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Item 6 of the provisional agenda*

Other matters

Letter from CropLife International

Note by the Secretariat

1. The annex to the present note contains a copy of a letter received from CropLife International, dated 14 August 2009, containing comments on the draft decision guidance document for endosulfan and on the Chemical Review Committee's review of the notifications pertaining to that chemical at its fifth meeting.

2. Those comments related to the draft decision guidance document are included in the tabular summary of comments set out in document UNEP/FAO/RC/CRC.6/INF/5. A tabular summary of the comments in the letter related to the Committee's review of the notifications and an indication as to the extent to which they were considered at the Committee's fifth meeting is contained in the annex to the present note. The material contained in the annex has not been formally edited.

* UNEP/FAO/RC/CRC.6/1.

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Annex

1. Copy of a letter received from CropLife International dated 14 August 2009.
2. Tabular summary of the comments and an indication as to the extent to which they were considered at the Committee's fifth meeting.

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14 August 2009
L/BGJ/ln/09-14

Dear Ms Roda Martin,

Please find attached the response to the drafted DGD proposal on endosulfan submitted by CropLife International on behalf of Makhteshim Agan Industries (MAI).

MAI strongly supports the intention of the PIC procedures, if it is used according to the Rotterdam Convention principles. It should be common goal to prevent an erosion of PIC standards. Following the standards and procedures as set by the Rotterdam Convention, endosulfan should not be subject to the PIC procedure and listing in Annex III. In summary form, the reasoning is as follows.

In the case of the Sahelian notifications, there are several deficiencies and inconsistencies: first, the notifications are incomplete, and thus, should never have been accepted as meeting the requisite screening criteria by the Convention's Secretariat. Therefore, the drafting of a DGD is pre-mature until all the raised questions (see CRC5 final report) have been answered. Second, the Sahelian notifications were untimely filed under Article 5(1) of the Convention. Thirdly, they lack any form of robust scientific or quantified exposure analysis to justify the claims made, and fourth essential background information or documentation is missing.

In summary, based on the Sahelian notifications and in view of the Rotterdam Convention data/information requirements, the subject notifications cannot be considered as valid, and should therefore be set aside. Under these circumstances, it is unacceptable to pursue drafting a DGD for endosulfan.

May we kindly ask you to add the document to the Secretariat compilation and forward it to the intersessional drafting group on endosulfan, which we trust will give it full consideration following the intention and the spirit of the Rotterdam Convention?

Yours sincerely,

Bernhard Johnen
Director, International Regulatory Policy

Makhteshim Agan Industries

ENDOSULFAN

Comments Prepared by Makhteshim Agan Industries to the Internal Proposal for a Decision Guidance Document (Draft 10 July, 2009)

Makhteshim Agan Industries (MAI) would like to provide the following comments concerning the recently circulated internal draft DGD proposal based on the notifications of final regulatory actions on endosulfan by the European Community (UNEP/FAO/RC/CRC.5/5/Add.1), as well as the Sahelian Pesticides Committee with Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal (UNEP/FAO/RC/CRC.5/5, plus supporting documentation, contained in document UNEP/FAO/RC/CRC.5/5/Add.2.) for including endosulfan in the interim PIC procedure and its listing in Annex III.

It is our understanding that a chemical can only be listed in Annex III, when the submitted notifications including its supporting documents contain all the information required by Annex I (verified by PIC Secretariat), fulfil the criteria of Annex II of the Convention, have been reviewed by the Intersessional Drafting Group (IDG), and are submitted in a timely matter (within 90 days after the date on which the regulatory action has taken effect).

Based on the above given requirements, the MAI specifically reviewed the subject draft DGD proposal and accompanying documents as provided by the Secretariat.

We identified the following main deficiencies and procedural inconsistencies that do not support or justify the listing of endosulfan under the PIC procedure. These comments are not inclusive and touch only on a few key items that should be considered in the assessment and PIC decision making process:

2. Reasons for inclusion in the PIC procedure

2.1 Final regulatory action (see Annex 2 for further details)	
Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal: The Sahelian Pesticide Committee (8 May 2007) recommended that endosulfan be prohibited for use in agriculture. In line with the Common Regulations of the Members States of CILSS on the registration of Pesticide (Resolution No: 08/34/CM/99) taken by the Council of Ministers of CILSS in 1999 in N'Djamena Tchad, and based on the recommendation by the Sahelian Pesticide Committee Le Ministre Coordonnateur du CILSS decided to prohibit the use of endosulfan in agriculture. Taking into account the necessary delay for the use of existing stocks, the decision entered into effect for distribution on 13 November 2007 and 31 December 2008 for use. **Effective date(s) of entry into force of actions (Annex 2, p.25):** November 13, 2007 for all distribution; December 31, 2008 for all uses.	**MAI Response:** The notifications prepared by Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal (Sahelian Pesticides Committee – CSP) were submitted to the Secretariat for verification after the last Conference of the Parties (COP4) in October 2008. In December 2008, the Secretariat verified that the notifications met the information requirements of Annex I (UNEP/FAO/RC/CRC.5/5). In the case of these notifications and the drafting of the subject Internal Proposal for a Decision Guidance Document (DGD) on Endosulfan, there are several deficiencies and inconsistencies in view of the provisions and criteria of the Convention. The key issues that need to be addressed before a DGD can be proposed are the following: 1. A DGD should only be drafted after an adequate decision was taken by the CRC. At the last CRC meeting (CRC5; see final report

Reference to the regulatory document (Annex 2): Common Regulations for Member States of the CILSS on the Regulation of Pesticides (Resolution No. 08/34/CM/99 taken by the Council of Ministers in 1999 in N'Djamena Tchad). Decision taken by Le Ministre Coordonnateur du CILSS November 13, 2007.	UNEP/FAO/RC/CRC.5/16, p.26), it was decided: *Decides, in the light of past practice in drafting decision guidance documents, to establish a drafting group to develop a decision guidance document for endosulfan for consideration at its next meeting on the understanding that responses to the outstanding questions regarding the notifications from the above-mentioned Sahelian countries will be made available at its next meeting to inform further discussion on whether all the criteria of Annex II have been met.* The necessary information to complete the evaluation under Annex II was not available at the CRC5, and therefore no valid decision could be taken regarding the Sahelian notification to list endosulfan on Annex III and draft a DGD complying with Article 7, paragraph 1 of the Convention: "*For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document"*. 2. The Rotterdam Convention allows the CRC to begin preparing only after it has decided to recommend a chemical for listing in Annex III. 3. In addition, the Sahelian notifications were untimely filed under Article 5(1) of the Convention (within 90 days after the date on which the regulatory action has taken effect). 4. The notifications are incomplete, as also stated by CRC5, and thus, should never have been accepted as meeting the requisite screening criteria by the Convention's Secretariat, in particular considering that six of the seven notifications did not include information on import volumes, which is required by the Convention under Annex I -2(b) (iii), indicating that where available, quantities of the chemical produced, imported, exported and used should be provided. No documentation for endosulfan product formulation types (EC, WP) and concentrations that were registered and used in Sahel were provided (missing product labels). The use directions and precautions (PPE, restrictions) contained in the notifications were based on anecdotal information and not documented by current product labels or conducted surveys. The notifications did not include socio-economic assessments. Although these assessments are not strictly required, such information is particularly important for judging the risks and benefits of banning endosulfan. 5. The subject notifications lack any form of robust scientific or quantified exposure analysis to justify

