UNITED NATIONS

RC

UNEP/FAO/RC/CRC.5/INF/9

Distr.: General
19 February 2009

English only

United Nations Environment Programme

Food and Agriculture Organization of the United Nations

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009
Items 4 (c) (ii) and 5 of the provisional agenda*

Listing of chemicals in Annex III to the Rotterdam Convention: consideration of draft decision guidance documents: aldicarb; other matters

Communication of the Secretariat

Note by the Secretariat

The annex to the present note contains copies of letters received from Croplife International regarding the draft decision guidance document on aldicarb and the prior informed consent procedure listing process.

The content of the annex has been reproduced without formal editing.

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

K0950776 030309

Annex

CropLife International A.I.S.B.L.
Avenue Louise 326, box 35 - B-1050 - Brussels – Belgium
TEL +32 2 542 04 10 FAX +32 2 542 04 19 www.croplife.org

Ms. I. RodaMartin
Rotterdam Convention Secretariat
Plant Protection Service
Plant Production and Protection Division
Food and Agriculture Organisation of the United Nations (FAO)
Viale delle Terme di Caracalla
00100 Rome Italy

22 August 2008
BGJ/L/ln/08-6

Dear Ms. Roda Martin,

Subject: **The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade – Your letter of 11 July 2008 and your invitation to review and comment on the draft internal proposal for aldicarb**

Please find attached the comments and explanatory letter concerning the draft aldicarb DGD produced by our member company Bayer Cropscience, which I submit on their behalf.

We would like to request that the enclosed letter and comments are considered by the inter-sessional drafting group on aldicarb in their task of finalising the internal proposal for aldicarb. We would like to further request that this information is made available to and brought to the attention of all members of the PIC Chemical Review Committee.

We thank you for your consideration of the enclosed information.

Yours sincerely,

Bernhard Johnen
Director, International Regulatory Policy

Cc: Peter Ohs, Bayer CropScience

Bayer CropScience

Ms. Inma RodaMartin
Rotterdam Convention Secretariat
Plant protection Service
Plant Production and Protection Division
Food and Agriculture Organization of the united nations (FAO)
Viale delle Terme di Caracalla

00100 Rome

Italy

August 15, 2008

Peter Ohs

Bayer CropScience AG
Alfred-Nobel-Straße 50
40789 Monheim
Germany
phone +49 2173 38 4298
fax +49 2173 38 3572
peter.ohs
@bayercropscience.com
www.bayercropscience.com

Comments on the Draft DGD for aldicarb

Dear Ms. Inma RodaMartin

Many thanks for giving industry observers the opportunity to make comments on the draft DGD for Aldicarb. The comments are mostly focusing on the wording of the incorporation of the Jamaican notification in the draft DGD to ensure that the wording in the DGD is backed up by **received and verified** documents from Jamaica and industry.

We offer them in the sincere belief that they will be considered seriously as a constructive contribution to help improve the quality of the DGD.

Yours sincerely

Peter Ohs

Dr. Peter Ohs

Appendix: Review Comments on the Draft DGD on Aldicarb

Review Comments on the Draft DGD on Aldicarb

Comments from Bayer CropScience

The comments are mostly focusing on the wording of the incorporation of the Jamaican notification in the draft DGD to ensure that the wording in the DGD is backed up by **received and verified** documents from Jamaica and industry. They are offered in the sincere belief that they will be considered seriously as a constructive contribution to help improve the quality of the DGD.
To make it easier for the working group of the draft DGD the comments are numerated and the page, the chapter, the Country and if necessary the paragraph of the relevant sentence(s) are given.

Comments:

Comment 1
Page: 6
Chapter: 1
Country: Jamaica

DGD Proposal
Granular formulations of aldicarb were known to be used as insecticides to control sucking aphids, mites, leaf miner and nematodes particularly in citrus fruit and ornamentals.

New proposal
Temik 15 GR formulation of Aldicarb was known to be used as insecticide to control sucking aphids, mites, leaf miner and nematodes in citrus fruit and ornamentals.

Reasoning
The sentence in the draft DGD does not reflect the wording given in the supporting documentation by Jamaica, which was only mentioning Temik 15 GR.

Comment 2
Page: 6
Chapter: 1
Country: Jamaica

DGD Proposal
Before 1975 they were available to all farmers and could be applied to vegetables. They were applied to soil by hands.

