



UNEP



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**Rotterdam Convention on the Prior Informed  
Consent Procedure for Certain Hazardous  
Chemicals and Pesticides in International Trade  
Chemical Review Committee**

Second meeting

Geneva, 13–17 February 2006

Item 5 (b) of the provisional agenda\*

**Inclusion of chemicals in Annex III of the Rotterdam Convention:  
review of notifications of final regulatory actions to ban  
or severely restrict a chemical: cyhexatin**

## **Information on cyhexatin supplied by the industry sector**

### **Note by the Secretariat**

The annex to the present note contains information and comments supplied by the industry sector on cyhexatin.

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\* UNEP/FAO/RC/CRC.2/1.

## Annex



Attention to : Mr. Niek VAN DER GRAAF  
Secretariat for the Rotterdam Convention  
Plant Protection Service  
Plant Production and Protection Service  
FAO  
Viale delle Terme di Caracalla  
00100 Rome, Italy

December 5<sup>th</sup>, 2005

**Subject : Notifications for Cyhexatin inclusion in the PIC procedure**

Dear Sir,

Cerexagri and Oxon are both notifiers for Cyhexatin at EU level, and both are manufacturers of this active ingredient. So Oxon and Cerexagri would like to act together to defend Cyhexatin in the frame of its notification for the PIC procedure.

~~You will find below a rough summary of the past PIC story of Cyhexatin. We think these information are very important in the frame of the examination of the current notification for Cyhexatin inclusion in the PIC procedure and should be considered by the CRC.~~

Cyhexatin was originally included in the original voluntary PIC procedure in 1991 because it was banned or severely restricted in 5 countries due to teratology concerns mentioned by the former manufacturer, Dow.

In the meantime, Cerexagri and Oxon developed additional data on Cyhexatin teratogenic potential. This new/additional information was considered by the 1994 FAO/WHO Joint Meeting on Pesticide Residues (JMPR). The 1994 JMPR stated that *"After taking into consideration the results of all the studies on teratogenicity in rabbits, the Meeting concluded that cyhexatin is not teratogenic to this species."*

The original DGD on cyhexatin was revised (toxicology section) to reflect the conclusions of the 1994 JMPR and, as mentioned in document UNEP/FAO/RC/CRC.2/12, Cyhexatin was eventually removed from that procedure in 1996.

The notifications submitted by Japan and Canada refer only to data older than 1994. The FAO/UNEP Joint Group of Experts has therefore already reviewed the data package presented in these notifications and consequently the conclusion drawn from FAO/UNEP experts was that Cyhexatin had to be withdrawn from the PIC list, and this was effective in 1996.

Moreover, during the past 10 years, Cerexagri and Oxon have built a complete registration dossier which was submitted in Italy in November 2004 as an application for inclusion on Annex 1 of Directive 91/414/EEC. The dossier has been declared administratively as complete by EU authorities, the EU draft assessment report is being prepared to be due in May 2006.

*Rec'd 12/1/06*



This updated complete data package was scientifically reviewed very recently by the last JMPR (September 2005, Geneva) which concluded again that there is no teratogenicity issue with Cyhexatin.

Finally, after a detailed review of the profile of the active ingredient EPA has recently re-granted the import tolerance in orange juice since it was possible to conclude that there is no harm to any population subgroup resulting from exposure to cyhexatin treated oranges (Federal Register . Vol. 70, No. 143 / Wednesday, July 27, 2005).

We can assume that you have in your hands all the related documents, including the minutes of the FAO/UNEP Joint Group of Experts meetings since the early 90's. We just would like to draw your attention on the fact that the data mentioned in the notifications for Cyhexatin inclusion in the PIC procedure have already been reviewed by the FAO/UNEP experts, and this resulted in the withdrawal of Cyhexatin from the PIC procedure. Therefore we are wondering whether it is a standard procedure to come back on a previous decision taken by the FAO/UNEP experts on the basis of an identical data package already reviewed.

Should you need any additional information on this file, please feel free to contact the product registration managers from Oxon or Cerexagri at the addresses indicated below.

Sincerely yours,

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