	potential risk estimates. 6. The CSP claims that endosulfan poses unacceptable ecological and occupational risk. These assertions are subjective and based on anecdotal information. None of them is supported by any form of robust scientific or quantified exposure analysis. Additionally, the Sahelian countries notifications did not follow the necessary risk evaluation procedures. Instead they relied totally on "bridging information" from one risk assessment to another, which is not appropriate unless the use of such bridging information (see UNEP/FAO/RC/CRC.1/11) complies with the following principles: • The assessment should be science-based, on the best available knowledge and data; • Exposure is a key element – measurable and quantifiable; • The information should also be sufficiently detailed and transparent; • The risk assessment should be based on exposure scenarios and conditions from the notifying country. 7. The provided information lacks scientific integrity because it is based on inadequate scientific methods and reviews that do not appear to have been performed and documented according to recognized scientific principles and procedures. In short, the CSP failed to sufficiently comply with the guidelines for using "bridging information" from other countries.

2.2 Risk evaluation –page 8 (see Annex 1 for further details)	
European Commission (EC) **DGD proposal** **Human health (p.8):** Occupational: Using common exposure scenarios, the use of endosulfan on tomatoes in greenhouses, spraying with tractor mounted hydraulic nozzles for high crops, led to exposure potentially greater than the Acceptable Operator Exposure Level (AOEL), even when using standard Personal Protective Equipment (PPE). Exposure of operators under indoor conditions was not considered to have been sufficiently addressed with the available information.	**MAI response** **Human health:** Based on the official minutes of the tripartite meeting (May 2004), the rapporteur and a representative of the Commission stated "*Rapporteur identified a safe use for operators…RMS considered the rest of the points in toxicology fulfilled*". At that time, it was concluded that endosulfan is safe for operators and that the requirements in the area of toxicology according to 91/414 were fulfilled. The reference of the working group legislation to insufficient data regarding the operator risk is inaccurate, arbitrary, and not justified based on the available information.
Sahelian Pesticides Committee (CSP) **DGD proposal (p.8)**	**MAI response**
3.4 Occupational Exposure (p.17): In the Sahel, endosulfan is applied to cotton generally twice per season using handheld and sometimes backpack sprayers by farmers, generally without any specialised training or personal protective equipment. Application rates in the Sahel are comparable to those	**Occupational Exposure and Risk Assessment:** The Rotterdam Convention allows notifying countries using risk evaluations from other authorities for consideration in support of the CRC's final regulatory decision following the Policy Guidance Document ("Bridging Information" - UNEP/FAO/RC/CRC.1/11 –

in Australia and the USA although the concentration of endosulfan in the material sprayed is higher. In the light of the risk mitigation measures in place in Australia and the USA it was concluded that the occupational risk to farmers from using endosulfan in cotton under the conditions in the Sahel were considered unacceptable. It was further observed that many dwellings in the Sahel were surrounded by cotton fields which could lead to unacceptable bystander exposure.

Endosulfan is applied to cotton at 300-750 g ai/ha generally twice per cotton growing season. As a rule it is sprayed in very low volumes, at about 10 litres of diluted product per hectare using handheld and sometimes backpack sprayers by the farmers themselves. Applicators generally use little if any protective equipment because of limited financial resources or because the climate is too hot to wear it.

In Australia endosulfan may be used in cotton at a dose rate of 735 g ai/ha up to three times per season. The product is applied in a volume of water of at least 50 litres per ha generally using vehicle or tractor mounted sprayers. The product is only used by authorized persons having a pesticide applicator licence and under the condition that applicators wear full personal protective equipment including overalls closed at the neck and wrists, in addition, when filling the sprayer, long PVC gloves and a respirator with a complete face mask must also be worn.

In the USA endosulfan may be applied at a maximum dose rate of 1700 g ai /ha. For applications with pressurised backpack sprayers, overalls worn over a long-sleeved shirt and trousers as well as chemical resistant shoes and gloves and a respirator are required. Engineering measures, such as closed mixing and loading systems or tractors/vehicles with closed cabs are also recommended.

In the Sahel, while overall dose rates are comparable to those in Australia and the USA, mixers and applicators are exposed to more concentrated spray solutions due to the low spray volumes used. In light of the absence of PPE and engineering measures required in Australia and the USA to mitigate the risks associated with the use of endosulfan in cotton, and the limited training of Sahelian farmers in judicious pesticide use, the risks of occupational exposure in the Sahel were considered unacceptable.

In addition in Sahel countries human dwellings may often be found adjacent to cotton fields. As a result there are unacceptable risks to bystanders from the use

Annex), which states: *"Risk or hazard evaluations completed in one country may be used by another country in support of its notification of final regulatory action submitted in accordance with Article 5 of the Rotterdam Convention. This document provides guidance on the sort of information that will need to be considered by the Interim Chemical Review Committee in determining that the conditions in the country which completed the original risk evaluation are similar to and compatible with those in the notifying country."*

If this "bridging approach" is being used by the notifying country, in this case by CSP, the following standards and principles must be applied by the CRC in order to fulfil the criteria in Annex II for further consideration:

1. Exposure is a key element – formulation type (EC, WP or Granules) -use pattern (rate and frequency of application, method of application and equipment), climatic and environmental conditions (are they comparable);
2. Information must be science-based (quantitative, measurable);
3. Information is sufficiently detailed to enable for risk assessment (risk mitigation measures);
4. Risk assessment is based on exposure scenarios and conditions from the notifying country (comparable environmental exposure).

