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Chemical Review Committee
Eighth meeting
Geneva, 19–23 March 2012
Item 5 (c) (iv) of the provisional agenda*

Technical work: consideration of draft decision guidance documents: Gramoxone Super

Comments and further information related to the draft decision guidance document for 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

Note by the Secretariat

1. In accordance with the process for the development of decision guidance documents set out in decision RC-2/2 of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, an internal proposal for Gramoxone Super was circulated to the Chemical Review Committee and its observers for their information and comments. A tabular summary of the comments received thereon and how they were taken into account in preparing the draft decision guidance document for 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, was considered by the Chemical Review Committee at its eighth meeting. The Committee revised and then agreed upon for consideration by the Conference of the Parties both the tabular summary and the draft decision guidance document.

2. The tabular summary is set out in the annex to the present note. It has not been formally edited. The draft decision guidance document is set out in the annex to document UNEP/FAO/RC/CRC.8/9/Rev.1.

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

Annex

Gramoxone Super: comments and responses thereto

Tabular summary of comments on the internal proposal on liquid formulations (EC and SL) containing paraquat dichloride at or above 276 g/L, corresponding to paraquat ion at or above 200 g/L

Country	Section	Comment/Suggestion	Response
Australia	Annex IV - 4.1 Fate	Generally we agree with what is presented, unless stated otherwise, but in some areas further details could be provided, if known, for clarification.	Noted.
	Annex IV - 4.1.2 Fate in water	It should be made clear that the DT50 (< 24 hours) refers to dissipation from water to sediment and that once in the sediment paraquat is persistent.	Agreed and amended.
	Annex IV - 4.1.	Effects on non-target organisms Generally Australia agrees with the author's endpoints, unless stated otherwise, which are usually included in the ranges that we noted for that species or at least of a similar magnitude. General points to note are: • If single endpoints are used in the document, they should be the most sensitive and it should be made clear that these are the most sensitive endpoints. Alternatively, the range of endpoints for each representative species and for each study type should be provided; and • It should be made clear if the endpoints are for the active constituent or a formulation.	Noted. In case a range is given for toxicity endpoints, the lowest figure represents the most sensitive data point from the sources available. Annex IV relates to the active ingredient, hence if not otherwise mentioned, units are related to a.i., not a formulation. For some endpoints, where this information was found, it was added.
	4.2.2 Effects on aquatic species	With respect to the frog effects endpoint it would be helpful to know the species. Regarding the "Chronic toxicity invertebrate: 14 – 21 day NOEC: 0.12 mg/L" it should be made clear what species this refers to and what effect it's based on.	No information on the species is found in the source cited. However, in the EU monograph similar (non-GLP) data are reported and relate to *Rana pipiens*. As we can not verify that the same study was cited by PAN, we prefer not to add the species. The source is added: EU review report, 2003. Unfortunatly more details are not mentioned.
	4.2.3 Effects on honeybees and other arthropods	The author should check their honeybee contact endpoint (9.26 µg paraquat/bee, 120 hours) to ensure it's not the contact endpoint for the formulation. The author should also confirm the endpoints for the wolf spider (*Pardosa sp*) and the ground beetle (*Pterostichus melanarius*) because Australia has previously noted that there were no mortalities to either of these species after exposure at field rates of ~1 kg paraquat ion/ha.	Again this information is from EU review report, 2003; the unit relates to the active substance. These endpoints were listed in the EU review report, however, after checking the original EU monograph, the review report values seem inaccurate (see also Crop Life comment). They were corrected to 1 kg/ha.

