



**Committee for Risk Assessment
(RAC)**

Annex 4

**Request from the Executive Director of ECHA
to RAC (17 January 2011) for an opinion on
epoxiconazole**

ECHA/RAC/ A77-O-0000001412-86-02/F

Date of adoption

11 March 2011

Helsinki, 17 -01- 2011
SMH/mak I(2011)0005

Note for the attention of
Jose Tarazona, Chair of the Committee for Risk Assessment

Subject: Request to the Committee for Risk Assessment for an opinion on epoxiconazole

1 Background

The Committee for Risk Assessment (RAC) is requested to draw up an opinion according to the following mandate:

On 17 March 2010 RAC adopted an opinion on a proposal for the harmonised classification and labelling of epoxiconazole. During the adoption of the RAC opinion, RAC was informed that industry is currently conducting additional studies as required by Annex I to Commission Directive 2008/107/EC amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances.

The results of these studies were expected to be available as of June 2011, well after the RAC deadline for adopting the opinion. In order for the Commission to decide, in accordance with Article 37(5) of the CLP Regulation, if the current harmonised classification and labelling of epoxiconazole should be revised at this point in time or after the finalisation of these studies, the Commission has requested ECHA to ask RAC for a new opinion on epoxiconazole. The request from the Commission to the Executive Director of ECHA is attached as Annex 1 to this mandate.

Specifically, the European Commission would like to know if the results of the already performed, currently ongoing, or planned studies that have been discussed with Regulatory Authorities under the approval regime of Directive 91/414/EEC, could be relevant for deciding on the appropriate classification of the substance as toxic for reproduction Cat. 1B. The studies referred to are the six studies that are listed on page 6 of the RAC opinion on epoxiconazole of 17 March 2010 (Annex 2). For each of these studies study plans have been provided by industry and these should be the basis for the RAC opinion. The six study plans are hereafter referred to as the 'reference documents' and are listed in Annex 3 to this mandate.

2 Terms of Reference

To allow the European Commission, on the basis of scientific advice, 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, pursuant to Article 77(3)(c) of REACH, RAC is requested to:

Review and evaluate the reference documents in order to decide whether the results of the studies therein could be relevant for deciding on the appropriate classification of the substance as toxic for reproduction Cat. 1B.

3 Timescale for the RAC opinion

The European Commission has not specified a deadline to receive the opinion of the Committee for Risk Assessment. However, it is understood that the Commission is considering the inclusion of epoxiconazole in the next adaptation to technical progress of the CLP Regulation. In order to meet the timetable for this amendment, a decision at RAC-15 (scheduled for week 10 (7-11 March 2011)) would be preferable.

Nevertheless, sufficient time should be permitted for RAC to put in place the necessary arrangements to prepare a draft opinion e.g. appoint a (co-) rapporteur and then to prepare and adopt the opinion itself. If there is not an agreement at RAC-15, agreement would need to be reached by written procedure after the meeting which should not normally be shorter than 10 calendar days. I therefore request RAC to provide an opinion by 31 March 2011 if feasible.

4 Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) No 340/2008 and therefore no remuneration will be paid by the Agency.

Geert Dancet
Executive Director

Cc: Pilar Rodriguez Iglesias, Joerg Lebsanft, Jukka Malm.

Annex 1 - Request to ECHA from the European Commission of 10 December 2011.

Annex 2 - RAC opinion on epoxiconazole of 17 March 2010.

Annex 3 - Description of the study plans of the studies listed on page 6 of the RAC opinion on epoxiconazole of 17 March 2010.