New proposal
It has been reported that Temik is in the hands of persons that are not capable of handling the product and it is being used on vegetables and other products for which the health consequences to both, user and consumer as well as the environment may be regrettable.

Reasoning
The sentence in the draft DGD does not reflect the wording given in the supporting documentation by Jamaica and furthermore is misleading. Nothing is stated in the

documentation from 1995 concerning the time before 1975. Nothing is stated on the application method. The quotation in the 1995 document (PCA 1995) only reflects the time before the 1994 decision. No documentation is available on the reasoning of the prohibition of 1975, which was the basis for the notification.
In this connection it has to be stressed again that according to Annex II (b) to establish whether a risk evaluation has been conducted, "the documentation provided shall demonstrate" that "data have been generated according to scientific recognized methods". "It has been reported", whatever this means, can as such not be seen as data generated according to scientific recognized methods.

Comment 3
Page: 7
Chapter: 2.1
Country: Jamaica

DGD Proposal
Aldicarb was on the second schedule (prohibited list) of the Pesticides act 1975, however, a registration was subsequently found on the Jamaican register of pesticides. In 1994, re-registration was refused and it was decided that no further registrations would be considered.

New proposal
Aldicarb was on the second schedule (prohibited list) of the Pesticides act 1975, however, a registration was subsequently found on the Jamaican register of pesticides. In December 1994, the decision was made to prohibit Aldicarb from importation and use in Jamaica.

Reasoning
The sentence in the draft DGD does not reflect the wording given in the supporting documentation by Jamaica. It only mentioned that Aldicarb was prohibited from importation and use in 1994.
The 1995 part of the documentation still has under "Conclusion" the proposal to the PCA Board to stay with the decision of 1975. No documentation of the final decision of the PCA Board in 1995 has been provided. The DGD drafting group should encourage the DNA from Jamaica to provide the respective documentation from the PCA Board, to be able to use the **right wording and dates** in this chapter.

Comment 4
Page: 8
Chapter: 2.2 (Risk to workers)
Country: Jamaica

DGD Proposal
Aldicarb is used primarily on citrus and ornamentals on small and medium farms in Jamaica. There is no program to manage the distribution of Aldicarb which meant that small farmers would have access to and use Aldicarb on a wide range of crops including tomatoes.

New proposal
Aldicarb was used on citrus and ornamentals in Jamaica. In the years before 1994, specific products were available to a limited number of farms under a stewardship program implemented by the manufacturer.

Reasoning
The sentence in the draft DGD does not reflect the wording given in the supporting documentation by Jamaica. It is also in contradiction to the statement in the DGD on page 6. The new proposal reflects the information given by the supporting documentation of Jamaica and the supporting documentation of the manufacturer.

Comment 5
Page: 8
Chapter: 2.2 (Risk to workers)
Country: Jamaica

DGD Proposal
Pesticide operators on such small farms do not have access to protective gear. Also hot tropical conditions make protective clothing uncomfortable. Use of the product represents an unacceptable risk to the health of these small farmers.

New proposal

Reasoning
The sentence in the draft DGD is not supported by verified information from Jamaica, therefore the sentences in bold should be deleted. As mentioned on page 6 of the draft DGD, farmers using Aldicarb under the respective stewardship scheme were provided with the necessary protective equipment.
The DGD Drafting Group should encourage the Jamaican DNA to deliver the reference to the pages presented by the Jamaican DNA at the CRC meeting on the availability of protective clothing. Without reference nothing should be stated in the DGD on the availability of personal protective equipment (PPE), as this was not, as written before, mentioned in the supporting documentation of Jamaica (PCA 1995).

Comment 6
Page: 9
Chapter: 2.2 (Environmental impact)
Country: Jamaica

DGD Proposal
Jamaica has several areas of limestone and underground rivers where much of the farming is done. Consequently, as evidenced by the incidents of pollution in the US, there is a risk of contamination of groundwater and surface water.