Country	Section	Comment/Suggestion	Response
Berne Declaration	Annex III	The inclusion of the whole WHO/FAO Data Sheets is in our view problematic, as it was published in 1978 (with reference studies from 1965 till 1972) and therefore does not represent the state of the art.	Noted. It`s the official publication of one of the RC`s partners and should be kept.
	Annex IV	In Annex IV – Further information on the pesticide active ingredient, we suggest to change the first sentence in the second para of 3.5 to: *Peer reviewed published literature and many reports from NGOs are available that report … .* [Reasoning: Most of NGO Reports are based on peer reviewed literature, therefore it's more adequate to mention the literature first.]	Agreed and amended.
	Annex IV	In Annex IV – Further information on the pesticide active ingredient, we suggest to replace the last sentence of the first para of 3.7 to be more precise (In the EU paraquat containing products ….). The new sentence would be: *In the EU in a judgement of July 11th 2007 the court of first instance annulled the directive authorising Paraquat as an active plant protection substance. The Court noted that in a Guatemala n study one of the participating oper ators underwent exposure to paraquat equivalent to 118% of the acceptable operator exposure level fixed for that substance, despite use under the prop osed conditions. Accordingly, the Community requirement, which prohibit any exposure higher than the acceptable operator exposure level, have not been satisfied. Consequently, the Directive authorizing Paraquat failed to satisfy the requirement of protection of human health*. [source: http://curia.europa.eu/en/actu/communiq ues/cp07/aff/cp070045en.pdf">http://cur ia.europa.eu/en/actu/communiques/cp07/ aff/cp070045en.pdf]	Not agreed – this is considered to be too detailed.
	Annex V References	As an additional comment we ask to take into account following reports/studies which are not mentioned in the draft DGD: - Dawson AH, Eddleston M, Senarathna L, Mohamed F, Gawarammana I, Bowe SJ, Manuweera G, Buckley NA (2010): *Acute Human Lethal Toxicity of Agricultural Pesticides: A Prospective Cohort Study* [http://www.plosmedicine.org/article/inf o:doi/10.1371/journal.pmed.1000357] - Yoon KC, Im SK, Kim JC, Yoon KW & Choi SK (2009): *Prognosis of paraquat-induced ocular surface injury: therapeutic effect of amniotic membrane transplantation.* Cornea 28(5):520-3 [http://www.ncbi.nlm.nih.gov/pubmed/1 9421046] - Richard Isenring, Lars Neumeister, April 2011, 3rd edition; *Paraquat: Unacceptable health risks for*	No change. The information for the DGD should be obtained from the submitted proposal from Burkina Faso and the additional information available to the CRC at the time the proposal was discussed.

Country	Section	Comment/Suggestion	Response
		users; [http://www.evb.ch/cm_data/Paraquat_UnacceptableHealthRisk_3rdEdition_2011_6_2.pdf]	
Canada	Title	To be verified whether Annex III listing is meant to apply only to "Gramoxone Super" or to any formulations containing paraquat ion at or above 200 g/L.	Agreed. The title is amended.
	List of abbreviations	Change "l" to "L" for litre	Agreed and amended.
	1. Trade name	To be verified	No change. Here the trade name is stated and not the definition for Annex III listing
	2.	Formulation Gramoxone Super to be verified	The proposal was received for this formulation
	2.	Change "is listed" to "is recommended by CRC7 to be listed"…	No change. The DGD becomes relevant after listing of the SHPF. This wording is consistent with other DGDs.
	2.	Replace "may be found" by "can be found"	Amended as suggested.
	3.1.	Dosage 1.5-3 L/ha to be amended to 2-3 L/ha or state reference.	No change. The reference is Part A of the proposal (UNEP/FAO/RC/CRC.7/11, p.3 and 8). The discrepancy to other places where 2-3 L are stated is agreed.
	4.1.	Amend text regarding the dates of the incidences	Agreed. The sentence "No date of intoxication was reported for some of the incidents" is added.
	4.1.	Replace "three provinces" by "three regions"	Agreed and amended.
	4.1	Add following sentence: … "such as lack of financial means to acquire it, inappropriateness of PPE for local climatic conditions and an underestimation of the dangers of pesticides"	Amended as suggested.
	4.1.	Comment on the numbers where unknown treatment, treatment and hospitalisation were reported	Amended to 16 cases with unknown treatment
	4.1	Delete the repetition of the reasons for not using PPE	Agreed. A reference to point 3.3 was included.
	4.3.	Provide reference or revise texts on the classification class Ib. This information is not found in WHO 2010.	This information is given in Annex 1 of the proposal and is confirmed (e.g. by SDS). "WHO 2010" relates to the last sentence only, therefore a space was included between the paragraphs.
	4.4.	Amend sentence to: "*A campaign conducted in June 2010 in three regions of Burkina Faso (Boucle du Mouhoun, Cascades and Hauts Bassins) reported that* fifty-three males aged between 20 and 65 years, who had applied Gramoxone Super in the field, were affected"	No change, but the following was added: Detailed information on the reported incidents is contained in chapter 4.1