In view of these principles, MAI specifically reviewed CSP's notification and accompanying documents (UNEP/FAO/RC/CRC.5/5/Add.2 including Annex Ref. Sect.2.4.2.1 and 2.4.2.2). Using cotton applications in Australia and the USA for bridging purposes is unacceptable for many reasons: The application method in Australia & USA is mainly by air or groundboom versus handheld or backpack sprayer; the rates (USA) and PPEs are different from those in the Sahel, and the load of product (endosulfan) handled and exposed to per day is much higher (USA, Australia), e.g. per air application (300 ha x 0.7 kg ai = 210 kg ai), and groundboom (50 ha x 0.7 kg = 35 kg ai) versus backpack sprayer in Sahel (3 ha x 0.7 kg ai = 2.1kg ai). This demonstrates that the total amount handled per day and its associated potential exposure using the application techniques in cotton (by air or groundboom) from the USA, and Australia seem to be 15 to 100 times larger than in Sahel (Backpack).

The following provides a more detail analysis of the occupational exposure and risk assessment under Sahel conditions:
Occupational exposures for mixers/loaders were calculated based on information from the CSP notification, available endosulfan labels from the Sahel region, and data from the US-EPA Reregistration Document (RED) for endosulfan

of endosulfan in cotton. **3.7 Summary: Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal (p.18):** In countries like the USA and Australia endosulfan may only be used by trained operators with full personal protective equipment (PPE; full overalls, chemical resistant shoes and gloves, respirator etc.). In the Sahelian countries farmers do not have access to PPE or training. In conclusion, the risk for operators and for families who have their habitations in or near cotton fields was considered unacceptable.	,and using US-EPA's Pesticide Handlers Exposure Database (PHED). Personal Protective Equipment (PPE) for mixers/loaders from the label are: ▪ Use glasses or eye protective equipment ▪ Use masks covering mouth and nose ▪ Use rubber gloves ▪ Use long sleeved shirts, pants, and boots As concern has been raised regarding the use or lack of PPE by Sahelian applicators, this assessment was conducted using a minimum of PPE: typical work clothes worn when applying a pesticide: long-sleeved shirt, long pants, and shoes and socks and rubber gloves as stated on the label. Based on the use of gloves as PPE and using the Unit exposures (UE in mg ai/g ai handled) from PHED, the occupational exposures for mixers/loaders were estimated using the equation above with an application rate of 750 g ai/ha treating 3 hectares with a handgun (*e.g.*, from a backpack sprayer). The calculated dermal daily dose was 0.0007 mg/kg/day for mixing/loading endosulfan with gloves. The inhalation daily dose was 0.000085 mg/kg/day for mixing/loading endosulfan with no respiratory protection (not even the required mask covering mouth and nose which would provide protection resulting in an even lower dose). Occupational exposures for applicators were calculated based on the same assumptions and information provided as for the mixer/loaders (see above). The assessment for PPE was normal worker clothing with gloves, as included on the label. Based on the UEs from PHED, the occupational exposures for applicators were estimated using the equation above assuming 3 hectares treated with an application rate of 750 g ai/ha, using a handgun sprayer typically carried on a backpack. The dermal daily dose was 0.01 mg/kg/day for applying endosulfan with gloves. The inhalation daily dose was 0.0000001 mg/kg/day for applying endosulfan with no respiratory protection. The Risk Estimates (MOE = Margin OF Exposures) for mixers/loaders and applicators for exposure to endosulfan range from 435 to over 5,000 using EPA's toxicity values and assuming gloves are worn. The inhalation mixer/loader risks were 2,300 with no additional respiratory protection, while the applicator risks were greater than one million. MOEs of over 100 are acceptable and considered safe. **Conclusions:** These analyses show that with reasonable certainty there is no harm for mixers/loaders and applicators handling endosulfan EC under conditions of use described in Sahel, even with minimal PPE (e.g., gloves and no respiratory

	protection). Therefore, if CSP would use a scientific approach following other countries occupational assessment procedures and methodologies for bridging purposes, the calculated risk is acceptable.
Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal	**MAI response**
Environment (p.9): Endosulfan is highly toxic to fish and certain aquatic invertebrates. Reviews in both Australia and the USA, at application rates to cotton comparable to those used in the Sahel, led to strict measures to reduce contamination of surface waters. In the USA, such measures include general buffer zones of up to 33 m and vegetated buffer zones of 10 m between treated plots and surface waters. In Australia the required mitigation measures include the avoidance of spray drift onto adjacent areas and water bodies, no applications if heavy rains or storms that are likely to cause surface runoff are forecasted within two days and no applications during hot weather conditions (temperatures >30°C). In the cotton growing areas of the Sahel, surface waters are abundant and are often situated adjacent to cotton fields, particularly during the rainy season when treatments are carried out. The rainy season is characterized by hot temperatures and heavy rainstorms of which the locality and timing are difficult to predict. The conditions thus make it virtually impossible to put in place comparable risk reduction measures such as those required in Australia or the USA. Given the high toxicity of endosulfan to aquatic fauna, the risk of surface water exposure in the cotton growing areas of the Sahel and taking into account the risk mitigation measures required under similar conditions in Australia and the USA, it was concluded that the risks to the environment from endosulfan under the conditions of use in the Sahel were unacceptable.	**Environment:** The referred environmental risk evaluation for Burkina Faso was conducted by Adama Toe et al. (2003) using the "Pesticide Impact Rating Index" (PIRI) model, a simple risk indicator, which supposed to cover a range of scenarios such as toxicity to organisms, health of farm workers, consumer health, and residues for different pesticides and cropping systems. The referenced PIRI risk assessment provided a ranking among 14 different pesticides (see Fig.1 and Table IV), but it did not demonstrate any quantitative estimations of potential environmental exposure (EEC = Expected Environmental Concentration) from the use of endosulfan. Therefore, CSP's notification lacks information related to calculated or measured environmental concentrations of endosulfan, which would allow for a science based risk assessment as required by the "Bridging Policy" Guidance Document: 1. *Use pattern (formulation type, rate and frequency of application, method of application and equipment, climatic and environmental conditions):* Most exposure scenarios, the key element for comparability and bridging information, are not equivalent to USA and Australia conditions and scenarios. The application of endosulfan in the Sahel region is mainly used on cotton by handheld rotary disc sprayers compared to application by air or large groundboom sprayers in Australia and the USA. There is no information about the formulation type (EC or WP). The application rates in the US are almost twice as high, and on cotton only the EC-formulation is being registered and used. In addition, weather and soil conditions of the Sahel zone need to be evaluated for proven adequacy to use as surrogates.
Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal **5. Environmental Exposure/Risk Evaluation (p. 20 -23):** A risk evaluation for surface waters for 14 pesticides applied to cotton was carried out in Burkina Faso using an Australian computer model (PIRI – Pesticide Impact Rating Index). Five exposure scenarios were evaluated, including buffer zones and possible rain events. Data specifying the prevailing conditions in Burkina Faso were included in the model: e.g. land use data, application rates and time of year, soil type and	2. *Information is science based (quantitative, measurable):* The CSP notification did not conduct a science based exposure and risk evaluation for the given environmental scenarios. The provided environmental evaluation (PIRI) represents a qualitative risk ranking and is not supported by sound data (measured or predicted using proven models). Comparisons to Australia and USA are difficult to draw because of the different use patterns and environmental conditions. Even if comparisons are made based on quantitative model systems (PHED, PRZM/EZAMS) calculating different exposure scenarios, potential environmental risks are