New proposal

Reasoning
These sentences should be deleted as no evidence is given in the supporting documentation of Jamaica that Aldicarb was used on limestone areas (PCA 1995). This sentence is only cited in the notification without reference.
It has to be emphasized that for using a risk evaluation from another country for bridging purposes, in minimum the use pattern in both countries must be compared (clear evidence of the prevailing conditions have to be submitted, as recommended by COP3). To be able to compare the exposure scenarios the following information has to be submitted:

- product used
- use pattern (rate, frequency, period)
- climatic conditions
- soil types (in case of certain environmental comparisons)

The relevance of recommended risk mitigation measurers can only be taken into consideration, if product and use pattern are comparable. In the supporting documentation of Jamaica, **no use pattern** is given.

Comment 7
Page: 12
Chapter: 4.5 (Specific information of on aldicarb)
Country: Jamaica

DGD Proposal
Sweep spilled aldicarb into containers. If appropriate, moisture first to prevent dusting. Carefully collect remainder, and then remove to a safe place.

New proposal
Sweep spilled aldicarb into containers. After careful collection, store the container in a safe place.

Reasoning
Temik granules are designed in a way that they are virtually dust free. Dermal toxicity of the product is low as long as the active substance stays in the granule. Watering releases the active substance. This should be avoided. Watering/irrigation are only recommended in definite cases (in agricultural & horticultural practice) after the application of the granules according to the label to ensure that the active substance in the granule is transferred into the subsoil.

Comment 8
Page: 14
Chapter: Annex I (Introductory text to Annex I, 1st paragraph)
Country: ----

DGD Proposal
The information presented in this Annex reflects the conclusions of the two notifying parties: European Community and Jamaica. In a general way, information provided by these two parties on the hazards are synthesized and presented together, while the risk assessments specific to the conditions prevailing …….

New proposal
The information presented in this Annex reflects the conclusions of the two notifying parties: European Community and Jamaica. In a general way, information provided by these two parties on the hazards are synthesized and presented together, while the risk assessment / risk evaluation specific to the conditions prevailing …….

Reasoning
As Jamaica has not done a risk assessment but in maximum a risk evaluation, if at all, this should be reflected in the introduction.

Comment 9
Page: 14
Chapter: Annex I (Introductory text to Annex I, third paragraph)
Country: ----

DGD Proposal
The notification of Jamaica includes consideration of the Environmental Health Criteria ……. (US EPA, 1988), **comparing the worker exposure and leaching conditions with the conditions of use in Jamaica**.

New proposal
The notification of Jamaica drafted in 2007 includes consideration of the Environmental Health Criteria ……. (US EPA, 1988).

Reasoning
The sentence in the draft DGD in bold should be deleted as nothing was given in the notification on the use pattern of aldicarb in Jamaica. To use a risk assessment from other countries (bridging) for the own evaluation, in minimum the use pattern in both countries must be compared (clear evidence of the prevailing conditions have to be submitted, as recommended by COP3; see comment 6). A comparison of use conditions without knowing how the substances were used is not leading to the desired result.

Comment 10
Page: 17
Chapter: 3.1 Food (1st paragraph)
Country: Jamaica

DGD Proposal
Residues have been detected in a variety of crops on which Aldicarb has been applied.

New proposal
Residues have been detected **in the US** in a variety of crops on which Aldicarb has been applied.

Reasoning
The sentence should be changed to the proposal, as this makes it clear to the reader that residues have been found in the US. No residue results are available from Jamaica.

Comment 11
Page: 17
Chapter: 3.1 Food (3rd paragraph)
Country: Jamaica

DGD Proposal
The evaluation by Jamaica reported that the aldicarb product, Temik, was in the hands of persons that were not capable of handling the product and were not wearing PPE, and it was used on vegetables and other products where there were potential health concerns for both the consumer and user (PCA, 1995).

New proposal
The evaluation by Jamaica stated that it has been reported that the aldicarb product, Temik, was in the hands of persons that were not capable of handling the product and were not wearing PPE, and it was used on vegetables and other products where there were potential health concerns for both the consumer and user (PCA, 1995).

Reasoning
The sentence should be changed to truly reflect the PCA report **("It has been reported").**
In this connection we want to mention again that the PCA report was from 1995 and "one" decision from 1994. Therefore, we want to ask the working group on the draft DGD to clarify this inconsistency, as this means that the preliminary risk evaluation was done after the "prohibition" in 1994 and far after the given date of the ban in 1975, which was the basic date of the regulatory decision in the notification.