Country	Section	Comment/Suggestion	Response
	6.	LD50 reported are not for Gramoxone Super but for paraquat technical concentrate.	Agreed. Amended LD50s for Gramoxone Super were taken from Syngenta`s SDS for Gramoxone Super.
	Annex I - Rationale	Several changes of the text	No changes of the rationale are accepted as the original text is to be reflected.
	Annex III Part B	Suggest indentifying form as a copy of the form that was submitted to CRC7.	Preferably this is not stated (a copy of the format 1:1 was not possible).
	Annex III	Suggest identifying the following sheet as a copy of the WHO/FAO DATA SHEETS ON PESTICIDES No. 4 Rev.1 (8/78).	Addition is considered not required.
	Annex III	Few amendments of the SDS text proposed	No change. The original text of the SDS has to be kept without changes.
	Annex V references	CRC document numbers to be added	Not added for reasons of consistency with other DGDs.
Brazil	Section 3.1	The meaning of the sentence "the CSP has not registered formulations containing paraquat since 2006" is not clear. It is suggested that the administrative or legal measures undertaken should be mentioned. Furthermore the actual permitted uses are not clear.	CSP decided to not list any formulation containing paraquat in 2006 and cancelled previous authorizations. Hence, the registration of paraquat containing products expired in 2006. See also UNEP/FAO/RC/ CRC8/INF/12. The uses permitted from 2000 to 2006 are listed. A paragraph was added to section 3.1. to make it clearer.
	Section 3.4	It is unclear which were the actual uses.	See above. Since 2006 there are no actual uses permitted.
	Section 4.1	It is proposed to include a paragraph in the beginning describing the survey.	Agreed. Section was amended accordingly.
	Section 4.4	Include at the beginning of the sentence "During the study carried out, were reported…"	Agreed and amended accordingly.
	Section 7	Amend the para as follows: 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 the local conditions of use.*	Agreed and amended accordingly.
	Part B, section II, item 7, 10, 24, 26	Several small changes are proposed	No change. Part B is copied from the original proposal without change.
Crop Life	general	There seems to be no attempt anywhere in the draft DGD to acknowledge Syngenta's intellectual property in "Gramoxone" as a registered trademark for example by the use of the ® symbol or inverted commas.	The ® symbol was added, although this was not done in former DGD`s.
	general	We appreciate that trade names are used to facilitate the preparation of DGDs when using referenced information in the listing proposals, however, trade names should not be used in the title page, introduction section and in general context on the SHPF. It would otherwise appear that a particular product of a particular company was targeted. The terminology of the adopted rationale and	The title was amended (trade name deleted).

Country	Section	Comment/Suggestion	Response
		listing recommendation in UNEP/FAO/RC/CRC.7/15 Annex IV should be used. A precedent is set in UNEP/FAO/PIC/INC.10/9.	
	p.2 purpose of DGD	Adapt process description to the SHPF process. See e.g. UNEP/FAO/PIC/INC.10/9	Agreed and amended.
	p.4 CILLS	Typographical error. Correct: CILSS	Agreed and amended.
	Page 6. 2nd cell. Title	Title should refer to terminology used in UNEP/FAO/RC/CRC.7/15 Annex IV (see comment 2)	Agreed and amended.
	Page 6. Section 1	Trade names of other paraquat products should be added. Toé (2010) reported "Benaxone Super", "Calloxone Super", "Gramoquat Super", „Kamaxone" and „Supraxone".	Not agreed. All reported incidents were related to Gramoxone Super.
	Page 6. Section 1	Multiple paraquat formulations (trade names) were identified in the survey. Not all of them were associated with incidents. Due to the brand awareness, many incidents may have erroneously been linked to Gramoxone® Super. Syngenta is not in a position to confirm the formulation type of the other brands, however, Syngenta's Gramoxone® Super is not of type EC, but SL (Soluble Concentrate). This is another example which demonstrates the lack of robustness of the pilot study; see also the corresponding note in the cover letter to which this is an appendix. In addition the Working Procedures guidance to the CRC drafters underlines that the purpose of this section is "to clearly identify" the formulation(s) subject to the PIC procedure. There has been a major shortfall in this regard by virtue of this error and the error identified in the next comment.	The formulation type EC is explicitly stated at several places in the incident report form. Furthermore, the proposal contains a label with Syngenta logo stating "Gramoxone Super emulsifiable concentrate" However, information on Gramoxone Super® formulated as SL was also found. Consequently, the identification of the formulation in the DGD will be amended to „Liqid formulations (EC and SL) containing paraquat dichloride at or above 276 g/L, corresponding to paraquat ion at or above 200 g/L".
	Page 6. Section 1	Error in chemical structure	Structure was amended.
	Page 6. Section 2	As prescribed by the Working Procedures, add a disclaimer with regards to the formulations subject to the PIC procedure. There may be other formulations marketed under the same or similar names. Only those formulations which meet the specification as defined in the listing recommendation (UNEP/FAO/RC/CRC.7/15 Annex IV) will be subject to the PIC procedure.	Agreed and amended.
	Page 7. Section 3.1. 3rd line	Use "authorized" instead of "registered" as a provisional sales authorization had been granted. While many other paraquat products were available at that time, Gramoxone® Super was the only product with authorization.	Agreed and amended.
	Page 7. Section 3.1. Last para	This proposed text does not properly reflect the status of paraquat since 2006. Suggestion: There is no evidence that the CSP has received any application for the registration of a paraquat product and therefore it has not registered any such product since the expiry of the APV of	Noted; the status is considered properly reflected. No changes.