moisture, field cover, soil organic matter content, rainfall and temperature range. Endosulfan was the only substance which posed a high or very high risk for aquatic ecosystems under all 5 scenarios even when buffer zones of up to 1000 m were taken into account. (Toé et al., 2003)

Reviews in both Australia and the USA of the use of endosulfan in cotton at application rates comparable to those used in the Sahel led to measures to reduce contamination of surface waters. In the USA these included general buffer zones of up to 33 m and vegetated buffer zones of 10 m between treated plots and surface waters. In Australia the required mitigation measures for the use of endosulfan include the avoidance of spray drift onto adjacent areas and water bodies, no applications if heavy rains or storms that are likely to cause surface runoff are forecast within two days, and no applications during hot weather conditions (temperatures >30^{o}C). In the cotton growing areas of the Sahel surface waters are abundant and are often situated adjacent to cotton fields, particularly during the rainy season when treatments are carried out. The rainy season is characterized by hot temperatures and heavy rainstorms of which the locality and timing are difficult to predict. The conditions thus make it virtually impossible to put in place risk reduction measures comparable to those required in Australia or the USA.

Taking into account the high toxicity of endosulfan to aquatic fauna, the likelihood of the contamination of surface water in the cotton growing areas of the Sahel and the outcome of the two risk evaluations in particular the risk mitigation measures required under similar conditions in Australia and the USA, the CSP concluded that the environmental risks from endosulfan under the conditions of use in the Sahel were unacceptable.

Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal

Conclusions (p.23):

The risk evaluation performed by the Sahelian countries identified a very high risk to aquatic ecosystems. Because of the climatic conditions in the rainy season, when endosulfan is applied, and because of the soil characteristics, a high input of endosulfan into surface water bodies takes place due to run-off and soil erosion. Because of the very high toxicity to aquatic organisms, a high lethality of those organisms is predicted in surface water bodies, which are important water and food sources for human and animal life. Under the conditions of use in the Sahelian countries, the respecting of buffer zones to acceptable.

3. *Information is sufficiently detailed to enable for risk assessment:* Again, the provided information is not sufficient to allow for a sound risk assessment.

4. *Risk mitigation measure:* The notifying country did not implement any mitigation measures prior to banning endosulfan. Sufficient evidence of non-enforceability is missing in its notification.

The PIRI model has not been used by the cited Registration Authorities (EU, APVMA or US-EPA) in their assessments. It is known that PIRI lacks the accuracy and scientific robustness of other available models in this area. Regarding Burkina Faso's notification, no real quantitative measurements of any surface water monitoring or model verification were provided confirming endosulfan concentrations that could cause potential adverse effects in the aquatic environment. The only citation (Toe et al. 2004) referring to measurements in water was not accessible for review. The provided document did not list any exposure levels (soil or water). Reports of any adverse effects (e.g. fish kills) related to the use of endosulfan are also missing.

Environmental Exposure/Risk Evaluation:

Usually, for deriving more accurate environmental exposure estimates, Tier II exposure modeling is being conducted, e.g. by using the US-EPA models PRZM and EXAMS. These models can estimate environmental concentrations for different cropping systems including the use of "protective" buffers. The results of the modeling are expressed as a 1-in-10 year peak concentration and maximum average Environmental Exposure Concentrations (or EECs) in the water column and sediment at 96 hours, 21 days, 60 days, and 90 days post application. These results are compared to information on the effects of endosulfan to aquatic organisms so as to determine the potential risk of adverse effects in aquatic ecosystems. Since these scenarios may be considered "worst case", additional model runs can be performed with more typical application scenarios if necessary.

Based on the CSP provided information, endosulfan is applied to cotton by handheld sprayers twice at application rates between 300 and 750 g a.i./ha. Cotton treated in Australia and in the USA is mainly treated by air and less by ground boom applications at higher rates (up to 850 g a.i./ha). Considering the difference in application equipment and rates (handheld sprayer versus vehicle drawn or mounted groundboom or aircraft spray equipment) and the areas treated per day (up to 300 ha by air and day @ 0.7 kg ai/ha or 210 kg ai/day versus up to 3 ha or 2.1 kg a.i./ha for handheld equipment), it seems that

surface waters is not feasible. As a consequence, the Sahelian Pesticide Committee considered the risk to the aquatic environment from the use of endosulfan to be unacceptable.	it is very difficult to allow "bridging" information for these scenarios. In addition, the comparability of weather and soil conditions at the Sahel locations should have been verified prior to any "bridging" arguments. However, if one assumes the exposure scenarios and environmental conditions of the notifying countries for the given cotton scenarios are actually similar to Australia and the USA (weather and soil data for the Sahel cotton region were not available), the United States cotton growing regions and weather were chosen as surrogates in following environmental exposure assessment: Input data for this modeling exercise (Tier II exposure modeling – PRZM/EXAMS) were taken from a previous modeling study, standard model default values, and scenarios published by US-EPA (RED-2002). Based on the given parameters, the results demonstrate that endosulfan exposures are generally low. The calculated 96 hour average concentration (relevant to acute exposure) for the "worst case" usage scenario in cotton (one application at 0.7 kg a.i./ha – no buffer) amounts to 0.05 ppb. This estimate is considered very conservative considering the handheld application scenario and given favorable environmental conditions in Sahel. Handheld sprayers usually allow for a more direct spray with less drift, and therefore less environmental exposure considering the smaller treatment area and faster degradation in the warmer climates of the Sahel region. **Conclusions:** Comparisons of these predicted concentrations to known acute effects levels indicate no exceedances of effect levels. The toxicity of endosulfan has been determined in a multitude of studies and is well characterized. It is highly toxic to fish, less so to aquatic invertebrates, and practically non-toxic to algae and higher aquatic plants. A complete list of available acute toxicity data for fish and invertebrates for all forms of endosulfan is presented below in Table 3. The most sensitive species are marine invertebrates *(Penaeus duorarum*) with an LC50 of 0.04 ppb and for *Cyprinus carpio* (freshwater fish) at 0.1 ppb. Considering the inland freshwater scenarios, it can be assumed that based on the predicted environmental concentration of 0.05 ppb (worst case) that even the most sensitive species (Carp - LC50 = 0.1 ppb) will not be affected.

