

**Committee for Risk Assessment**  
**RAC**

**Annex 3**  
**to the RAC Opinion on toxicity to reproduction of**  
**Epoxiconazole**

ECHA/RAC/A77-O-0000001412-86-08/A3

**Adopted**

**28 November 2012**

25.04.2012

## **Note for the attention of Pilar Rodríguez Iglesias, Acting Chair of the Committee for Risk Assessment**

### **Ref: Request to the Committee for Risk Assessment for an opinion on epoxiconazole**

In accordance with a request from the Commission to ECHA of 6 March 2012, this note is to give a mandate to RAC to develop and adopt a new opinion on the harmonised classification and labelling of epoxiconazole, taking into account the previous RAC opinions, the new information as soon as it has been made available in a suitable report format as well as the comments received during public consultation.

#### **1. Background**

In 2010, the Committee for Risk Assessment (RAC) adopted an opinion on the proposed harmonised classification and labelling of epoxiconazole (opinion of 17 March 2010). Subsequently, following the mandate from 17 January 2011 RAC adopted on 11 March 2011 a second opinion on certain scientific study plans for epoxiconazole. After these opinions had been adopted, the Commission started consultations with the Member States in the REACH Committee with the view to modify the existing harmonised classification and labelling for epoxiconazole in Annex VI to the CLP Regulation, and eventually proposed to modify the existing entry in line with the RAC opinions. However, a qualified majority to modify the existing entry could not be obtained at the meeting of the REACH Committee on 23 February 2012.

The absence of a qualified majority was due to a number of additional studies that have recently been made available by industry to the Commission. Several of these studies had been noted already by RAC when it adopted its first opinion, but the study reports had not been available and could not be taken into account by RAC at that time.

The mentioned reports originate from the company BASF; they are dated 29 February 2012. Subsequently, the Commission requested the company to provide the new data in a suitable report format which reflects agreed rules of data presentation for CLH opinion development. It is foreseen that the new data is afterwards submitted for consultation by third parties (public consultation).

#### **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, the appropriate harmonised classification and labelling of epoxiconazole, RAC is requested, pursuant to Article 77(3)(c) of REACH, to:

*Develop and adopt an opinion on the classification and labelling of epoxiconazole, taking into account the previous RAC opinions, the aforementioned additional information that has recently become available and the comments received during public consultation.*

### **3. Timescale for the RAC opinion**

The European Commission has not specified a deadline to receive the opinion of the Committee for Risk Assessment. I understand that a first discussion will take place at RAC-21 (scheduled for 12-15 June 2012) at which the time table shall be agreed. I assume at this point in time that the opinion can be achieved before the end of the year and wish to be informed if such deadline is not feasible.

Nevertheless, sufficient time should be permitted for this new opinion development process, including the necessary arrangements to prepare an opinion, i.e. the timely availability of the new information in the format specified by ECHA, appointment of a (co-) rapporteur, launch and evaluation of a public consultation and finally the preparation and adoption of the opinion itself.

### **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) 340/2008 and therefore no remuneration will be paid by the Agency.

***[signed]***

Geert Dancet  
Executive Director

Cc: Jukka Malm, Jack de Bruijn