Country	Section	Comment/Suggestion	Response
		Gramoxone® Super in 2006. Any paraquat products currently found in CILSS are illegally traded.	
	Page 7. Section 3.2. 1st line	To align with wording of Working Procedures, replace "statements on use" by "statements relevant to worker exposure"	As in the new text also storage and disposal is mentioned, the wording is not changed.
	Page 7. Section 3.3. Para 1	The Syngenta label which was attached to the listing proposal contains very detailed pictograms in line with best practice advocated by FAO. The proposed summary of PPE instructions should better reflect the specific recommendations for the various tasks of an application (mixing, loading, spraying).	A reference to section 3.2. was included.
	Page 7. Section 3.3. Para 2 & 3	This general description of the use of PPE in Burkina Faso for all pesticides is not instructive in describing typical application of paraquat products. The Working Procedures require a clear description of how the specific formulation is typically used in the reporting country. This information is not available. This fact should be added and/or a rationale provided why it is assumed that the PPE typically used in general pesticide applications is relevant for specific paraquat formulations. Paraquat can be applied with basic and readily available PPE and does not require special PPE like e.g. dust mask or impermeable suit. Long trousers, long-sleeved shirts and boots are recommended for sprayers, additional eye protection and gloves for mixer/loaders. This is also the PPE recommended by FAO when working with pesticides in tropical climates.	Not agreed. The section describes what the Pilot study reports on the availability / applicability of protective clothing which was the outcome of a survey.
	Page 8. Section 3.4. Info on average duration of exposure by Toé (2010)	This information cannot be found in Toé (2010), but in the listing proposal. There is no indication how these data were extracted from the survey. The questionnaire suggests that this information was not requested for specific products.	This information was given by the DNA of the proposing country in the incident report form and is considered adequate.
	Page 8. Section 4.1. Para 2	We understand from the stated intent of the guidance provided in the Working Procedures that incidents need to be clearly described and a link between a specific exposure and the reported effect be demonstrated. The general description on pesticide use in Burkina Faso provided in the proposed text does not achieve this objective.	Not agreed.
	Page 8. Section 4.1. Para 3. Listed effects	Many of the listed effects are non-specific health effects from pesticide application. Some of them are not typical for paraquat exposure (e.g. fever, bone pain, locked jaw, or loss of consciousness). Misidentification of products may have occurred in the survey.	Not agreed. It is reported that those symptoms occurred after the use of Gramoxone Super.