3. Human exposure/Risk evaluation (p.13)	**MAI response**
3.1. Food: Food is the main source of exposure of the general population to endosulfan. Endosulfan residues in food have been found to be generally below the FAO/WHO maximum residue limits (JMPR 1993).	**Food:** We agree that dietary assessments (acute, chronic) for endosulfan are acceptable.

3.2 Air: Not considered relevant for endosulfan.	No further comment.
3.3 Water: Not considered relevant for endosulfan.	No further comment.

3.4 Occupational Exposure – EC (p.17):
Using the German BBA model, exposure during mixing and loading and spray application was estimated, then the amount potentially absorbed and inhaled was calculated. This exposure was then compared to the AOEL (0.0042 mg/kg bw/day) to decide whether a potential use was acceptable.

The following scenarios were accepted in the final endpoints of the European Community risk evaluation based on the use of Thiodan EC 35:

Scenario 1: field crop (cotton, tomatoes) sprayed with tractor mounted hydraulic nozzle, low crop
Scenario 2: Greenhouse (tomatoes) sprayed with tractor mounted hydraulic nozzles, high crop.
It was predicted that in Scenario 2, there was the potential for the exposure to exceed the AOEL (119 %) leading to a risk to the operator.

Occupational Exposure –EC Assessment:
Using sound science-based input parameters that differ from those developed and used by the EC result in lower risks to Mixer/Loaders and Applicators. Specifically, the use and mischaracterization of the nature and severity of toxicological endpoints (dermal vs. inhalation) to generate the total systemic Acceptable Operator Exposure Level (AOEL) combining the inhalation and dermal route of exposure is unacceptable.

Before dermal and inhalation exposure can be aggregated for occupational risk, it is essential that the toxicological endpoint for each route of exposure must be the same and the route-specific doses must have a common mechanism of toxicity. The endpoints from the 1-year dog study (Brunk 1989) and repeat dose inhalation study (Hollander and Weigand 1984) are distinct and should not be combined when calculating the AOEL. This summation of risk is not appropriate for endosulfan's occupational risk assessment.

In addition, a dermal penetration factor of 20% is excessive. In view of the existing data base it should be less than 14% and can be as low as 2%.

Taking all of this into consideration would result in acceptable AOELs (<100%).

Annex I – 2. Toxicological Properties (p.14 -17)	**Annex I - MAI's response**
Endosulfan does not significantly accumulate in fat or any other tissue: in rats, dosed for 7 days, 3.7 and 4.7 % remained in organs and tissues (male and females, respectively); in rats, 1.5 % remained in kidneys and liver following one single dose; in mice, 0.4 % remained following 24 days; and in mice, small amounts were detected after 35 days. Endosulfan appears to remain preferentially in the liver and kidneys. Endosulfan has been detected in cow's milk, however, bioaccumulation was reported not to occur. No carcinogenic potential was observed in either of the chronic studies outlined above or in the 1-year Beagle dog study. Endosulfan is not classified as being either an endocrine disrupter or an immunotoxicant. Endosulfan is neither genotoxic nor were carcinogenic effects observed in studies on mice and rats. In studies reported, no effects were observed at the doses tested	MAI agrees concerning the toxicological property of endosulfan, stating that endosulfan does not bioaccumulate, is not an endocrine disruptor or immunotoxicant, not a mutagen or carcinogen, and not a reproductive toxicant. The WHO classified endosulfan as moderately hazardous.

with respect to reproductive performance in rats or the growth or development of the offspring in rats and rabbits (EU, 2005). WHO has classified endosulfan as moderately hazardous (WHO 2004b). The LD_{50} of endosulfan varies widely depending on the route of administration, species, vehicle, and sex of the animal.	

SUMMARY

MAI response to the Sahelian Pesticides Committee (CSP)

MAI strongly supports the intention of the PIC procedures, if it is used according to the Rotterdam Convention principles. We feel, it should be a common goal to prevent an erosion of PIC standards. Following the standards and procedures as set by the Rotterdam Convention, endosulfan should not be subject to the PIC procedure and listing in Annex III.

While Parties to the Convention are within their rights to file notifications, these notifications must be timely (within 90 days after the date on which the regulatory action has taken effect), complete containing the requisite information set out in the Convention with related working documents for notifications made available, as well as handled in a transparent way. Taking all of this into consideration, we believe that the "Two Region Trigger" has not been met, as indicated in MAI's position paper submitted to the Secretariat on Match 19, 2009 in response to the Sahelian notifications.

In the case of the Sahelian notifications, there are several deficiencies and inconsistencies: First, the notifications are incomplete, and thus, should never have been accepted as meeting the requisite screening criteria by the Convention's Secretariat. Therefore, the drafting of a DGD is pre-mature until all the raised questions (see CRC5 final report) have been answered. Second, the Sahelian notifications were untimely filed under Article 5(1) of the Convention. Thirdly, they lack any form of robust scientific or quantified exposure analysis to justify the claims made, and fourth essential background information or documentation is missing.

In summary, based on the Sahelian notifications and in view of the Rotterdam Convention data/information requirements, the subject notifications cannot be considered as valid, and should therefore be set aside. Under these circumstances, it is unacceptable to pursue drafting a DGD for endosulfan.

We appreciate your consideration in this matter, and trust your involvement following the intention and spirit of the Rotterdam Convention.

