

**OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT  
COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL  
UPDATE FOR THE YEARS 2017-2019  
ADOPTED ON 8 FEBRUARY 2017**

**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 update, and the Agency shall adopt the final CoRAP update on the basis of this opinion.

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 draft CoRAP annual update for 2017-2019, the same selection criteria were applied as for the previous years.

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](http://www.echa.europa.eu/documents/10162/17221/background_doc_criteria_ed_32_2011_en.pdf).

Draft CoRAP update for the years 2017-2019:

Based on the agreed selection criteria and a screening process, ECHA and the MSs proposed substances that could be included in the CoRAP. MSs also proposed substances that were not included in the 2016 screening process. Substances for which the MSs indicated an interest for evaluation were then included in the draft CoRAP update for 2017-2019 which was submitted on 13 October 2016 to the MSs. At the same time, the draft CoRAP update for years 2017-2019 was submitted also to the MSC for their opinion. In this draft CoRAP update 22 new substances were included, 12 came from the 2016 screening process, 4 were screened but not chosen in 2015, and 6 other new entries were notified or added by MSs. One of these substances was withdrawn from the list submitted to MSC on 30 November 2016, resulting in 21 new substances in the first draft Opinion Annex. With the new entry from France, there are 22 new entries in the draft CoRAP update for 2017-2019

The procedure foreseen in Article 45(3) of REACH (no agreement when more than one MS having expressed an interest in evaluating the same substance) was not triggered for the draft CoRAP update for the years 2017-2019.

## **Process for adoption of the opinion**

At its 49<sup>th</sup> meeting (13 September 2016) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of 9 MSC members and experts) in order to develop an opinion on the draft CoRAP annual update for the years 2017-2019.

On 13 October 2016 the draft CoRAP update for 2017-2019, including 117 substances with justifications, was submitted to the MSs and to the MSC. A non-confidential version of the draft CoRAP update was published 27 October 2016 on the ECHA homepage. The draft CoRAP update for 2017-2019 was then introduced to the Committee in its 50<sup>th</sup> meeting (25-27 October 2016), so the Committee could provide its first comments. Consequently, the CoRAP working group distributed among themselves for further scrutiny the 22 substances that are new additions to the draft CoRAP and four substances with updated justification documents that are already in CoRAP.

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 2017-2019 (confidential version), dated 13 October 2016
- Justification documents (JD) on each substance suggested for evaluation

The Rapporteur provided a first draft opinion with explanatory annex to the MSC on 30 November. In this draft 115 substances, 21 new and 94 existing, were included. Two substances (one new and one existing) were removed from the list in agreement with the relevant evaluating MS. This draft opinion and explanatory annex were discussed at the 51<sup>st</sup> MSC meeting on 12-16 December 2016. It was decided that the MSC members could further comment on the documents until 12 January 2017. No specific MSC comments were given. One new notification of substance was received after the 51<sup>st</sup> MSC meeting. An updated draft opinion with Annex with 116 substances was provided by the Rapporteur to the MSC on 25 January 2017, changed according to agreements with MSs or as results of justification documents being updated by MSs (by own initiative or after requests from the WG or ECHA). The documents were discussed at the 52<sup>nd</sup> MSC meeting (7-9 February 2017) and some late changes introduced. The amended opinion was adopted by the MSC on 8 February 2017.

## **The draft CoRAP update for years 2017-2019 and focus of the opinion**

### *1. Existing CoRAP entries*

The MSC used the previous MSC opinion on the final CoRAP update adopted in February 2016 and any new input from MSs to express its opinion on the substances already on the CoRAP update as adopted in March 2016.

Prior to the referral of the draft CoRAP update 2017-2019 to MSC the following changes took place to some of the existing CoRAP entries. The JDs were updated for four substances already on the CoRAP as adopted in March 2016. The changes cover adding and/or deleting some part(s) of the initial grounds of concern and amending the justification. 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. The changes for single substances were included in the relevant column of the Annex to the Opinion.

Four of the existing entries have been withdrawn upon justified requests of the eMSCAs. These four are glycolic acid (EC 201-180-5), 2-amino-2-methylpropanol (EC 204-709-8), o-cresol (EC 202-423-8), m-cresol (EC 203-577-9).