Country	Section	Comment/Suggestion	Response
	Page 8. Section 4.1. Para 3. 11 cases…	As already questioned at CRC7, there may be a misunderstanding regarding cases requiring hospitalization. Toé (2010) does not refer to hospitalization cases. Medical treatments in Health Care Centers might have erroneously been interpreted as hospitalization. These cases would then more accurately be described as those seeking 1st level medical advice, e.g. equivalent to a local doctor. The effects summarized in the 53 individual case reports (Annex II of Burkina Faso's listing proposal) appear not to have been severe and all individuals recovered.	The proposal reports hospitalization for 11 cases, this wording is kept.
	Page 9. Section 4.1. Reasons for not using PPE…	This list is irrelevant here and just a repetition of aforementioned information. We would propose it deleted.	Agreed and deleted.
	Page 9. Section 4.2	See comment on section 4.1.	Not agreed.
	Page 9. Section 4.3. Para 1. WHO classification	WHO lists paraquat under class 2. Paraquat containing formulations are not listed under class 1b in the official WHO document. The WHO classification is usually based on acute oral and dermal toxicity. Inhalation may be taken into account for volatile compounds in exceptional cases. Paraquat has a very low vapor pressure and is essentially not volatile. References to trade names of paraquat formulations locally classified by different criteria are misleading in that context and we suggest the deletion of the 2nd sentence of that paragraph or at least to delink it clearly from the WHO (2010) document and to provide the appropriate reference.	No change. The labelling of Gramoxone Plus as highly toxic by inhalation is confirmed.
	Page 9. Section 4.3. Para 2	Section 4.3 should relate adverse observed effects to recognized acute toxicological effects. This paragraph, however, relates to effects after high dose oral ingestions typically of deliberate intent. It is therefore not relevant for the consideration of paraquat formulations under the SHPF procedure based on the specific reports from Burkina Faso. We propose the deletion of this paragraph.	Para 2 describes in general toxicological effects, not only by oral route. It is considered relevant in the context of the incidents reported.
	Page 9. Section 4.3. Last para	The level of detail on the incidents in the survey of Burkina Faso does not allow a causal relationship to be established between a reported incident and exposure to a paraquat formulation. We recognize that some of the reported effects are not inconsistent with significant exposure to paraquat products. We propose to amend this paragraph to reflect these uncertainties.	Not agreed. The reported effects occurred after agricultural use of Gramoxone, the causal relationship is obvious.
	Page 9. Section 4.4	The number of incidents alone is meaningless as it may simply reflect the volume of a widely used product. It is necessary to put this number in context.	The time period was added.

Country	Section	Comment/Suggestion	Response
	Page 10. Section 6. Table	The values quoted here are for paraquat technical material, not formulation. We suggest following values (taken from products of similar composition): Acute oral LD50 (WHO II): male rat, 707 mg/kg female rat, 612 mg/kg Acute dermal LD50 (WHO II): male rat, 590 mg/kg female rat, 735 mg/kg	Agreed, the section was corrected in the meanwhile.
	Page 27ff. Annex IV	General observation: Where relevant, the units should contain the reference to the ion, salt or technical material, and a reference should be clearly provided to the source of the information.	This information was included where available; in case a range is given, not all sources are listed.
	Page 27. Section 2.1.2. 2nd para	This is a mix of symptoms from operator exposure and ingestion. We suggest to use following text based on the Handbook of Pesticide Toxicology. Potential effects following operator exposure are predominantly skin irritation (mainly on hands and feet), nausea and headaches associated with the smell of the product (due to the added stenching agent) and, to a lesser extent, eye irritation, nail damage and nose bleeds. Potential effects following oral ingestion include nausea (which may be prolonged especially following ingestion of emeticised formulations), vomiting and diarrhoea as a result of its local irritant effect on the gastrointestinal tract. Patients may develop a burning sensation, soreness and pain in the mouth, throat, chest and abdomen. Ulceration in the mouth and throat, an inability to swallow saliva, difficulty in swallowing and speaking are common. The further clinical course is dependent on the amount of paraquat absorbed into the body. This ranges from full recovery after possible minimal renal and hepatic lesions and an initial decrease in lung function to multiorgan failure, pulmonary fibrosis and oedema with fatal outcome after few days to several weeks. Based on Handbook of Pesticide Toxicology, Third Edition (2010); Bipyridines, Edward A Lock and Martin F Wilks. Paraquat	The here cited Handbook was not available to the CRC7, therefore the text will not be changed.
	Page 27. Section 2.2.1	Rat LD50 oral (40 mg/kg) and rabbit LD50 dermal (80 mg/kg) should be verified and proper references provided.	In case a range is given, not all sources are listed. The figures are derived from the documentation available.
	Page 28. Section 2.2.6	This text does not reflect the outcome of the EU regulatory evaluation on the alleged association between paraquat exposure and the onset of Parkinson's disease. The reference to the EU as one source of this text should be removed. The evidence linking herbicides in general and paraquat in particular to Parkinson's disease is fragmentary and does not support the existence of a	The wording indicates that there is "some evidence", the issue is discussed in the EU documentation.