Comment 12
Page: 17
Chapter: 3.1 Food (4th paragraph)
Country: Jamaica

DGD Proposal
It was concluded that there was an unacceptable risk of contamination of food products in Jamaica based on known incidents in the USA **and the normal pattern of use under the prevailing conditions in Jamaica**.

New proposal
It was concluded that there was an unacceptable risk of contamination of food products in Jamaica based on known incidents in the USA.

Reasoning
The sentence in the draft DGD in bold should be deleted as no use pattern of aldicarb in Jamaica was in the notification. A comparison of the use conditions (US versus Jamaica) without the use pattern in the two countries is, according to my knowledge, without any scientific basis. Also nothing was given in the supporting documentation on the prevailing conditions in Jamaica (PCA 1995). Assumptions should not be used in a DGD to substitute facts.

Comment 13
Page: 18
Chapter: 3.3 Water (1st paragraph)
Country: Jamaica

DGD Proposal
….. (PCA, 1995).

New proposal
??????.

Reasoning
The working group on the draft DGD for aldicarb should clarify with the DNA from Jamaica how an evaluation from 1995 could be used for a decision in 1994 or even for the earlier decision in 1975, as this was the basic date of notified regulatory decision of Jamaica.

Comment 14
Page: 18
Chapter: 3.3 Water (3rd paragraph)
Country: Jamaica

DGD Proposal
As Jamaica has several areas of limestone and underground rivers where much of the farming is done it was concluded that there was a risk of contaminating ground water and hence, drinking water, based on known incidences in the USA.

New proposal
It was concluded that there was a risk of contaminating ground water and hence, drinking water, based on known incidences in the USA.

Reasoning
The working group on the draft DGD for Aldicarb should verify with the notifying DNA whether before 1994 Aldicarb was really used in these areas, as this statement in the notification is not backed by the supporting documentation of Jamaica (PCA 1995). As long as this could not be verified, the sentence in bold should be kept deleted.

Comment 15
Page: 19
Chapter: 3.4 Occupational exposure (3rd paragraph)
Country: Jamaica

DGD Proposal
Pesticide operators, mainly small farmers, in Jamaica do not have access to protective gear. A further reason why they fail to wear protective clothing is that it is uncomfortable in the hot tropical climatic conditions. Therefore, use of the product was considered to represent an unacceptable risk to the health of small farmers (PCA, 1995).

New proposal

Reasoning
This chapter should be deleted until the working group on the draft DGD for Aldicarb received from the Jamaican DNA the **reference of the paper presented** during the CRC showing that this may have been used in the evaluation. Furthermore, the working group should clarify with the DNA from Jamaica how an evaluation from 1995 could be used for a decision in 1994.

Comment 16
Page: 23
Chapter: 5.2 Aquatic species
Country: Jamaica

DGD Proposal
…… (PCA, 1995). **Jamaica has several areas of limestone and underground rivers, where much of the farming is done.**

New proposal

Reasoning
The working group on the draft DGD for Aldicarb should verify with the notifying DNA whether before 1994 Aldicarb was really used in these areas, as this statement in the notification is not backed by the supporting documentation of Jamaica (PCA 1995). As long as this could not be verified, the sentence in bold should be kept deleted.

Comment 17
Page: 24
Chapter: 5.6 Summary
Country: Jamaica

DGD Proposal
Jamaica has several areas of limestone and underground rivers, where much of the farming is done. Consequently, as evidenced by the incidents of pollution in the US, there is a risk of contamination of ground water and surface water

New proposal

Reasoning
The working group on the draft DGD for Aldicarb should verify with the notifying DNA whether before 1994 Aldicarb was really used in these areas, as this statement in the notification is not backed by the supporting documentation of Jamaica (PCA 1995). As long as this could not be verified, the sentence in bold should be kept deleted.

Furthermore, the working group should verify with the Jamaican DNA the use pattern used in 1995 by the PCA for their risk evaluation. As stated above, bridging without use pattern is scientifically not possible.