Tabular summary of comments from Crop Life (MAI) on the internal proposal on endosulfan

Section	Comment	Response
Annex 2 Final Regulatory Action	The notifications prepared by Burkina Faso, Capo Verde, Gambia, Mali, Mauritania, Niger and Senegal (Sahelian Pesticides Committee - CSP) were submitted to the Secretariat for verification after the last Conference of the Parties (COP4) in October 2008. In December 2008, the Secretariat verified that the notifications met the information requirements of Annex 1 (UNEP/FAO/RC/CRC.5/5). In the case of these notifications and the drafting of the subject Internal Proposal for a Decision Guidance Document (DGD) on Endosulfan, there are several deficiencies and inconsistencies in view of the provisions and criteria of the Convention. The key issues that need to be addressed before a DGD can be proposed are the following:	/
Cont`d	1. A DGD should only be drafted after an adequate decision was taken by the CRC. At the last CRC meeting (CRC5; see final report UNEP/FAO/RC/CRC.5/16, p.26*), it was decided: Decides, in the light of past practice in drafting decision guidance documents, to establish a drafting group to develop a decision guidance document for endosulfan for consideration at its next meeting on the understanding that responses to the outstanding questions regarding the notifications from the above-mentioned Sahelian countries will be made available at its next meeting to inform further discussion on whether all the criteria of Annex II have been met.* The necessary information to complete the evaluation under Annex II was not available at the CRC5, and therefore no valid decision could be taken regarding the Sahelian notification to list endosulfan on Annex III and draft a DGD complying with Article 7, paragraph 1 of the Convention: "For each chemical that the Chemical Review Committee has decided to recommend for listing in Annex III, it shall prepare a draft decision guidance document".	Paragraph 72 of UNEP/FAO/RC/CRC.5/16 explains that CRC.5 proceeded with the understanding that outstanding questions would be addressed at the next meeting. The outstanding information is now (February 2010) available to CRC members in document UNEP/FAO/RC/CRC.6/12.
Cont`d	2. The Rotterdam Convention allows the CRC to begin preparing only after it has decided to recommend a chemical for listing in Annex III	See response above
Cont`d	3. In addition, the Sahelian notifications were untimely filed under Article 5(1) of the Convention (within 90 days after the date on which the regulatory action has taken effect).	Paragraphs 174 - 176 of UNEP/FAO/RC/CRC.5/16 deal with this issue.
Cont`d	4. The notifications are incomplete, as also stated by CRC5, and thus, should never have been accepted as meeting the requisite screening criteria by the Convention's Secretariat, in particular considering that six of the seven notifications did not include information on import volumes, which is required by the Convention under Annex I -2(b) (iii), indicating that where available, quantities of the chemical produced, imported, exported and used should be provided. No documentation for endosulfan product	Information on formulation types, concentrations and products used in the Sahel is provided in the notifications and their annex (UNEP/FAO/RC/CRC.5/5) as well as in UNEP/FAO/RC/CRC.5/5/Add.2 (e.g. on p. 12 of Mission Report 2007). Information on socio-economic effects of the FRA or on import volumes may be provided where available according to Annex I, therefore is not mandatory.

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	formulation types (EC, WP) and concentrations that were registered and used in Sahel were provided (missing product labels). The use directions and precautions (PPE, restrictions) contained in the notifications were based on anecdotal information and not documented by current product labels or conducted surveys. The notifications did not include socio-economic assessments. Although these assessments are not strictly required, such information is particularly important for judging the risks and benefits of banning endosulfan.	The use conditions as described in the notifications are reflected in the DGD e.g. on p. 10, para. 6 (UNEP/FAO/RC/CRC.6/11).
Cont`d	5. The subject notifications lack any form of robust scientific or quantified exposure analysis to justify potential risk estimates.	Paragraphs 36 and 172 of UNEP/FAO/RC/CRC.5/16 are dealing with this issue, reflecting the debates that took place at CRC5. The risk evaluations (hazard linked to local exposure conditions) that were performed by the notifying countries are also detailed in the DGD, section 2.2 (p. 10) and in the respective sections in Annex I of the DGD (UNEP/FAO/RC/CRC.6/11).
Cont`d	6. The CSP claims that endosulfan poses unacceptable ecological and occupational risk. These assertions are subjective and based on anecdotal information. None of them is supported by any form of robust scientific or quantified exposure analysis. Additionally, the Sahelian countries notifications did not follow the necessary risk evaluation procedures. Instead they relied totally on "bridging information" from one risk assessment to another, which is not appropriate unless the use of such bridging information (see UNEP/FAO/RC/CRC.1/11) complies with the following principles: • The assessment should be science-based, on the best available knowledge and data; • Exposure is a key element - measurable and quantifiable; • The information should also be sufficiently detailed and transparent; • The risk assessment should be based on exposure scenarios and conditions from the notifying country.	See response above. The environmental risk evaluation using the PIRI model is not based on any bridging approach. This is reflected in the rationale on Endosulfan in annex II of UNEP/FAO/RC/CRC.5/16, paragraph 5, and in the DGD, annex I, 5.2 (UNEP/FAO/RC/CRC.6/11, p. 24).
Cont`d	7. The provided information lacks scientific integrity because it is based on inadequate scientific methods and reviews that do not appear to have been performed and documented according to recognized scientific principles and procedures. In short, the CSP failed to sufficiently comply with the guidelines for using "bridging information" from other countries	See response above.
Section 2.2 Risk evaluation, EC	**Human health:** Based on the official minutes of the tripartite meeting (May 2004), the rapporteur and a representative of the Commission stated "Rapporteur identified a safe use for operators. ..RMS considered the rest of the points in toxicology fulfilled". At that time, it was concluded that endosulfan is safe for operators and that the requirements in the area of toxicology according to 91/414 were fulfilled. The reference of the working group legislation to	The EC notification was discussed at CRC3. Any issues should have been raised at that meeting. The risk evaluation is described in the DGD (UNEP/FAO/RC/CRC.6/11).

