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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009
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: alachlor; other matters

Communication of the Secretariat regarding alachlor

Note by the Secretariat

The annex to the present note contains a copy of a letter received from Croplife International providing comments on the draft decision guidance document process for alachlor.

The letter has been reproduced without formal editing.

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

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Annex

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16 March 2009
L/BGJ/ps/09-03

Dear Ms Roda Martin

Subject: The Rotterdam Convention on Prior Informed Consent (PIC) Procedure – Comments submitted by CropLife International on behalf of Monsanto on Alachlor

On behalf of our member company Monsanto I have the pleasure of including the enclosed comments regarding Alachlor and the DGD process.

I kindly request that this information be made available to the Chemical Review Committee prior to its forthcoming meeting on 22 to 27 March 2009. We would also appreciate it if this document could be made available as a Room or Information document at the CRC.

We apologise for the late submission of these comments and hope that this does not cause you any undue inconvenience.

I thank you in advance and remain with best regards

Yours sincerely

B. G. Jo

Bernhard Johnen
Director, International Regulatory Policy

Alachlor in the DGD process: A submission from the Monsanto Company

The purpose of this paper is to allow the Chemical Review Committee to consider improving its decision making processes and thus develop a more consistent approach to the DGDs which it forwards to the COP . The principles which we consider need resolution are based on evidence from the Alachlor DGD documentation but raise issues of general concern.

Alachlor is a candidate for PIC listing based on two notifications which are reviewed in the DGD. We consider that both are flawed according to the criteria set out in Annex II, and that open questions should be addressed before the DGD is finalized.

Canada

After 7 years of asking to publish the risk evaluation on which the final Canadian Notification was based it is still not available.

The CRC approved the Canadian notification notwithstanding the fact that it did not see (and still has not seen) the risk evaluation on which the final regulatory action was based. It is difficult to see how the CRC could conclude that the Annex II(b) criteria were satisfied under these circumstances. This is particularly true in light of statements in the Alachlor Review Board report (the primary supporting information submitted by Canada) that called into question whether assumptions used in the risk evaluation were reasonable. *See,* ***Chapter 4, The Safety of Alachlor: The analysis by the Health Protection Branch, Conclusions, page 72.*** **"The board does not consider that the assumptions used to estimate human exposure were reasonable ones.... In addition, the failure to adequately convey the extent of these assumptions (worst case) made it impossible for the ultimate decision maker to properly evaluate this information in assessing the potential risks to determine if they were acceptable".** It is difficult to see how the CRC could conclude, based on the information supplied by Canada, that the evaluation that served as the basis for the final regulatory action was based on data reviews that were "performed and documented according to generally recognized scientific principles and procedures."

European Union

We have been made aware by the responses to questions concerning the DGD **(CRC5 Inf7)**that the critical supporting information for the EU notification of Alachlor, as detailed in the Notification letter, and the Decision Guidance Document, is the results of a "Canadian Bio-monitoring study."

1. **No assessment of the scientific validity of the study has been provided.**

   i) The study was conducted in 1985 using equipment which was, even at that time 30 years old, and under conditions which did not reflect the prevailing conditions in Canada. In the last 60 years there have been may advances in application technology.

   ii) Spillages, accidents, improper actions, unsuitable clothing, a limited number of participants and positive findings in the control cause the validity of this study to be questioned.

2. **No bridging data has been provided between the EU and Canadian exposure situations as required by: UNEP/FAO/PIC/INC.10/14 Annex Para 4 ; confirmed by UNEP/FAO/RC/CRC.1/11 and 1/28** and **UNEP/FAO/RC/CRC.3/4**

   "The Chemical Review Committee will consider such bridging information on a case-by-case basis. In reviewing the information, the Committee will apply the following principles:

   (a) Exposure is a key element;

   (b) The information should be science-based, on the best available knowledge;

   (c) The information should also be sufficiently detailed to enable the Chemical Review Committee to make an assessment."

The EU risk evaluation was based on a Canadian biomonitoring study which **did not even reflect the prevailing Canadian use conditions in 1985** and therefore it is extremely unlikely that the Risk evaluation was based on prevailing conditions within the EU.

3. The CRC is expected to accept that there is no need to evaluate the Risk Assessment or the scientific validity of the study used in the DGD. **(Position of the EU in CRC5 Inf 7).**

The EU's assertion that "it is not the role of the CRC to question the risk assessment or to decide on the quality of a certain study" (EU submission in CRC 5 INF 7) is puzzling in light of the requirement in Annex II(b) that **the CRC is required to establish that the risk evaluation is based on a review of scientific data in the context of the conditions prevailing in the Party** in question, and that the documentation must demonstrate that the data were generated according to scientifically recognized methods and reviewed according to generally recognized scientific principles and procedures.

Annex III listing or Annex IV

1. Although the study "Canadian Bio-monitoring Study" included Microencapsulated formulations no risk assessments have been provided in the notification, the supporting data to the CRC, or the DGD for this type of formulation.
2. The DGD should include reference to the fact that uses under 10ha every day of the Emulsifiable Concentrate were acceptable even under the EU conservative risk assessment and formulations which lead to lower exposure are available.

The EU risk evaluation is sufficient only to support a listing of the Emulsifiable concentrate as a severely hazardous pesticide formulation (i.e., under Annex ***IV***) rather than a listing for a pesticide under Annex II criteria.