

**OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT
COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL
UPDATE FOR THE YEARS 2014-2016
ADOPTED ON 6 FEBRUARY 2014**

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 Member State who will carry out the evaluation of the substances listed therein as determined according to Article 45."

For the draft annual updates to the CoRAP, Article 44(2) of REACH states:

"[...] the Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year."

(Details of the process timelines can be seen in the section below).

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 this second draft CoRAP annual update for years 2014-2016, the same selection criteria were applied as for the first draft CoRAP and its first annual update.

More details 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.

Second draft CoRAP update for years 2014-2016:

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 update for years 2014-2016 which was submitted on 24 October 2013 to the MSs. At the same time, the draft CoRAP update for years 2014-2016 was submitted also to the MSC for opinion.

The procedure foreseen in Article 45(3) of REACH (more than one MS having expressed an interest in evaluating the same substance) was not triggered for the draft CoRAP update for the years 2014-2016.

Process for adoption of the opinion

At its 31st meeting (25-27 September 2013) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of 10 MSC members, alternates and experts) in order to develop an opinion on the draft CoRAP annual update for the years 2014-2016.

On 24 October 2013 the draft CoRAP update for years 2014-2016, including 125 substances with justifications, was submitted to the MSs and to the MSC and a non-confidential version of the draft CoRAP update was published on the ECHA homepage. The second draft CoRAP update for the years 2014-2016 was then introduced to the Committee in its 32nd meeting (4-8 November 2013), where the Committee provided its first comments. Consequently, the CoRAP working group distributed the 56 new substances among themselves for further scrutiny and, where needed, requested information from the relevant MSs on changes for the 69 substances already included in the CoRAP as adopted in February 2013.

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 update for the years 2014-2016 (confidential version), dated 24 October 2013
- Justification documents (JD) on each substance suggested for evaluation

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 29 November. This draft opinion and explanatory annex were discussed at the 33rd MSC meeting on 10-13 December 2013. It was decided that the MSC members could further comment on the documents until 7 January 2014. An updated draft opinion, taking into account comments and JD updates received from the MSC members and the MS, was provided by the Rapporteur to the MSC on 23 January 2014 for discussion/adoption at the 34th MSC meeting (3-7 February 2014). On 5 February 2013 the document was discussed at the 34th MSC meeting and some late changes were introduced. The rapporteur presented an updated version on 6 February 2013 which was adopted by the MSC.

The draft CoRAP update for years 2014-2016 and focus of the opinion

1. Old CoRAP entries

The MSC used the previous MSC opinion on the final CoRAP update adopted in February 2013 and the input from MSs to express its opinion on the substances already on the CoRAP as adopted in February 2013.

The MSC notes that for Gallium arsenide substance evaluation is currently not considered necessary anymore by the MSs originally proposing the substances. Therefore, this substance is no longer included in the CoRAP for years 2014-2016.

The MSC notes that some changes were made in years of evaluation and for the MS conducting the evaluation (eMS).

The respective JDs were updated for several substances already on the CoRAP as adopted in February 2013. The updated JDs were assessed with the selection criteria as explained above and it was concluded that the changes made do not affect the general conclusion to support their inclusion in the CoRAP. Remarks for single substances were included in the relevant column of the Annex to Opinion.

For all other substances, there were no indications on the need to re-evaluate the JDs for the substances already on the CoRAP as adopted in February 2013 to decide on the appropriateness of the inclusion of the substance in the updated CoRAP.

2. New CoRAP entries

The MSC used the confidential draft CoRAP update for the years 2014-2016 and the JDs as a basis to express its opinion on the single substances.

The confidential draft CoRAP update table was extended in order to provide information for every substance inter alia on the tonnage band, the reflection of the MSs' justification for the selection as indicated in the JDs (selection criteria met, initial grounds of concern) and to express the MSC conclusion for every substance on whether or not the substance 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 (2014-2016). The following information is specified for each of the substances:

1. Expected evaluation year
2. Evaluating MS
3. EC number
4. CAS number
5. Substance name
6. Initial grounds of concern
7. Legal basis for the proposal (Art. 44 or 45 REACH)
8. Member State contact details
9. Status (whether it is a new or an old entry)
10. Tonnage band (as indicated in JD)

11. Selection criteria met for the substance¹
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 each substance on the draft CoRAP:

- Does the ground of concern given in the draft CoRAP update match with the justification stated in the JD²?
- Does the concern given in the JD fulfil the selection criteria agreed on and which of the selection criteria are fulfilled?
- If Article 45(5) is used as legal basis to propose the substance, does the JD describe a risk based concern?
- Are there any other relevant inconsistencies between the JD and the draft CoRAP update?