Section	Comment	Response
	insufficient data regarding the operator risk is inaccurate, arbitrary, and not justified based on the available information.	
Annex I, Section 3.4 and 3.7	**Occupational Exposure and Risk Assessment**: The Rotterdam Convention allows notifying countries using risk evaluations from other authorities for consideration in support of the CRC's final regulatory-decision following the Policy Guidance Document ("Bridging Information" - UNEP/T'AO/RC/CRC.l/ll - Annex), which states: *"Risk or hazard evaluations completed in one country may be used by another country in support of its notification of final regulatory action submitted in accordance with Article 5 of the Rotterdam Convention. This document provides guidance on the sort of information that will need to be considered by the Interim Chemical Review Committee in determining that the conditions in the country which completed the original risk evaluation are similar to and compatible with those in the notifying country. "* If this "bridging approach" is being used by the notifying country, in this case by CSP, the following standards and principles must be applied by the CRC in order to fulfil the criteria in Annex II for further consideration: 1. Exposure is a key clement formulation type (EC, WP or Granules) -use pattern (rate and frequency of application, method of application and equipment), climatic and environmental conditions (are they comparable); 2. Information must be science-based (quantitative, measurable); 3. Information is sufficiently detailed to enable for risk assessment (risk mitigation measures); 4. Risk assessment is based on exposure scenarios and conditions from the notifying country (comparable environmental exposure). In view of these principles, MAI specifically reviewed CSP's notification and accompanying documents (UNEP/FAO/RC/CRC.5/5/Add.2 including Annex Ref. Sect. 2.4.2.1 and 2.4.2.2). Using cotton applications in Australia and the USA for bridging purposes is unacceptable for many reasons: The application method in Australia & USA is mainly by air or groundboom versus handheld or backpack sprayer; the rates (USA) and PPEs are different from those in the Sahel, and the load of product (endosulfan) handled and exposed to per day is much higher (USA, Australia), e.g. per air application (300 ha x 0.7 kg ai = 210 kg ai), and groundboom (50 ha x 0.7 kg = 35 kg ai) versus backpack sprayer in Sahel (3 ha x 0.7 kg ai = 2.1kg ai). This demonstrates that the total amount handled per day and its associated potential exposure using the application techniques in cotton (by air or groundboom) from the USA, and Australia seem to be 15 to 100 times larger than in Sahel (Backpack). The following provides a more detail analysis of the occupational exposure and risk assessment under Sahel conditions:	The rationale on endosulfan, paragraph 4, deals with the human health risk evaluation. Paragraph 9 of the ratrionale reflects the conclusions of the Committee. Accordingly, this point was closed during the meeting and is not contained in the outstanding issues as reported under Annex II, point 5 of UNEP/FAO/RC/CRC.5/16 (p.29).

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	Occupational exposures for mixers/loaders were calculated based on information from the CSP notification, available endosulfan labels from the Sahel region, and data from the US-EPA Reregistralion Document (RED) for endosulfan and using US-EPA's Pesticide Handlers Exposure Database (PHED). Personal Protective Equipment (PPE) for mixers/loaders from the label are: "Use glasses or eye protective equipment • Use masks covering mouth and nose • Use rubber gloves • Use long sleeved shirts, pants, and boots As concern has been raised regarding the use or lack of PPE by Sahelian applicators, this assessment was conducted using a minimum of PPE: typical work clothes worn when applying a pesticide: long-sleeved shirt, long pants, and shoes and socks and rubber gloves as stated on the label. Based on the use of gloves as PPE and using the Unit exposures (UE in mg ai/g ai handled) from PHED, the occupational exposures for mixers/loaders were estimated using the equation above with an application rate of 750 g ai/ha treating 3 hectares with a handgun *(e.g.,* from a backpack sprayer). The calculated dermal daily dose was 0.0007 mg/kg/day for mixing/loading endosulfan with gloves. The inhalation daily dose was 0.000085 mg/kg/day for mixing/loading endosulfan with no respiratory protection (not even the required mask covering mouth and nose which would provide protection resulting in an even lower dose). Occupational exposures for applicators were calculated based on the same assumptions and information provided as for the mixer/loaders (see above). The assessment for PPE was normal worker clothing with gloves, as included on the label. Based on the UEs from PHED, the occupational exposures for applicators were estimated using the equation above assuming 3 hectares treated with an application rate of 750 g ai/ha, using a handgun sprayer typically carried on a backpack. The dermal daily dose was 0.01 mg/kg/day for applying endosulfan with gloves. The inhalation daily dose was 0.0000001 mg/kg/day for applying endosulfan with no respiratory protection. The Risk Estimates (MOE = Margin OF Exposures) for mixers/loaders and applicators for exposure to endosulfan range from 435 to over 5,000 using EPA's toxicity values and assuming gloves are worn. The inhalation mixer/loader risks were 2,300 with no additional respiratory protection, while the applicator risks were greater than one million. MOEs of over 100 are acceptable and considered safe. **Conclusions:** These analyses show that with reasonable certainty there is no harm for mixers/loaders and applicators handling endosulfan EC under conditions of use described in Sahel, even with minimal PPE (e.g.. gloves and no respiratory protection).	

Section	Comment	Response
	Therefore, if CSP would use a scientific approach following other countries occupational assessment procedures and methodologies for bridging purposes, the calculated risk is acceptable.	
2.2	**Environment:** The referred environmental risk evaluation for Burkina Faso was conducted by Adama Toe el al. (2003) using the "Pesticide Impact Rating Index" (PIRI) model, a simple risk indicator, which supposed to cover a range of scenarios such as toxicity to organisms, health of farm workers, consumer health, and residues for different pesticides and cropping systems. The referenced PIRI risk assessment provided a ranking among 14 different pesticides (see Fig.l and Table IV), but it did not demonstrate any quantitative estimations of potential environmental exposure (EEC = Expected Environmental Concentration) from the use of endosulfan. Therefore, CSP's notification lacks information related to calculated or measured environmental concentrations of endosulfan, which would allow for a science based risk assessment as required by the "Bridging Policy" Guidance Document: *1.Use pattern (formulation type, rate and frequency of application, method of application and equipment, climatic and environmental conditions):* Most exposure scenarios, the key element for comparability and bridging information, are not equivalent to USA and Australia conditions and scenarios. The application of endosulfan in the Sahel region is mainly used on cotton by handheld rotary disc sprayers compared to application by air or large groundboom sprayers in Australia and the USA. There is no information about the formulation type (EC or WP). The application rates in the US are almost twice as high, and on cotton only the EC-formulation is being registered and used. In addition, weather and soil conditions of the Sahel zone need to be evaluated for proven adequacy to use as surrogates. *2. Information is science based (quantitative, measurable):* The CSP notification did not conduct a science based exposure and risk evaluation for the given environmental scenarios. The provided environmental evaluation (PIRI) represents a qualitative risk ranking and is not supported by sound data (measured or predicted using proven models). Comparisons to Australia and USA are difficult to draw because of the different use patterns and	General: The PIRI-approach was only one part of the environmental risk evaluation – see rationale on endosulfan, UNEP/FAO/RC/CRC.5/16, Annex II. The rationale has been adopted at CRC5. Open points from the discussion among the Committee members were defined as outstanding issues under Annex II, point 5 of UNEP/FAO/RC/CRC.5/16 (p.29). New information about PIRI has become available since CRC5 (UNEP/FAO/RC/CRC.6/12). An overview of the new information as it relates to the outstanding issues (point 5 of UNEP/FAO/RC/CRC.5/16, p.29) can be found in UNEP/FAO/RC/CRC.6/ INF/9 Information on formulation types, concentrations and products used in the Sahel is provided in the notifications and their annex (UNEP/FAO/RC/CRC.5/5) as well as in UNEP/FAO/RC/CRC.5/5/Add.2 (e.g. on p. 12 of Mission Report 2007). The rationale on endosulfan, UNEP/FAO/RC/CRC.5/16, Annex II, paragraph 4., stating that the use pattern is comparable, has been adopted at CRC5. ad 1. and 2: The environmental risk evaluation using the PIRI model is not based on any bridging approach. See also rationale on endosulfan, UNEP/FAO/RC/CRC.5/16, Annex II, and the respective sections of the DGD (UNEP/FAO/RC/CRC.6/11).

