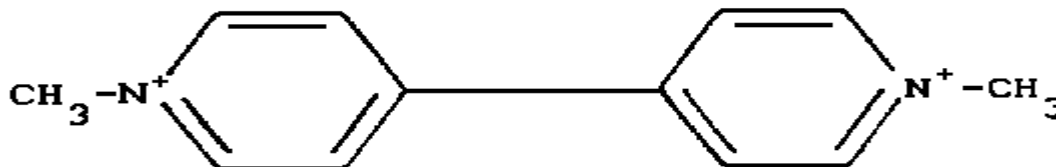
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1. GENERAL INFORMATION

1.1 COMMON NAME: Paraquat (ISO)

1.1.1 Identity: 1,1'-dimethyl-4,4'-bipyridilium ion. It should be stated which anion is present (e.g. paraquat dichloride).



Synonyms:

Local synonyms:

1.2 SYNOPSIS - Paraquat is a bipyridyl herbicide, highly toxic to man on oral ingestion; its toxic effect in mammals is due largely to damage to lung alveoli. It is a severe eye and moderate skin irritant, but is not significantly absorbed through intact skin. Absorption of spray mist can occur but does not appear to be of practical significance.

1.3 SELECTED PROPERTIES

1.3.1 Physical characteristics - Available as the dimethyl sulfate or the dichloride. White crystalline solids; the dimethyl sulfate is deliquescent. Both have m.p. ca 300°C with decomposition. Concentrated solutions corrode steel, tinsplate, galvanized iron and aluminium.

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1.3.2 Solubility - Water at 20°C about 700 g/l; slightly soluble in alcohol, insoluble in most other organic solvents.

1.3.3 Stability - Stable in acid and neutral solutions, unstable in alkaline solutions. Decomposes in ultra-violet light. Inactivated by anionic surface-active agents and by inert clays. Rapidly inactivated on contact with soil.

1.3.4 Vapour pressure (volatility) - Not measurable: nonvolatile.

1.4 AGRICULTURE, HORTICULTURE AND FORESTRY

1.4.1 Common formulations - Aqueous solutions of the dichloride containing 200 g/l of the cation, together with anticorrosive and surface-active agents. A formulation without surface active agents is used as an aquatic herbicide.

Mixtures containing 100-200 g/l paraquat with diquat (80-90 g/l) or a residual herbicide are available.

Also formulated as water-soluble granules containing 25 g/kg paraquat + 25 g/kg diquat.

There is an FAO specification for the aqueous salt solution.

1.4.2 Susceptible pests - Green plant tissue generally, on contact and in the presence of light. Used particularly to control broad-leaved weeds and grasses.

1.4.3 Use pattern - As contact herbicide before and after crop emergence on plantation and vegetable crops, in orchards, for aquatic weed control, stubble clearing and pasture renovation. Main uses are for weed control around trees in orchards and plantations and, by directed application, between rows of growing crops, and as cotton defoliant and dessicant on various crops, particularly potato haulm and sugar cane. Application rates usually range from 250 to 1500 g/ha. Up to 2200 g/ha is used for grass and stubble clearing.

1.4.4 Unintended effects - Damage can occur to bulbs in very sandy soil. Not harmful to wildlife or soil processes when used correctly.

1.5 PUBLIC HEALTH PROGRAMME - Not used.

1.6 HOUSEHOLD USE - The granule formulation (25 g/kg paraquat + 25 g/kg diquat) is used for weed control in home gardens. Liquid formulations for dilution before use are sometimes marketed.

2. TOXICOLOGY AND RISKS

2.1 TOXICOLOGY - MAMMALS

2.1.1 Absorption route - May be absorbed through the gastrointestinal tract. Paraquat is not absorbed to any great extent by intact skin and there is no evidence of significant absorption from spray mist.

2.1.2 Mode of action - After a latent period, produces marked congestion of the lungs with oedematous fluid in many of the alveoli and excess macrophages in others. Paraquat may also produce severe kidney damage giving rise to renal failure.

2.1.3 Excretion products - Oral administration of paraquat dichloride to rats resulted in 94% excretion in the faeces and 6% in the urine within 48 hours.

