OPINION OF THE MEMBER STATE COMMITTEE ON THE FIRST DRAFT COMMUNITY ROLLING ACTION PLAN (CoRAP)

Adopted on 9 February 2012

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 (MS). 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."

For this first draft CoRAP, Article 44(2) of REACH states that the Agency shall submit the first draft CoRAP to the MSs by 1 December 2011 and draft annual updates by 28 February each year (Details of the process timelines can be seen in Section 1 below).

2011 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.

In October 2010 ECHA organised a Workshop on Prioritisation Criteria for Dossier and Substance Evaluation and presented a proposal for the selection criteria for substance evaluation, which were discussed with the MSs. Based on this discussion and comments received from the MSs, the criteria were further refined and adopted in May 2011.

While developing for the first time the CoRAP criteria, ECHA followed the risk-based approach listed in Article 44(1) of REACH and took into account the following principles:

1. Refinement of the three general criteria; i.e. hazard, exposure and risk characteristics,
2. Ability to detect the substances of greatest concern,

3. Ability to search of specific criteria in registration dossiers, and
4. The expected outcome of substance evaluation i.e. a decision to request further information but also go beyond standard information requirement of Annexes VII to X to the REACH Regulation and the relevance to other REACH or Community level processes.

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.

Draft CoRAP:

Based on the agreed selection criteria, ECHA and the MSs proposed substances that could be included in the CoRAP. MSs proposed substances also based on other specific risk-based concerns. Substances for which the MSs indicated an interest for evaluation were then included in the draft CoRAP which was submitted 20 October 2011 to the MSs. At the same time, the draft CoRAP was submitted also to the MSC for opinion.

The procedure foreseen in Article 45(3) of REACH was not triggered for the first draft CoRAP.

1. Process for adoption of the opinion

At its 19th meeting (20-23 September 2011) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of six MSC members, alternates and experts) in order to develop an opinion on the first draft CoRAP.

On 20 October 2011 the draft CoRAP, including 91 substances with justifications was submitted to the MSs and to the MSC and a non-confidential version of the draft CoRAP was published on the ECHA homepage. The first draft CoRAP was then introduced to the Committee in its 20th meeting (2-4 November 2011), where the Committee provided its first comments and consequently the CoRAP working group distributed the 91 substances among themselves for further scrutiny.

For the preparation of its opinion the Committee has been provided with 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)
- ECHA's draft CoRAP (confidential version) dated 20 October 2011
- Justification documents on each substance suggested for evaluation.

The Rapporteur provided a draft for the opinion to the MSC on 25 November 2011. The opinion was finalised and adopted by the Committee on 9 February 2012 after discussion at the 22nd meeting of the MSC. It was also agreed that the publication of the first CoRAP and the MSC opinion would take place on 29 February 2012.

The draft CoRAP and focus of the opinion

The MSC used the confidential draft CoRAP as a basis to express its opinion on the single substances.

The confidential draft CoRAP table was extended in order to provide for every substance information i.a. on the initial concern and to express for every substance the MSC conclusion if it should be selected for substance evaluation. This information is presented in an Annex to this opinion.

The Annex consists of a list of the substances to be evaluated for every year in the next three years (2012-2014). The following information is specified for each of the substances:

1. Substance name
2. EC number
3. CAS number
4. Evaluating MS
5. Initial grounds for concern
6. The legal basis of the inclusion (Art. 44(1) or 45(5) REACH)
7. Selection criteria met for the substance[1]
8. Statement if the grounds of concern match with the rationale in the Justification Document
9. Conclusion of the MSC on the application of the selection criteria

The MSC assessed the following questions for each substance on the draft CoRAP:

- Does the ground of concern given in the draft CoRAP match with the justification given in the justification document[2]?
- Does the concern given in the justification document fulfil the selection criteria agreed on?
- If Art. 45(5) is used as legal basis to propose the substance, does the justification document describe a risk based concern?

The MSC used the documents listed in Section 1. The justification documents and the draft CoRAP were assessed based on the above mentioned questions.

The MSC checked the justification documents and analysed which of the agreed selection criteria are met for each substance.

[1] Based on the document „Selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria)"; only criteria that refer to the identified concern are listed here.

[2] The document „Justification for the selection of a candidate CoRAP substance" prepared by the Member State planning to evaluate the substance

Finally, the MSC verified whether the grounds for concern for the individual substances meet the selection criteria agreed on. For substances where Article 45(5) 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 inclusion of the substance into the CoRAP.

3. MSC Opinion on the draft CoRAP

For all substances on the draft CoRAP the MSC is of the opinion that there are sufficient grounds for considering that the substance might constitute a risk to human health and/or the environment.

Therefore, the MSC supports the draft CoRAP and appreciates that all the substances included, shall be evaluated by the MSCAs in the next three years. However, the MSC also acknowledges that for one substance, based on new information from the MS originally proposing the substance, substance evaluation is not considered necessary anymore[3]*.*

Annex

Table of substances on the draft CoRAP including criteria used for the proposal (grounds for concern), legal basis and conclusion of MSC on application of prioritisation criteria.

[3] *The MS that proposed 1,1-bis(tertbutyldioxy)-3,3,5-trimethylcyclohexane (EC No. 229-782-3, CAS No. 6731-36-8) and was foreseen as evaluating MS for this substance meanwhile – after further consideration – concluded that a final evaluation of the risk can already be taken on the basis of the available information. Therefore, the MS does not consider substance evaluation as a necessary step and therefore proposed to remove the substance from this draft CoRAP.*