Section	Comment	Response
	environmental conditions. Even if comparisons are made based on quantitative model systems (PHED, PRZM/EZAMS) calculating different exposure scenarios, potential environmental risks are acceptable. *3. Information is sufficiently detailed to enable for risk assessment:* Again. The provided information is not sufficient to allow for a sound risk assessment. *4. Risk mitigation measure:* The notifying country did not implement any mitigation measures prior to banning endosulfan. Sufficient evidence of non- enforceability is missing in its notification. The PIRI model has not been used by the cited Registration Authorities (EU, APVMA or US-EPA) in their assessments. It is known that PIRI lacks the accuracy and scientific robustness of other available models in this area. Regarding Burkina Faso's notification, no real quantitative measurements of any surface water monitoring or model verification were provided confirming endosulfan concentrations that could cause potential adverse effects in the aquatic environment. The only citation (Toe et al. 2004) referring to measurements in water was not accessible for review. The provided document did not list any exposure levels (soil or water). Reports of any adverse effects (e.g. fish kills) related to the use of endosulfan are also missing. **Environmental Exposure/Risk Evaluation:** Usually, for deriving more accurate environmental exposure estimates, Tier II exposure modeling is being conducted, e.g. by using the US-EPA models PRZM and EXAMS. These models can estimate environmental concentrations for different cropping systems including the use of "protective" buffers. The results of the modeling are expressed as a l-in-10 year peak concentration and maximum average Environmental Exposure Concentrations (or EECs) in the water column and sediment at 96 hours, 21 days, 60 days, and 90 days post application. These results are compared to information on the effects of endosulfan to aquatic organisms so as to determine the potential risk of adverse effects in aquatic ecosystems. Since these scenarios may be considered "worst case", additional model runs can be performed with more typical application scenarios if necessary. Based on the CSP provided information, endosulfan is applied to cotton by handheld sprayers twice at application rates between 300 and 750 g a.i./ha. Cotton treated in Australia and in the USA is mainly treated by air and less by ground boom applications at higher rates (up to 850 g a.i./ha). Considering the difference in application equipment and rates (handheld sprayer versus vehicle drawn or mounted groundboom or aircraft spray equipment) and the areas treated per day (up to 300 ha by air and day @ 0.7 kg ai/ha or 210 kg ai/day versus up to 3 ha or 2.1 kg a.i./ha for handheld equipment), it seems that it is very difficult to allow "bridging" information for these scenarios. In addition, the comparability of weather and soil conditions at the Sahel locations should have been verified prior to any "bridging" arguments.	

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	However, if one assumes the exposure scenarios and environmental conditions of the notifying countries for the given cotton scenarios are actually similar to Australia and the USA (weather and soil data for the Sahel cotton region were not available), the United States cotton growing regions and weather were chosen as surrogates in following environmental exposure assessment: Input data for this modeling exercise (Tier II exposure modeling - PRZM/EXAMS) were taken from a previous modeling study, standard model default values, and scenarios published by US-EPA (RED-2002). Based on the given parameters, the results demonstrate that endosulfan exposures are generally low. The calculated 96 hour average concentration (relevant to acute exposure) for the "worst case" usage scenario in cotton (one application at 0.7 kg a.i./ha - no buffer) amounts to 0.05 ppb. This estimate is considered very conservative considering the handheld application scenario and given favorable environmental conditions in Sahel. Handheld sprayers usually allow for a more direct spray with less drift, and therefore less environmental exposure considering the smaller treatment area and faster degradation in the warmer climates of the Sahel region. **Conclusions:** Comparisons of these predicted concentrations to known acute effects levels indicate no exceedances of effect levels. The toxicity of endosulfan has been determined in a multitude of studies and is well characterized. It is highly toxic to fish, less so to aquatic invertebrates, and practically non-toxic to algae and higher aquatic plants. A complete list of available acute toxicity data for fish and invertebrates for all forms of endosulfan is presented below in Table 3. The most sensitive species are marine invertebrates *(Penaeus duorarum)* with an LC50 of 0.04 ppb and for *Cyprinus carpio* (freshwater fish) at 0.1 ppb. Considering the inland freshwater scenarios, it can be assumed that based on the predicted environmental concentration of 0.05 ppb (worst case) that even the most sensitive species (Carp - LC50 = 0.1 ppb) will not be affected.	
Annex I Section 3.4 Occupational Exposure	**Occupational Exposure -EC Assessment:** Using sound science-based input parameters that differ from those developed and used by the EC result in lower risks to Mixer/Loaders and Applicators. Specifically, the use and mischaracterization of the nature and severity of toxicological endpoints (dermal vs. inhalation) to generate the total systemic Acceptable Operator Exposure Level (AOEL) combining the inhalation and dermal route of exposure is unacceptable. Before dermal and inhalation exposure can be aggregated for occupational risk, it is essential that the toxicological endpoint for each route of exposure must be the same and the route-specific doses must have a common mechanism of toxictly. The endpoints from the 1-year dog study (Brunk 1989) and repeat dose inhalation study (Hollander and Weigand 1984) are	The EC notification was discussed at CRC3. Any issues should have been raised at that meeting. The risk evaluation is described in the DGD.

Section	Comment	Response
	distinct and should not be combined when calculating the AOEL. This summation of risk is not appropriate for endosulfan's occupational risk assessment. In addition, a dermal penetration factor of 20 % is excessive. In view of the existing data base it should be less than 14 % and can be as low as 2 %. Taking all of this into consideration would result in acceptable AOELs (< 100 %)	