2.1.4 Toxicity, single dose

Oral: LD₅₀ rat (M): 100 mg/kg
LD₅₀ rat (F): 110 mg/kg

Dermal: LD₅₀ rat (M): 80 mg/kg
LD₅₀ rat (F): 90 mg/kg

Inhalation: LC₅₀ (four hours) rabbit, dichloride, 6.4 mg/m³

Most susceptible species - Guinea-pig, oral LD₅₀ 30 mg/kg.
Man appears to be a highly susceptible species.

2.1.5 Toxicity, repeated dose

Oral: Daily oral doses of 20 (mg/kg)/day to sheep for five days resulted in the death of all animals within two weeks. At 10 (mg/kg)/day for five days, one out of six sheep died while 5 (mg/kg)/day for 14 days resulted only in listless animals. Similar effects were observed in cattle.

Dermal: Rabbits were given daily percutaneous doses of paraquat. At 14.5 (mg/kg)/day, two out of three animals died within 20 days. At 7.3 (mg/kg)/day there were no deaths but there was some consolidation in lung alveoli. The no-effect level was 2.8 (mg/kg)/day. In another study, one out of five rabbits died when a daily percutaneous dose of 1.5 (mg/kg)/day was administered under an impervious layer for 20 days.

Inhalation: Repeated daily six-hour exposure of rats to paraquat aerosols over a three week period produced signs of lung irritation but no deaths at 0.4 µg/m³.

Cumulation of compound: Does not appear to accumulate in mammalian tissues.

2.1.6 Dietary studies

Short-term: No information.

Long-term: In a 26-27 month feeding study of paraquat dichloride to dogs there was increased mortality and lung changes at 125 mg/kg diet (3.125 (mg/kg)/day) but no effect at 50 mg/kg (1.25 (mg/kg)/day). No adverse effects were observed at a dietary level of 250 mg/kg (12.5 (mg/kg)/day) of paraquat dichloride (the maximum level) fed to rats over a two-year period.

2.1.7 Supplemental studies of toxicity

Carcinogenicity

Rat: No increase in tumour incidence at a maximum dietary level of 250 mg/kg diet (12.5 (mg/kg)/day) for two years.

Reproduction studies: A multi-generation study in rats has shown that 100 mg/kg paraquat in the diet did not interfere with the reproduction of three successive generations.

Teratogenicity

Rat: A single intraperitoneal injection of 6.5 mg/kg of paraquat on day 6 of gestation produced a high incidence of costal cartilage malformation in the embryos. This defect was not noted when injections were given on days 7 to 14 of gestation.

Grazing studies: Paraquat, when ingested as a residue in herbage, has been reported to present no toxicological hazard to farm animals.

2.1.8 Modifications of toxicity: No special features reported.

2.2 TOXICOLOGY - MAN

2.2.1 Absorption - See 2.1.1

Ingestion has proved to be the main cause of poisoning with this compound. One fatal case of percutaneous absorption has been described.

2.2.2 Dangerous doses

Single: The fatal dose in adults is estimated to be 10-15 ml of the 20 g/l concentrate (i.e., 30-50 mg/kg). However, it has been suggested that the ingestion of 3 g is the maximum compatible with survival.

Repeated: No information.

2.2.3 Observations of occupationally exposed workers - No reported incidence of serious systemic toxic effects from plant workers engaged in the manufacture of paraquat. Irritation of skin and mucous membranes, severe irritation of the eye and effects on finger-nails have resulted from careless use.

2.2.4 Observations on exposure of the general population - No information available.

2.2.5 Observations of volunteers - No information available.

2.2.6 Reported mishaps - There are no known outbreaks of poisoning by paraquat. There have, however, been numerous cases, mostly with a fatal outcome. About half of these have been accidents, the others suicides. It has been suggested that the incidence of mortality from accidental ingestion of paraquat is 50%. In 40% of all fatal cases the interval between ingestion and death has been more than a week.

2.3 TOXICITY TO NON-MAMMALIAN SPECIES

2.3.1 Fish - Not hazardous: rapidly absorbed by aquatic plants and inactivated in mud.

2.3.2 Birds - Not highly toxic. No hazard under normal conditions of use.

2.3.3 Other species - Toxic to bees, but method of use avoids risk.

3. FOR REGULATORY AUTHORITIES - RECOMMENDATIONS ON REGULATION OF COMPOUND

3.1 RECOMMENDED RESTRICTIONS ON AVAILABILITY

(For definition of categories, see introduction) .

Liquid formulations 10% or more, category 4.