Comment 18
Page: 26
Chapter: 4.2 Criteria used
Country: Jamaica

DGD Proposal
Comparison of conditions in agricultural areas in Jamaica with similar conditions in the USA where contamination of ground and drinking water has been described despite use under very restricted conditions. The island ecology of Jamaica is more vulnerable than conditions in the USA. Contamination of citrus fruit has also been observed in the USA. **The lack of access to and proper use of protective equipment in Jamaica by small farmers were also considered.**

New proposal
The island ecology of Jamaica is more vulnerable than conditions in the USA. In the USA contamination of ground and drinking water has been described despite use under very restricted conditions. Contamination of citrus fruit has also been observed in the USA. It has been reported in Jamaica that Temik is in the hands of persons that are not capable of handling the product and is being used on vegetables and other products for which the health consequences both user and consumer as well as the environment may be regrettable.

Reasoning
In the supporting documentation from Jamaica (PCA 1995) there is only one statement given on the environmental conditions under point 4.1. :

"Aldicarb is registered for use in the united States of America under very restricted conditions: This entails strong enforcement measures under environmental conditions that are even less susceptible to contamination as for an island ecology like Jamaica."
The wording in the draft DGD should reflect this. Nothing else is given, especially nothing on the use pattern of the compound (bridging requirement, see also comment no. 6).
The sentence in bolt has to be deleted, as long as no reference to the pages presented at the CRC could be given.

Comment 19
Page: 28
Chapter: Documentation used for risk evaluation
Country: Jamaica

In the draft DGD reference list the following references of documents are missing:
1: PCA (1995).
2: Document on the availability of personal protective equipment (PPE) in Jamaica (reference)
They must be added to the reference list, to be in line with the citations and the given statements.

Reasoning
1: PCA (1995) is frequently cited in the document
2: Pages were shown during the CRC meeting on the availability of Personal Protective equipment (PPE) in Jamaica. These pages were taken into consideration without reference and without reference in the supporting documentation of Jamaica (PCA, 1995). The working group on the draft DGD for Aldicarb should implement this document in the reference list, as without this reference no backing of the statement on personal protective equipment is possible (see comments before).

CropLife International A.I.S.B.L.
Avenue Louise 326, box 35 · B-1050 · Brussels – Belgium
TEL +32 2 542 04 10 FAX +32 2 542 04 19 www.croplife.org

Ms. Karmen Krajnc,
Chair of the Chemical Review Committee
Ministry of Health
National Chemicals Bureau
Maly trg 6
1000 Ljubljana
Slovenia

12 February 2009

Re: Strengthening the Integrity of the PIC Listing Process

Dear Ms. Krajnc,

We are writing to share with you, as chair of the Chemical Review Committee, our response to the letter of 22 October 2008 of the Rotterdam Convention Secretariat in response to CropLife International's observations regarding the process for listing chemicals in Annex III of the Rotterdam Convention. We are grateful for the attention that the Secretariat and Bureau of the CRC have given to these issues. We believe that the careful consideration COP-4 applied in reviewing the CRC's work, as well as the explicit discussion in plenary about the CRC's procedures, confirms the importance of ensuring that the CRC's work processes and work products are as robust and as rigorous as possible. Toward that end, we provide the following additional observations or clarifications for your consideration.

Recommendation 1: Verification and Review of Notifications

- We appreciate the Secretariat's response to our concern about the past verification of incomplete notifications, but we are concerned that it understates the important role that the Secretariat plays in the Annex III listing process.
  - -- Although it is true that the CRC must decide whether a notification satisfies the Annex II criteria of the Convention in order to justify a recommendation for listing, it is *not* the CRC's responsibility to evaluate and verify whether a notification meets the requirements of Annex I. Instead, article 5 of the Convention expressly assigns that role to the Secretariat.
  - -- Under the scheme set out in the Convention, moreover, the CRC may only receive a chemical for review against the Annex II criteria once the Secretariat has received and verified one notification from each of two PIC regions. CRC members therefore should be able to assume that each of the notifications that they review have been so verified.
  - -- Although we agree that the CRC should prioritize its work based at least in part on the quality of documentation accompanying a chemical's notifications, the Convention itself sets a minimum threshold that notifications must meet before they are even eligible for the CRC's review.
  - -- That minimum threshold applies regardless of when the notification was originally submitted to the Secretariat.