Country	Section	Comment/Suggestion	Response
		causal association between paraquat and Parkinson's disease.	
	Page 29. Section 3.7	Citation: The US EPA further concluded that the MOE (margins of exposure) for backpack applicators is unacceptable also for applicators wearing long shirts and trousers and gloves. This sentence as written implies US-EPA concluded that all backpack applications result in unacceptable exposure risks. The US-EPA did not however conclude that all backpack applications would result in unacceptable risks, but instead established the maximum acceptable application rate for paraquat products that could be applied using backpack application equipment.	Agreed. The text was amended.
	Page 29. Section 3.7	Citation: 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. Comment: This sentence is misleading. There has been no final regulatory action by a competent authority in the EU against paraquat based on human health or environmental concerns. After a thorough scientific review, paraquat was included in Annex I of the EU registration directive in 2003. In 2007, the European Community Court of First Instance (now known as the General Court) determined to annul the EU registration of paraquat in 2003. The Court's decision related to the way in which the re-registration procedure for paraquat in the EU was handled and to the manner in which the Commission interpreted the relevant laws and applied them to its analysis of the data. At no stage did the Court find that paraquat was an inherently unsafe or dangerous product.	Not agreed. The EU registration was annulled because according to the Court's judgement the precautionary principle of a high level of protection of human and animal health and the environment had been breached by the decision of the inclusion of paraquat to Annex I of directive EEC/91/414.
	Page 29. Section 3.7	Citation: All solid formulations of paraquat should contain a suitable dye to reduce the risk of accidental oral ingestion of the product. Comment: The FAO specification only says that those formulations may contain a dye.	The word "should" is considered adequate in this context.
	Page 31. Section 4.2.3	The unit of the 3 endpoints from studies with "other arthropods" should be kg ion/ha (indeed, wrong units were mentioned in the SANCO doc of Oct 2003). The endpoint for aleochara bilineata is 0.6 kg ion/ha.	After checking the original EU monograph, this is agreed (see also NZ comment). Endpoints were corrected.
	Section 4.1, 2nd para	The draft DGD suggests that "chemical cartridge respirators" are needed for the application of "pesticide preparations (especially paraquat based preparations) in hot countries". Paraquat dichloride has an extremely low vapor pressure and the droplets produced by backpack sprayers are too big to be respired. "Chemical cartridge respirators" are therefore not needed for the application of preparations containing paraquat.	The words in brackets *(especially paraquat based preparations)* are deleted.

Country	Section	Comment/Suggestion	Response
Ecuador	4.1	"…53 males between 29 and 65 years old…" to be corrected to "between 20 and 65 years"	Amended as suggested. Actually, it has been corrected to: 53 males between 20 and **70** years old
	4.2	Reference to Annex I to be corrected to Annex II	Amended as suggested.
	5.	Citation of Toe (2010) to be amended	Amended as suggested by Canada.
	Annex I	Several small editorial corrections	No changes of the rationale are accepted as the original text is to be reflected.
	Annex III	Few amendments of the SDS text proposed	No change. The original text of the SDS has to be kept without changes.
EU	List of abbreviations	we should follow the abbreviation whenever there is a capital letter we should write in Cap	Amended as suggested.
	Annex III	Few amendments of the SDS text proposed	No change. The original text of the SDS has to be kept without changes.
	Annex III	T.L.V. and ACGIH should be included in the abbreviations list	Amended as suggested.
Jamaica	4.2	Reference to Annex I corrected to Annex II	Agreed and amended as suggested.
	Annex III 4.1.2	T.L.V. (what is this abbreviation/acronym? It is not in the list of abbreviations at the beginning of the document) ACGIH (what is this abbreviation? It is not in the list of abbreviations at the beginning of the document)	Agreed. Abbreviations were included in the list.
Japan	Whole document	Two words of 'corn' and 'maize' are used for one plant? For uniformity, it is advisable to use one word (preferably 'maize') throughout the text	Agreed and changed to "maize" except in the rationale and incident report form, where the original text should be kept.
	4.1.	The words of 'complete destruction of the contaminated area' [p.8, the 17th line in 4.1 Description of the incidenct(s) and several other places in the text] sounds odd.? Although it is hard to estimate what the author(s) intended to mean, it might mean 'irritation or inflammation of of contaminated areas of skin and mucous membrane', as described in the 2nd line, 2.2.3 Observation in p.22.	Although agreed in principle, to adequately reflect the incidents as reported the original wording of the proposal is kept.
	Annex I	'Gramoxone' [the 12th and 15th line of the para 14, P.13] might be changed to 'Gramoxone Super' to keep the consistency of the word as well as to use the official name.	No changes of the rationale are accepted as the original text is to be reflected.
Norway		No comment	Noted.
New Zealand	1. Identification and uses	Change in format proposed	Agreed and amended.
	3.2	New structure and text proposed for the listing of precautionary statements	Amended as suggested.
	3.3	Addition of "only"	Amended as suggested.
	3.4	Comment: Mixing and loading not mentioned. Where PPE is used mixing and loading is generally thought of as the most likely time for operator exposure.	Noted and agreed. No change – text reflects what is reported in the proposal.