Solids over 25% category 4, all other formulations, category 5.

3.2 TRANSPORTATION AND STORAGE

All formulations in categories 3 and 4 - Should be transported or stored in clearly labelled rigid and leak-proof containers. No food or drink should be transported or stored in the same compartment. Storage should be under lock and key, and secure from access by unauthorized persons and children.

Formulations in category 5 - Should be transported or stored in clearly labelled leakproof containers away from food.

3.3 HANDLING

All formulations in categories 3 and 4 - Protective clothing should be provided for those handling concentrates. Adequate washing facilities should be available close at hand. Eating, drinking and smoking should be prohibited during handling and before washing after handling.

Formulations in category 5 - No facilities other than those needed for the handling of any chemical are required.

3.4 DISPOSAL AND/OR DECONTAMINATION OF CONTAINERS - Containers must either be burned or crushed and buried below topsoil. Containers may be decontaminated (for method see paragraph 4.3 or sheet 4). Decontaminated containers should not be used for food and drink.

3.5 SELECTION, TRAINING AND MEDICAL SUPERVISION OF WORKERS

All formulations in categories 3 and 4 - Training of workers in techniques to minimize contact essential.

Formulations in category 5 - Warning of workers to avoid contact essential.

3.6 ADDITIONAL REGULATIONS RECOMMENDED IF DISTRIBUTED BY AIRCRAFT

All formulations - Pilots and loaders should receive special training in application methods. Use of flagmen not recommended. Flagmen, if used, should wear overalls and be located well away from the dropping zone.

3.7 LABELLING

All formulations in categories 3 and 4 - Minimum cautionary statement - Paraquat is a toxic substance. It is poisonous if swallowed and highly irritating to the eyes if splashed into them. Avoid skin contact; wear protective gloves while mixing and wear protective clothing while mixing and using the material. Wash thoroughly with soap and water after using. Keep the material out of reach of children and well away from foodstuffs, animal feed and their containers.

Formulations in category 5 - Minimum cautionary statement - This formulation contains paraquat which is a toxic substance. It is poisonous if swallowed and highly irritating to the eyes if splashed into them. Keep the material out of reach of children and well away from foodstuffs, animal feed and their containers.

3.8 RESIDUES IN FOOD

3.8.1 Maximum residue levels (tolerances) - The Joint FAO/WHO Meeting on Pesticide Residues has recommended maximum residue levels.

3.9 SPECIAL NOTE ON PARAQUAT - While poisoning is frequently fatal, it usually only results from misuse of paraquat, i.e. by accidental or deliberate ingestion. The hazard can be diminished by limiting the maximum concentrations of the chemical as marketed.

4. PREVENTION OF POISONING IN MAN AND EMERGENCY AID

4.1 PRECAUTIONS IN USE

4.1.1 General - Paraquat is a bipyridyl herbicide, highly toxic to man by oral ingestion, its toxic effect in mammals is due largely to the damage that it produces to lung alveoli. It is a severe eye and moderate skin irritant but is not absorbed to any great extent by intact skin; there is no evidence of significant absorption from spray mist.

4.1.2 Manufacture and formulations

T.L.V.

ACGIH - 0.5 mg/m³.

Closed systems and forced ventilation may be required to reduce as much as possible the exposure of workers to the chemical.

4.1.3 Mixers and applicators - When opening the container and when mixing, protective impermeable boots, clean overalls, gloves and a face mask should be worn. Mixing, if not mechanical, should always be carried out with a paddle of appropriate length. When spraying tall weeds or during aerial application a face visor should be worn as well as an impermeable hood, clothing, boots and gloves. The applicator should avoid working in spray mist and avoid contact with the mouth. Particular care is needed when equipment is being washed after use. All protective clothing should be washed immediately after use, including the insides of gloves. Splashes must be washed immediately from the skin or eyes with large quantities of water. Before eating, drinking or smoking, hands and other exposed skin should be washed.

- 4.1.4 Other associated workers (including flagmen in aerial operations) - Persons exposed to paraquat and associated with its application should wear protective clothing and observe the precautions described in 4.1.3 under "mixers and applicators".
- 4.1.5 Other populations likely to be affected - With good agricultural practice subject to 4.2 below, other populations should not be exposed to hazardous amounts of paraquat.

4.2 ENTRY OF PERSON INTO TREATED AREAS - No restrictions.

- 4.3 SAFE DISPOSAL OF CONTAINERS AND SPILLAGE - Containers should be emptied in a diluted form into a deep pit. The empty container may be decontaminated by rinsing two or three times with water and scrubbing the sides. An additional rinse should be carried out with 5% sodium hydroxide solution which should remain in the container overnight. Impermeable gauntlets should be worn during this work and a soakage pit should be provided for the rinsings. Decontaminated containers should not be used for food and drink.

Spillage of paraquat and its formulations should be removed by covering the area with soil and rinsing with large quantities of water.

4.4 EMERGENCY AID

- 4.4.1 Early symptoms of poisoning - Early symptoms of poisoning may include epigastric discomfort and vomiting as well as general malaise and weakness. There may be irritation of the mouth, pharynx and oesophagus with local burning. With very large doses there may be excitement and convulsions.
- 4.4.2 Treatment before person is seen by a physician if these symptoms appear following exposure - If swallowed, vomiting should be induced. A high fluid intake should be maintained, the patient kept at rest and sent to hospital immediately. In cases of contamination of skin or clothing, wash the affected skin with soap and water, if available, and flush the area with large quantities of water.

5. FOR MEDICAL AND LABORATORY PERSONNEL

5.1 MEDICAL DIAGNOSIS AND TREATMENT OF CASES OF POISONING

- 5.1.1 General information - A bipyridyl herbicide of moderately high acute toxicity which may be absorbed through the intact skin as well as by inhalation. The main hazard, however, is absorption by oral intake. Paraquat owes its toxic effect largely to the delayed damage that it produces on the lung alveoli. In rats it is excreted largely in the faeces but after absorption can be readily detected in the urine. The extent to which it persists in the tissues is still unclear.
- 5.1.2 Symptoms and signs - Initial symptoms of poisoning may be epigastric discomfort, diarrhoea and vomiting along with general malaise and weakness. There may be irritation of the mouth, pharynx and oesophagus with local burning. After one or two days signs of tissue and possibly liver damage will appear, if

appreciable quantities have been swallowed. After one to two weeks there may be dyspnoea with pulmonary oedema leading to massive pulmonary fibrosis and death due to respiratory insufficiency. With very large doses there may be excitement and convulsions.

5.1.3 Laboratory - The presence of paraquat in the urine is indicative of absorption of the compound. Urinary levels should be measured at frequent intervals. Blood levels are very low and do not provide a satisfactory method for determining the extent of absorption.

5.1.4 Treatment - If the pesticide has been ingested it is imperative that a prompt effort be made to remove as much paraquat as possible before absorption takes place so as to supplement its elimination via the kidneys. Gastric lavage should be carried out with care because of the possible oesophageal injury. At least 500 ml of a 7% bentonite (colloidal aluminium silicate) suspension should be introduced into the stomach within one to two hours after the paraquat has been ingested. The suspension is prepared by triturating bentonite with glycerine and adding water to a final concentration of 7% bentonite and 10% glycerine. Fuller's earth 30% can be used in place of bentonite. As paraquat is freely excreted by the renal glomeruli but is reabsorbed in the tubules, forced diuresis is of benefit in hastening excretion. Haemodialysis and peritoneal dialysis may be indicated if there is evidence of renal failure. Additional treatment may include immunosuppressive therapy and prednisone 60 mg and cyclophosphamide 3 mg/kg per day have been recommended to try to prevent the lung lesions. Oxygen may be necessary if cyanosis or dyspnoea occurs but there is some evidence that its effect may be harmful.

5.1.5 Prognosis - The prognosis in cases of paraquat poisoning is very poor. In 40% of cases death has occurred more than a week after ingestion. Progressive respiratory embarrassment may occur five to 10 days after taking the paraquat, sometimes after a period of apparent recovery. Once the lung changes become evident chances of recovery are practically nil.