-- Indeed, article 5.3 invests the Secretariat with the responsibility of circulating a summary to all Parties for those notifications that contain all required information. This responsibility exists entirely independently of the CRC's oversight. It reinforces the fact that the Secretariat plays a critical and autonomous role in evaluating notifications and rigorously verifying the Annex I criteria. The absence of a rigorous verification process increases the risk that the Secretariat may inform parties through the PIC Circular of verified notifications that in fact do not comply with the information requirements of Annex I.

- Our concern is that the Secretariat could have done more to ensure that this minimum threshold was consistently satisfied in order to avoid diverting the CRC's time and attention from its review of chemicals that are properly before it, and in order to avoid the risk of circulating inaccurate information to the Parties.
- We are hopeful that the Secretariat will review the context for our concern and take it into account as we move forward in handling future notifications.

Recommendation 2: Adequate Supporting Information for Notifications and Role of the CRC in Evaluating the Information Underlying Notifications

- We appreciate that the importance of adequate supporting information is largely a matter for the CRC rather than the Secretariat. Although we agree that the CRC has commendably upheld this requirement in certain instances by postponing action where information is incomplete, we remain concerned by the approach it has adopted to date in the cases of aldicarb and alachlor. We provide additional information below to clarify the basis for our concerns.
- In the case of aldicarb, CRC-4 approved a notification from Jamaica even though (a) the final regulatory action was taken many years *before* the cited risk evaluation took place; and (b) the cited risk evaluation failed to include bridging information on exposure and use pattern which were essential in this particular case to extrapolate the risk evaluation from another country.
  - -- With respect to the discrepancy between the final regulatory action and the risk evaluation, the CRC apparently relied on an oral explanation by the expert from Jamaica that a limited registration existed until after the risk evaluation took place, at which point the final regulatory action took effect. Unfortunately, there were no references in the documentation to support this explanation.
  - -- These practices convey the impression that the CRC may be willing to help construct a factual basis that fits the requirements of the Convention, rather than serving as a neutral technical review to ensure that the facts of each country notification satisfy the requirements on their own. In cases where there is an absence of clear supporting documentation in the written record, the CRC's reliance on oral supplementation raises the risk that its decisions may be perceived as *ex post facto* rationalizations, rather than reasoned decisions based on a reviewable record.
- In the case of alachlor, CRC-2 approved a Canadian notification despite the fact that the documentation that accompanied the notification did not include the actual risk evaluation on which the Canadian final regulatory action was based.
  - -- The information that was submitted was part of a report prepared two years *after* the final regulatory action was taken. Because the CRC has not yet seen the original risk evaluation, it is difficult to understand how the CRC could conclude that the data supporting the risk evaluation were developed and reviewed according to generally recognized scientific procedures.
  - -- Nevertheless, the alachlor notification from Canada forms the basis of the one of the two notifications that have been approved, and work on the DGD for alachlor is under way. It is difficult to reconcile this status with the CRC's recognition (at

CRC-3) that it was inappropriate to proceed in cases where "the *supporting documentation that described the underlying risk evaluation* was not available."

- We believe that these concerns are sufficiently important that they bear reconsideration by the CRC before it conducts further work on these substances, again keeping in mind the COP's practice of carefully evaluating the CRC's review of substances recommended for inclusion.
- We are also grateful for the opportunity to review (in CRC-5/INF.7) the response by the European Commission to comments on the alachlor nomination that CropLife International submitted on behalf of a member company. One of the observations made by the European Commission in that letter appears directly related to the general question about the adequacy of supporting information for these notifications. We refer here to the Commission's assertion that "[i]t is not the role of the CRC to question the risk assessment or to decide on the quality of a certain study."
  - -- CropLife International believes that this assertion raises an important, fundamental question about the role of the CRC and its function in evaluating notifications under Annex II.
  - -- We believe it is difficult to reconcile the Commission's assertion with the language in Annex II(b), which provides that the CRC "shall ... [e]stablish that the final regulatory action has been taken as a consequence of a risk evaluation," and that the "the documentation provided shall demonstrate that: (i) Data have been generated according to scientifically recognized methods; (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures; (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action."
  - -- We have to date understood this language as providing not just a role for the CRC in evaluating the risk evaluation documentation and the scientific value of the underlying data, but in fact an *affirmative responsibility* for the CRC to perform this evaluation.
  - -- We also believe that our understanding is shared by the Conference of the Parties and other stakeholders. If there are different views on this point that are shared by the CRC, therefore, we believe it would be useful to have those views aired as soon as possible, given the centrality of this issue to the work program of the CRC. We would therefore appreciate if this issue could be presented for discussion by the CRC at the next available opportunity.