Country	Section	Comment/Suggestion	Response
		However, in this case where PPE is not necessarily worn spraying is more likely to cause the greatest exposure.	
	4.3.	Proposal to provide information on the WHO classification system	No change, not considered necessary. For reasons of consistency with other DGD`s it is preferred not to include such information.
	4.4.	Addition of "…over a 14 year period"	Amended as suggested.
	7.	Comment on PIC link: Very general link I couldn't find any info on alternatives on the website.	This refers to the future, when the formulation is listed and governments send in information. It is therefore the general web page mentioned here. The PIC web site is restructured from time to time, so a specific link could be broken in the future.
	7.	Amendment on the sentence on alternatives.	Amended as suggested.
	p.11	Annex IV title corrected	Amended as suggested.
	Annex III	Question on the link to the formulation data sheet: What happens if the location is move? The link will not work. Is there a possibility of actually putting the SDS in full as part of this annex? If added I would leave in the supplier format.	Normally the website would direct you to the new location, we can only give the link available at the moment. It is not possible to include the industry`s document.
	Annex III	Include SDS in original, not reformatted	Original SDS was included as proposed.
	Annex IV	PAN to be spelled out	Agreed and amended.
	Annex IV 1.6	w/w to be included in list of abbreviations	Agreed and amended.
	Annex IV	Several abbreviations to be included in list of abbreviations	Agreed and amended.
Peru	p.2 purpose of DGD	Change "two or more parties" to "developing country or country with economy in transition"	Agreed. Text was amended to reflect procedures for SHPF`s.
	List of abbreviations	Several additions proposed	Amended as suggested.
	4.1.	"…53 males between 29 and 65 years old…" to be corrected to "between 20 and 65 years"	Amended as suggested. Actually, it has been corrected to: 53 males between 20 and **70** years old.
	4.2	Reference to Annex I corrected to Annex II	Amended as suggested.
	Annex IV 2.2.2 and 3.4	"d" to be spelled out "day"	"d" included in list of abbreviations.
	Annex IV 3.5	NGO to be spelled out	Agreed and amended.
	Annex IV 3.7	Change US to USA	Amended as suggested.
Sri Lanka	List of abbreviations	Several additions proposed	Amended as suggested except when used only once and explained.
	4.1.	"…53 males between 29 and 65 years old…" to be corrected to "between 20 and 70 years"	Text will be adapted accordingly in the whole DGD, a footnote will be inserted to the rationale and Part B of the proposal. (Incident no 26 was indeed 70 years old).
USA	Title	Amend the naming of the formulation	This had been considered in a former version

Country	Section	Comment/Suggestion	Response
	Section 4.3, paragraph 2	Comment on "The treatment of intoxication is symptomatic and no antidote exists to date," It is proposed to give some information on "treatment" and the reference to an antidote should possibly be deleted.	Noted, no change. The sentence is from the proposal and it is considered as a fact that no antidote exists for paraquat. It is acknowledged that this is true for many pesticides. More information on possible treatments is considered not appropriate for section 4.3.
	Section 4.3, paragraph 3	… If the full range of adverse effects are to be included, they should be associated with the route of exposure. The incident reports seem to indicate only dermal exposure.	Not agreed. The effects mentioned are related to exposure routes and in the incident reports in many cases exposition by "inhalation, ingestion, eyes, unknown.." is reported.
	Section 5	"The process to take a decision to prohibit the product will be launched by the Sahelian Pesticides Committee at its next meeting." Has such a process been initiated? If so, any regulatory action taken should be reported here.	Agreed and amended accordingly.
	Annex IV, 3.1.	"3.1 Food Paraquat residues in soybeans were above the maximum recommended limit (MRL) of 0.1 mg/kg in several cases (FAO & WHO 1981) " It is suggested that the current Codex MRL be included instead.	Agreed and amended accordingly.
	Annex IV, 3.7.	"…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." Please confirm the accuracy of the status of paraquat in the EU, because I understood that it was still permitted.	The status in the EU as reported is confirmed.