5.1.6 References of previously reported cases - The following references give methods of treatment used in cases of poisoning:

Kerr, F., Patel, A. R., Scott, P. D. R. & Thompson, S. L. (1968) Brit. med. J., 3, 290-291

McDonagh, B. J. & Martin, J. (1970) Arch. Dis. Childh., 45, 425-427

Clinicopathological Conference (1971) Scot. med. J., 16, 407

Malone, J. D. G., Carmody, M., Keogh, B. & O'Dwyer, W. F. (1971) J. Irish med. Ass., 64, 69

5.2 **SURVEILLANCE** - Levels of paraquat in the urine provide the most readily available method for indicating absorption of paraquat. However, actual levels cannot be correlated with the severity of intoxication because recovery is probably also dependent on the volume of urine excreted and therefore the total amount of paraquat eliminated from the body. By way of guidance the highest concentration of paraquat found in the urine of spray workers was 0.32 mg/l and the average was well below 0.1 mg/l. In poisoning cases it has been found that recovery may occur if the peak level is below 200 mg/l.

5.3 LABORATORY METHODS

References only are given.

5.3.1 Detection and assay of compounds - Detection of paraquat depends upon reduction to the free radical with sodium dithionite. In alkaline solution a stable blue colour is then formed which may be measured spectrophotometrically. For determination in urine see Thompsett (1970) and Berry & Grove (1971). (Thompsett also describes determination in other body fluids and tissues.) Residues in food crops can be determined by the method of Calderband & Yuen (1965) (see also Pack, 1967); later modifications are suitable for determinations in meat, milk and animal tissues (Plant Protection Ltd., 1972).

5.3.2 Other tests in cases of poisoning - None.

REFERENCES

- Thompsett, S. L. (1970) Paraquat poisoning, Acta. Pharmacol. Toxicol., 28, 346
- Berry, D. J. & Grove, J. (1971) The determination of paraquat (1,1'-dimethyl-4,4'-bipyridilium cation) in urine, Clin. chim. Acta, 34, 5
- Calderband, A. & Yuen, S. H. (1965) An ion-exchange method for determining paraquat residues in food crops, Analyst, 90, 99
- Pack, D. E. (1967) In: Zweig, G., ed., Analytical Methods for Pesticides, Plant Growth Regulators and Food Additives, Academic Press, New York and London, vol. V, p. 473
- Plant Protection Limited (1972) Details of the methods are available from Plant Protection Limited, Fernhurst, Hazlemere, Surrey, England (Personal communication)

Annex IV Further information on the pesticide active ingredient

Introduction

This annex provides further information on the physico-chemical, toxicological and environmental properties of the pesticide active ingredient paraquat. This information has been taken from the documents collected by the secretariat in line with part 2 of Annex IV of the Convention and made available to the Chemicals Review Committee in documents UNEP/FAO/RC/CRC.7/11/Add.2 to 6, including the review of paraquat by the European Union (finalised 2003); information from the US EPA and Australia, the Pesticide Action Network (PAN), the Berne Declaration, the IPCS (2009) and JMPR (2003).

Further information on the physico-chemical, toxicological and environmental properties of pesticide formulations containing paraquat may be found in safety data sheets for the respective products via the internet.

1. Physico-Chemical properties		
1.1	Identity	Paraquat dichloride
1.2	Formula	$C_{12}H_{14}N_2Cl_2$
1.3	Colour and Texture	colourless, hygroscopic crystals or white to yellow hygroscopic crystalline powder (Pesticide Manual, IPCS)
1.4	Decomposition temperature	300 - 340 °C (Pesticide Manual, IPCS)
1.6	Density (g/cm³)	1.5 g/cm ³ at 25 °C (purity 99.5 % w/w) 1.13 g/cm ³ at 25 °C (technical)
2 Toxicological properties		
2.1	General	
2.1.1	Mode of Action	Non-selective contact herbicide
2.1.2	Symptoms of poisoning	<p>The substance is irritating to the eyes, the skin and the respiratory tract. Inhalation of this substance may cause lung oedema. The substance may cause effects on the kidneys, liver, gastrointestinal tract, cardiovascular system and lungs, resulting in impaired functions, tissue lesions including haemorrhage and lung fibrosis. Exposure to high concentrations may result in death. (IPCS 2009)</p> <p>Common exposure symptoms include burns to the mouth, acute respiratory distress, loss of appetite, abdominal pain, thirst, nausea, vomiting, diarrhoea, giddiness, headache, fever, muscle pain, lethargy, shortness of breath and rapid heartbeat. There can be nosebleeds, skin fissures, peeling, burns and blistering, eye injuries, and nail damage including discolouration and temporary nail loss. (PAN Asia-Pacific 2010)</p>
2.1.3	Absorption, distribution, excretion and metabolism in mammals	<p>The pharmacokinetics and metabolism of paraquat have been the subject of many studies. Paraquat is not well-absorbed when administered orally. After oral administration of radiolabelled paraquat to rats, more than half the dose (60-70%) appeared in the faeces and a small proportion (10-20%) in the urine. In studies involving single or repeated doses, excretion of the radiolabel was rapid; about 90% was excreted within 72 h.</p> <p>Paraquat is largely eliminated unchanged; in rats, approximately 90-95% of radiolabelled paraquat in urine was excreted as the parent compound. (JMPR 2003)</p>
2.2	Toxicology studies	

2.2.1 Acute toxicity	<p>Rat LD₅₀ oral: 40-350 mg/kg bw Mouse LD₅₀ oral: 290-360 mg/kg bw Guinea pig LD₅₀ oral: 22-30 mg/kg bw Monkey LD₅₀ oral: 50-70 mg/kg bw (EU 2003, JMPR 2003) Rat LD₅₀ acute percutaneous > 911 mg/kg bw (Pesticide Manual) Rabbit LD₅₀ dermal 80 - > 660 mg/kg bw (JMPR 2003)</p> <ol style="list-style-type: none"> 1. Rat LC₅₀ inhalation 0.0006-0.0014 mg paraquat ion/L (4 h exposure) (JMPR 2003) <p>Paraquat was considered to be a mild skin irritant and a moderate eye irritant and was not a skin sensitizer in the Magnusson and Kligman test (JMPR 2003).</p>
2.2.2 Short term toxicity	<p>Oral, 13 weeks dog study, NOAEL 0.55 mg paraquat ion/kg bw/d Oral, 1 year dog study, NOAEL 0.45 mg/kg bw/day (alveolar damage in lungs) Dermal, 21-d -study in rabbits, NOAEL 1.15 mg paraquat ion/kg bw/d Inhalation, 3 week rat study, NOAEC 0.00001 mg/L (JMPR 2003)</p>
2.2.3 Genotoxicity (including mutagenicity)	<p>Clastogenic at high concentrations <i>in vitro</i>. Unlikely to pose a genotoxic risk to humans at dietary concentrations (JMPR 2003) Not genotoxic <i>in vivo</i> (EU 2003)</p>
2.2.4 Long term toxicity and carcinogenicity	<p>2 year chronic rat study, NOAEL 1.2 mg/kg bw/day (25 ppm; cataracts, kidney tubule degeneration, lung and testes)</p> <p>Not carcinogenic; unlikely to pose a carcinogenic risk to humans (JMPR 2003).</p> <p>Lung abnormalities observed in mice, rats and dogs consisted of increased lung weight and gross pathological changes. Associated histopathological changes included cell necrosis, alveolar cell proliferation and hypertrophy, oedema, infiltration of macrophages and mononuclear cells and exudate. Dogs were most sensitive to paraquat-induced lung toxicity, followed by rats and mice; a NOAEL of 0.45 mg paraquat ion/kg bw per day was found in a 1-year study in dogs, on the basis of signs of respiratory dysfunction and histopathological changes at higher doses. This finding was supported by the NOAEL of 0.55 mg paraquat ion/kg bw per day from a 13-week study in dogs. (JMPR 2003)</p>
2.2.5 Effects on reproduction	<p>Reproductive NOAEL = 2.5 mg/kg bw/day (lung lesion in parental animals - no effects on reproduction)</p> <p>Developmental NOAEL = 3 mg/kg bw/day (embryotoxic at maternally toxic doses)</p> <p>Three studies of reproductive toxicity in rats were reported. The overall NOAEL for parental toxicity was 1.67 mg paraquat ion/kg bw per day, and the NOAEL for pup toxicity was 5.0 mg paraquat ion/kg bw per day. Impaired fertility was not seen in these studies. Two studies of developmental toxicity in rats and two in mice were available for evaluation. The lowest NOAELs observed for both maternal and developmental toxicity in rats were 1 mg paraquat ion/kg bw per day, on the basis of clinical signs, and reduced body-weight gain in the dams and reduced mean fetal weights and retarded ossification in the fetuses. Higher NOAELs for maternal and developmental toxicity were seen in mice. Teratogenicity was not seen at any dose in any study in either rats or mice. (JMPR 2003)</p>
2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available	<p>Not neurotoxic by oral route (JMPR 2003)</p> <p>There is some evidence that paraquat is able to cause the onset, or accelerate the development, of Parkinson's disease. (PAN Asia-Pacific 2010, EU 2003)</p>

2.2.7	Summary of mammalian toxicity and overall evaluation	<p>Paraquat is of moderate acute oral toxicity, of low acute dermal toxicity, and of moderate acute inhalation toxicity. Paraquat is irritating to the skin and eyes.</p> <p>Paraquat may cause effects on the kidneys, liver, gastrointestinal tract, cardiovascular system and lungs, resulting in impaired functions, tissue lesions including haemorrhage and lung fibrosis. Exposure to high concentrations may result in death.</p> <p>Critical effects: Short-term: lungs - alveolar damage by oral route; upper respiratory tract damage by inhalation. Long-term: eyes (cataract), kidney (tubule degeneration), lung and testes.</p> <p>It is not genotoxic, carcinogenic or a reproductive toxin.</p>
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3 Human exposure/Risk evaluation

3.1	Food	Maximum residue limits (MRL) have been recommended for a variety of agricultural products and foodstuffs by the FAO/WHO. The MRL for maize is 0.03 mg/kg and for rice 0.05 mg/kg. MRL's for other products may be found under http://www.codexalimentarius.net .
3.2	Air	-
3.3	Water	MAC (maximum acceptable concentration) = 13 µg/L
3.4	Occupational and dietary exposure	<p>ADI: 0-0.005 mg/kg bw as paraquat ion (NOAEL from a 1 year dog study)</p> <p>AOEL systemic (short term): 0.0005 mg/kg bw/d (90 day dog study)</p> <p>AOEL systemic (long term): 0.0004 mg/kg bw/d (1 year dog study)</p> <p>ARfD: 0.006 mg/kg bw/d as paraquat ion (13 weeks dog study) (JMPR 2003)</p>
3.5	Medical data contributing to regulatory decision	<p>Published literature and company records report fatalities in cases of oral ingestion of concentrated paraquat formulations.</p> <p>Peer reviewed published literature and many reports from Non-Governmental Organisations are available that report health problems up to fatalities after occupational exposure during agricultural use of paraquat, especially but not exclusively in developing countries, mostly due to inadequate use of PPE and lack of instructions/unawareness of the risk (see also Annex I).</p> <p>Cases of skin irritation, nail discolouration and nosebleeds in manufacture and occupational use have been reported, related to inadequate working practises and poor hygiene.</p>
3.6	Public exposure	-
3.7	Summary-overall risk evaluation	<p>The EU and US EPA risk evaluations concluded that applicators and other handlers must wear PPE (long-sleeved shirt and long pants, chemical resistant gloves, shoes plus socks, protective eyewear, respirator with filter). In a study in the US on the exposure of workers who mixed, loaded and applied paraquat, it was concluded that the margins of skin exposure (the no observed effect level divided by total daily dose) were unacceptable for backpack applicators and workers who used low pressure sprayers - even when they wore long pants, a long-sleeved shirt, chemical-resistant gloves and shoes with socks as PPE (Berne Declaration). The use of paraquat containing products is restricted in the USA. In the EU paraquat containing products are no more permitted in order to ensure a high level of protection of human health and the environment.</p> <p>In Australia paraquat is currently under review because of concerns over the potential risk to occupational health and safety and the environment.</p> <p>All liquid formulations of paraquat should contain suitable alerting agents (dye and stench) to reduce the risk of accidental oral ingestion of the product.</p>

All solid formulations of paraquat should contain a suitable dye to reduce the risk of accidental oral ingestion of the product.

All formulations of paraquat should contain an appropriate level of emetic, to increase the likelihood of emesis in case of significant accidental or deliberate oral ingestion.

Countries should consider limiting, wherever practical and reasonable, availability and use of high-strength liquid formulations to bona fide agriculturalists, horticulturalists and professional users.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Due to strong adsorption to soil, the route of microbial degradation of paraquat has only been demonstrated in pure cultures. Paraquat is relatively stable, immobile and withstands anaerobic degradation.

In a UK study with annual application, soil residues of paraquat were 17% of the theoretical maximum after 20 years.

Koc = 8400 to 40 000 000 (very strong adsorption)

4.1.2 Water

Paraquat is adsorbed to suspended matter in water, and onto sediment.