The MSC used the documents listed in Section 1. The JDs and the draft CoRAP update for years 2014-2016 were assessed based on the above mentioned questions.

The MSC checked the JDs for each of the new entries and verified which of the agreed selection criteria were met based on the full content of the JD. Remarks for single substances were included in the relevant column of the Annex to Opinion.

MSC Opinion on the draft CoRAP update for years 2014-2016

The MSC acknowledges that the substance trixylyl phosphate has been added to the draft CoRAP update for years 2014-2016 compared to the version sent to the MSs and MSC on 24 October 2013.

The MSC acknowledges that for the substances 3,4,5,6,7,8,9,10,11,12,13,14-dodecahydro-2H-cyclododeca[b]pyran and yellow pigment additive present on the draft CoRAP update for years 2014-2016 sent to the MSs and MSC on 24 October 2013, substance evaluation is currently not considered necessary anymore by the MSs originally proposing the substances. Therefore, these substances are no longer included in the CoRAP update for years 2014-2016. After discussion in MSC-34, also the substances 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran (HHCB) and 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one were removed from the CoRAP update for years 2014-2016.

For all other substances on the draft CoRAP update for the years 2014-2016 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.

Some substances proposed for CoRAP were evaluated under the previous legislation (shale oil bitumen; naphthalene; potassium titanium oxide (K₂Ti₆O₁₃); 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol; 4-tert-butylphenol; 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-

¹ Based on the document „Selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria)“; all selection criteria identified in the JD were listed here even if they are not reflected in the initial grounds of concern.

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

2-naphthyl)ethan-1-one; S-(tricyclo[5.2.1.0 2,6]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl)phosphorodithioate; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran; Phenol, styrenated; and Reaction mass of 2,4,6-tris(1-phenyl-ethyl)phenol and Bis(1-phenylethyl) phenol). The MSC acknowledges that for each of them sufficient justification for a re-evaluation was given in the JDs.

The MSC also acknowledges some changes made with regard to the year of evaluation and also with regard to the eMS. Most changes were already introduced in the draft CoRAP update for years 2014-2016 sent to the MSs and MSC on 24 October 2013. However, some changes with regards to the issues mentioned above were also introduced later on in the process. For titanium dioxide, the year of evaluation changed from 2014 to 2015. For ethyl 3,5-dichloro-4-hexadecyloxybenzoate the year of evaluation changed from 2015 to 2016. For four substances the eMSs have changed: 2,2',2''-nitrilotriethanol and 2-aminoethanol, will be evaluated by UK instead of PL and 2-ethylhexan-1-ol and dimethyl glutarate will be evaluated by PL instead of UK.

The substances aluminium chloride and aluminium chloride, basic were originally covered by one JD and included in one entry in the draft CoRAP update for years 2014-2016 sent to the MSs and MSC on 24 October 2013. The MSC acknowledges that the Member State proposing these substances meanwhile provided two separate JDs and that these substances are now included with two separate entries in the draft CoRAP update for years 2014-2016. For both separate entries, there are sufficient grounds for considering that the substances might constitute a risk to human health.

The MSC notes for quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides that the exposure-based criteria are fulfilled but none of the hazard-based criteria of the "2011 CoRAP selection criteria". However, the MSC acknowledges that the classification as Aquatic Toxicity Chronic, class 1 (as well as Aquatic Toxicity Acute, class 1) and the persistency in soil in combination with the potential exposure of the environment form a risk-based concern that justifies the selection of the substance for substance evaluation.

The MSC notes for potassium titanium oxide (K₂Ti₆O₁₃) that "Exposure of workers" is identified as initial ground of concern in Chapter 4.3 of the JD but only hazard-based criteria are selected in Chapter 4.2 of the JD; although uses with potential for exposure of workers are included in the registration. However, the available information is not considered sufficient by the eMS to conclude on the fulfilment of the exposure-based selection criterion. Nevertheless, the selection of the substance can be considered to be risk-based.

Also, for tris(methylphenyl) phosphate, the MSC notes that as a consequence of a compliance check decision, the registrant may in future need to change the identifier of the substance.

Therefore, the MSC, based on the outcome of the assessment of the justification documents with the selection criteria as explained above, supports the draft CoRAP update for the years 2014-2016 and agrees that all the substances included shall be evaluated by the MSCAs in the next three years under the condition that the above mentioned points are clarified.

Annex

Table of substances on the draft CoRAP update for years 2014-2016 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria