

## **OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT COMMUNITY ROLLING ACTION PLAN (CoRAP) ADDITION FOLLOWING ARTICLE 45(5) NOTIFICATION**

**Adopted on 13 June 2013**

### **Introduction**

According to Article 44 of Regulation (EC) No 1907/2006 (REACH) the Agency shall compile a draft Community Rolling Action Plan (CoRAP) for three years based on prioritising criteria of Article 44(1) that are further developed in cooperation with the Member States (MSs). The Member State Committee (MSC) shall provide an opinion on ECHA's draft CoRAP.

The relevant Article 44 (2) states:

"[...] The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 76(1)(e) (hereinafter referred to as "the Member State Committee") and shall publish the plan on its website, identifying the MS who will carry out the evaluation of the substances listed therein as determined according to Article 45."

Moreover, Article 45(5) states:

A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. The Agency shall decide whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member State Committee. If the substance is added to the Community rolling action plan, the proposing Member State, or another Member State who agrees, shall evaluate that substance.

### 2012 CoRAP selection criteria:

According to Article 44(1) the Agency shall develop in cooperation with the MSs criteria for prioritising substances for substance evaluation (SEv). Prioritisation shall follow a risk based approach. Article 44(1a-c) further defines these criteria.

For the first draft CoRAP annual update for years 2013-2015, the same selection criteria were applied as for the first draft CoRAP.

Also for any proposed additions to the CoRAP following priority Article 45(5) notifications in 2013, the same selection criteria are applied.

More detail on the selection criteria to prioritise substances for Substance Evaluation can be found on the ECHA website on:

[http://www.echa.europa.eu/documents/10162/17221/background\\_doc\\_criteria\\_ed\\_32\\_2011\\_en.pdf](http://www.echa.europa.eu/documents/10162/17221/background_doc_criteria_ed_32_2011_en.pdf).

#### Article 45(5) notification:

A request from Germany was received on 10 May 2013 by ECHA in accordance with Article 45(5) to add *1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives* to the CoRAP. The proposal for this candidate CoRAP substance included a justification document and an indication that the processing of the request should follow an urgent process. The German CA clarified that they started preparing an Annex XV dossier for identification of *1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives* as a substance of very high concern. However, in January 2013 the registrant submitted new information which now questions current P and B assessment. Thus the German CA considers a substance evaluation of this substance necessary to verify whether these data may change the PBT assessment and to gain additional data, if required, for completing the assessment. The evaluation year is indicated as 2013, and Germany is intending to carry out the evaluation.

### **Process for adoption of the opinion on the draft CoRAP addition**

At its 25<sup>th</sup> meeting (19-21 September 2012) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of 7 MSC members, alternates and experts) in order to develop an opinion on the draft CoRAP annual update for years 2013-2015 and any Article 45(5) notifications received within the year following this appointment.

On 14 May 2013 the Article 45(5) notification, including one substance with justification was provided to the MSC.

For the preparation of its opinion the Committee used the following documents:

- Background document to the decision of the Executive Director of ECHA, ED/32/2011, Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria)
- The Article 45(5) notification by Germany with justification document for the proposed substance
- Annex to ECHA's draft CoRAP addition following Article 45(5) notification

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 31 May 2013. This draft opinion and explanatory annex were discussed and agreed at the 30<sup>th</sup> MSC meeting on 11-14 June 2013.

### **The CoRAP addition following Article 45(5) notification**

The MSC used the Article 45(5) notification with the justification document as a basis to express its opinion on *1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives*.

The Annex to the draft CoRAP addition following Article 45(5) notification on *1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives* consists of the following information for the substance to be evaluated:

1. Year of evaluation
2. Evaluating MS
3. EC number

4. CAS number
5. Substance name
6. Initial grounds for concern
7. The legal basis of the inclusion (Art. 44(1) or 45(5) REACH)
8. Whether it is a new or an old entry
9. The Member State contact details
10. The tonnage band as disseminated on the ECHA website
11. Selection criteria met for the substance<sup>1</sup>
12. Statement if the grounds of concern match with the rationale in the Justification Document
13. Conclusion of the MSC on the application of the selection criteria

The MSC assessed the following questions for the substance notified under Article 45(5):

- Does the ground of concern given in the draft CoRAP match with the justification given in the justification document<sup>2</sup>?
- Does the concern given in the justification document fulfil the selection criteria agreed on and which of the selection criteria are fulfilled?
- Does the justification document describe a risk based concern?

The MSC used the documents listed under the previous section. The Article 45(5) notification with the justification document were assessed based on the above mentioned questions.

The MSC checked the justification document and verified which of the agreed selection criteria were met based on the full content of the justification document (not only on the 'grounds for concern' part of the document).

Since for this substance a priority Article 45(5) based addition was chosen as legal basis, it was examined if the justification document sufficiently describes a risk based approach. If the selection criteria are fulfilled and/or a risk based concern is described, the MSC supports the addition of the substance into the CoRAP.

## **MSC Opinion on the CoRAP addition following Article 45(5) notification**

The MSC is of the opinion that there are sufficient grounds for considering that *1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives* might constitute a risk to the environment.

*Therefore, the MSC supports the addition of 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives to the CoRAP following the Article 45(5) notification and appreciates that the substance shall be evaluated by Germany in 2013.*

### **Annex**

Table of the notified substance including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria.

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<sup>1</sup> Based on the document „Selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria)“; all selection criteria identified in the justification document were listed here.

<sup>2</sup> The document „Justification for the selection of a candidate CoRAP substance“ prepared by the Member State planning to evaluate the substance