Paraquat is hydrolytically stable at pH 5, 7 and 9 after 30 days at 25 and 40°C.

Paraquat is photolytically stable at environmentally relevant wavelengths. In water, paraquat will mainly adsorb to sediment, with an expected DT50 in the range of < 24 hours for dissipation in water.

Persistent in the sediment.

4.1.3 Air

Paraquat has a low vapour pressure ($< 10^{-8}$ kPa at 25 °C) and is non-volatile. It is likely to exist predominantly in the particulate phase in the atmosphere.

4.1.4 Bioconcentration

Log P_{ow}: - 4.5 (20 °C), not bioaccumulating (EU 2003, Pesticide Manual)

4.1.5 Persistence

Highly persistent in soil (DT₅₀ 3000 days)

Soil DT₅₀ (field): 7-8 years (UK), 10-20 years (USA)

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

Mammalian toxicity see point 2.

Acute toxicity to birds: LD₅₀: 35 mg paraquat/kg bw (EU 2003)

Dietary toxicity to birds: LC₅₀: 698 ppm (EU 2003)

Reproductive toxicity to birds: NOEC: 30 mg/kg diet (EU 2003)

Paraquat can affect reproduction and hatchability of eggs when adult birds are exposed.

4.2.2 Aquatic species

Acute toxicity to fish: LC₅₀: 19 mg/L (Rainbow trout, 96 hour study)

21-days toxicity to fish (Rainbow trout, flow-through): NOEC 8.6 mg paraquat ion/L (EU 2003)

At a concentration of 500 µg/L paraquat adversely affects frog tadpoles. (PAN Asia-Pacific 2010, EU 2003)

Acute toxicity invertebrate: EC₅₀: 4.4 mg paraquat/L (*Daphnia magna*, 48 hour study) (EU 2003)

Chronic toxicity invertebrate: 14 – 21 day NOEC: 0.12 mg/L (EU 2003)

		<p>Acute toxicity algae: EC₅₀: 0.00023 mg/L (<i>Navicula pelliculosa</i>, 96 hour study)</p> <p>Chronic toxicity sediment dwelling organism: <i>Chironomus riparius</i>: 21 day NOEC in sediment: 100 mg/kg;</p> <p>21 day water phase only NOEC: 0.367 mg/L (EU 2003)</p> <p>Acute toxicity aquatic plants: EC₅₀: 0.037 mg/L for <i>Lemna gibba</i> (14 day semi static study) (EU 2003)</p>
4.2.3	Honeybees and other arthropods	<p>Bee LD₅₀ oral: 9.06 µg paraquat/bee - 120 hour acute study (SL formulation)</p> <p>Bee LD₅₀ contact: 9.26 µg paraquat/bee - 120 hour acute study (SL formulation) (EU 2003)</p> <p><i>Pardosa sp</i> Mortality: No effect on adults at 1.0 kg paraquat/ha (SL formulation)</p> <p><i>Aleochara bilineata</i> Mortality: No effect on adults at 0.6 kg paraquat/ha (SL formulation)</p> <p><i>Pterostichus melanarius</i> Mortality: No effect on adults at 1 kg paraquat/ha (formulation "Gramoxone 100") (EU 2003)</p>
4.2.4	Earthworms and other soil organisms	<p><i>Eisenia fetida</i> LC₅₀ > 1000 mg paraquat/kg soil (14 days, 200 g/L SL formulation)</p> <p>No adverse effects were observed on earthworm populations in a field study following an application of up to 720 kg paraquat/ha in one year. (EU 2003)</p> <p>Some negative effects have been shown on springtails and Acarides. (Sweden 1982)</p>
4.2.5	Soil microorganisms	<p>No adverse effects were observed on nitrogen or carbon mineralization after application of up to 720 kg paraquat/ha in one year. (EU 2003)</p>
4.2.6	Terrestrial plants	<p>Toxic to non-target crops and plants if off-target movement occurs. (US EPA 2010)</p>

5 Environmental Exposure/Risk Evaluation

Not relevant in the context of this DGD

Annex V References

- British Crop Production Council (2009_2010). E-Pesticide Manual, Version 5.0.1, 2010, 15th edition.
- EPA (2010). Sample paraquat product labels.
- EU (2003). Review report for the active substance Paraquat. Document SANCO/10382/2002 –final.
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- US EPA (2010). Sample paraquat product labels.
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