Recommendation 3: Transparency of the Listing Process

- We appreciate the Secretariat's support for our point about the importance of timely submissions and adherence to the deadlines that the CRC imposed at its second meeting. We observe that the Parties at COP-3 noted with approval these same deadlines. Although we recognize that the review process must necessarily be fluid in cases where a notifying party is asked to respond to specific questions from the CRC or its subsidiary bodies, we believe that the Secretariat can contribute to the rigor of the process in general by adhering to the CRC's timelines for major submissions.
- With respect to the Task Groups, we understand that observers do have the opportunity to comment on Task Group reports immediately prior to or at CRC meetings, but our experience has been that *ex post facto* comments are less meaningful, and less helpful to the CRC members, than the kind of contemporaneous contribution that would be possible if Task Force proceedings were made accessible to qualified observers. As we noted in our original letter, the inclusion of observers in intersessional work groups has been the practice in the Stockholm Convention on POPs, where we believe that all participants would agree that the practice for intersessional communications has worked well. More open Task Groups would contribute to the thoughtfulness and accuracy of Task Group work products, and

(given the increasing importance of these intersessional processes to the CRC's work) would in turn increase the quality of the CRC's work products as well.

Recommendation 4: CRC Reporting and Recordkeeping

- We appreciate the Secretariat's willingness to work with the CRC in the future to ensure that the meeting reports accurately capture and differentiate between recommendations of the Task Group and subsequent decisions of the CRC, particularly where they differ.
- We hope that this effort will avoid problems in the future such as the prior misstatement in the official CRC report regarding the Task Group's conclusions about whether the carbaryl notification met the Annex I information requirements.

Recommendation 5: Intentional Misuse

- We understand that the COP's decision at COP-4 to initiate further proceedings with respect to the meaning of the term "intentional misuse" means that the CRC will have occasion to revisit this issue, which we support.
- CropLife International looks forward to participating in that reconsideration and will share its views on this issue with the Secretariat.

Recommendation 6: Independence and objectivity of CRC Members

- We appreciate the Secretariat's observation that many CRC members are not government employees, and that even when they are government employees they may not be employed by the Ministry that prepared and submitted a notification.
- We therefore wish to clarify that our concerns apply equally to members having an apparent or potential interest in a notification other than a direct financial interest. The need to take account of these "other interests" was anticipated in the decision RC-1/7 of COP1 (UNEP/FAO/EC/COP.1/33 Decision RC-1/7). From our perspective, the employment by an official agency of a Party, even if that agency is not itself the submitting agency, can lend the impression that the CRC member is representing the interest of the notifying Party as a whole. We believe it is best to avoid the possible appearance that the CRC member's government position "...could unduly influence the expert's position with respect to the subject matter being considered." *See* COP.1/33 RC-1/7 ("Rules and procedures for preventing and dealing with conflicts of interest relating to the activities of the Chemical Review Committee"), at Annex.
- Moreover, we do not believe that the potential conflicts in such cases are ameliorated by the fact that CRC members are appointed to the CRC by the COP rather than by their governments. In such cases, the livelihood of the CRC member is dependent on the government agency whose notification is being reviewed, whereas CRC positions are time-limited and unpaid.
- As the Secretariat's letter notes, the CRC has adopted a practice of switching the Chair of the CRC when the Committee is reviewing a notification from the Chair's country. The same logic that led to that practice should likewise apply more broadly to any situation where a CRC member's objectivity might be called into question because of pre-existing employment arrangements with his or her government employer.

Next Steps

We appreciate your willingness to share our correspondence with the CRC membership in advance of CRC-5, and we would be grateful if you would include this reply along with the exchange that is found in CRC.5/INF/7. We look forward to our continued work together on the implementation of the Rotterdam Convention.

Yours Sincerely,

Michael A. Morelli, Ph.D.
Chair PIC Project Team
CropLife International

Director, Compliance & Global Regulatory Affairs
Agricultural Products Group
FMC Corporation
Tel: +1 215 299 6414
Email: michael.morelli@fmc.com

cc: Rotterdam Convention Secretariat