European Chemicals Agency

Committee for Risk Assessment

(RAC)

Annex 3

Request from Commission to ECHA on 10 December 2010

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENVIRONMENT
Directorate D - Water, Chemicals & Biotechnology
The Director

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Directorate G - Chemicals, metals, mechanical, electrical and construction industries; Raw Materials
The Director

10 -12- 2010

Brussels,
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NOTE FOR THE ATTENTION OF MR GEERT DANCET

EXECUTIVE DIRECTOR OF ECHA

Subject: Opinion of RAC on dossiers proposing harmonised C&L of epoxiconazole, gallium arsenide and tehtrahydrofurane

By letters of 23 March 2010 and 2 June 2010, respectively, ECHA has transmitted to us the opinions of RAC concerning the harmonised classification of epoxiconazole, gallium arsenide, and tetrahydrofurane.

Unlike for opinions from RAC for other substances, to which we have responded separately, we have some concerns that prevent us from proceeding directly with the process for harmonising the classification as proposed in RAC's opinions for these substances for the following reasons:

- **Epoxiconazole**

As required by the Annex I to the Commission Directive 2008/107/EC amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances, industry is currently conducting additional studies, the results of which are expected to be available as of June 2011. In order to decide, in accordance with Article 37(5) of the CLP Regulation, if the harmonisation of the classification and labelling of epoxiconazole is appropriate at this point in time, we would like to ask RAC to provide us with an opinion as to whether it is possible that the results of the already performed, currently ongoing or planned studies that have been discussed with Regulatory Authorities under the regulatory evaluation and approval regime of Directive 91/414/EEC (i.e., the studies listed on page 6 of the RAC opinion on epoxiconazole of 17 March 2010) could be relevant for deciding on the appropriate classification of the substance as toxic for reproduction Cat 1B. Therefore, the Commission would like ECHA to request, in accordance with Article 77 (3) (c) of REACH, the RAC to deliver such opinion..

- **Gallium arsenide**

We have concerns on the level of information available to stakeholders and their possibilities to react with regard to the scientific justifications supporting the opinion of the RAC on gallium arsenide. Our understanding is that the extensive read-across approach and the RAC's conclusion that gallium arsenide should be classified as Carc Cat. 1A arose during RAC

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discussions. Although the proposal to classify gallium arsenide as Carc. Cat.1A was raised during the public consultation, RAC selected the scientific justification from the IARC studies on its own when developing its opinion. This decisive justification had not been included in the original French dossier. Several stakeholders have rightfully objected to the fact that they were not given the chance to see the specific scientific justifications prepared by RAC and to comment on this proposal. Therefore, the Commission would like to ask ECHA, in accordance with Article 77 (3) (c) of REACH, to initiate a second public consultation, limited to carcinogenicity. RAC should then be requested to examine the comments received during the consultation and adopt an updated opinion, if necessary.

- **Tetrahydrofurane**

We have received a copy of a letter from industry with regards to the RAC opinion concerning the harmonised classification of tetrahydrofurane, in which concerns have been raised about the lack of possibilities for stakeholders to react in an adequate way to explain their views. We would like to recall that it is of utmost importance that the stakeholders concerned are given full possibility to react to the arguments advanced during the development of the opinions of RAC and be interested to receive the copy of the reply given by ECHA to CEFIC's sector group before deciding on our further course of action.

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