For the other substances already in the CoRAP as adopted in March 2016, there were no indications of changes in concern(s) or available information that should trigger the need to re-evaluate the appropriateness of the inclusion of the substance in the CoRAP update.

The MSC notes that 53 changes were made in the year of evaluation. Only one was moved to an earlier year, while the rest were postponed mainly to wait for results of ongoing compliance checks or a few for results of substance evaluation of similar substances.

Concerning the titanium dioxide entry (EC 236-675-5), which was included in the CoRAP already in 2012 for evaluation in 2014, it is proposed to maintain the evaluation year 2018 for that substance as indicated in the draft CoRAP update, because some relevant information on the substance, and in particular some information requested in a compliance check decision (due to an on-going appeal), and the opinion of RAC on the proposal for harmonised classification will, most likely only become available later on in 2017.

However, the MSC notes that the national competent authority mandated for the evaluation of the substance has clearly indicated a priority to evaluate this substance and to maintain 2017 as the evaluation year for that substance, in accordance with the 2016-2018 CoRAP, because the evaluation of the substance has been planned for a long time and because very recently new evidence of toxicity for human health has been revealed in studies.

Since it is proposed not to evaluate the substance in 2017 and considering the position expressed by the national competent authority, it is acknowledged that it is necessary to accelerate the substance evaluation process of titanium dioxide in 2018. In order to do so, sufficient resources need to be released in 2017 to enable a deep analysis of all new elements available for titanium dioxide and adequately prepare the evaluation of the substance in 2018. For this purpose, the n-butyltin trichloride entry (EC 214-263-6), initially scheduled for 2017, is also postponed to 2018.

In addition to the above, bis(2-ethylhexyl)amine (EC 203-372-4) has been withdrawn after the referral of the draft CoRAP update 2017-2019. 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-nortall-oil alkyl derivs. (EC 263-171-2) was removed early February.

## 2. New CoRAP entries

The MSC used the confidential draft CoRAP update for the years 2017-2019 and the justification documents as a basis to express its opinion on the single (new) substances.

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 justification document<sup>1</sup>?

---

<sup>1</sup> The document „Justification for the selection of a candidate CoRAP substance“ prepared by the Member State planning to evaluate the substance

- Does the concern given in the justification document 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 justification document describe a risk based concern?
- Are there any other relevant inconsistencies between the justification document and the draft CoRAP update?

The MSC checked the justification documents for each of the new entries and verified which of the agreed selection criteria were met based on the full content of the justification documents. The confidential draft CoRAP update table was extended in order to provide information for every substance on which selection criteria are met and whether the initial grounds for concern match with the MSs' rationale in the justification documents. It also includes the MSC conclusion for every substance on whether or not the substance should be selected for substance evaluation. The information is presented in the Annex to this opinion.

The Annex consists of a list of the substances to be evaluated for every year in the next three years (2017-2019). The following information is specified for each of the substances:

1. Expected evaluation year
2. Whether year of evaluation has changed (existing entries)
3. Evaluating MS
4. EC number
5. CAS number
6. Substance public name
7. Initial grounds of concern
8. Member State contact details
9. Source (whether it is a new or an old entry)
10. Legal basis for the proposal (Art. 44 or 45 of REACH)
11. Tonnage band disseminated
12. Selection criteria met for the substance<sup>2</sup>
13. Statement if the grounds of concern match with the rationale in the Justification Document
14. Conclusion of the MSC on the application of the selection criteria

## **MSC Opinion on the draft CoRAP update for years 2017-2019**

For only very few substances the MSC working group were in doubt whether the exposure or risk related selection criteria were met. For about half of the new substances the justification documents needed to be updated to solve some inconsistencies or better explain the risk from the use(s) of the substances. This updating also resulted in some changes in initial concerns, either by adding and/or removing one or more concerns. One new substance included in the published draft CoRAP, benzoic acid (EC 200-618-2), was removed in agreement with the MS, due to ongoing compliance check. This makes it premature to decide whether the substance is a good CoRAP candidate. The results will not be ready within 2019, and the need for SEV will be re-evaluated later.

---

<sup>2</sup> 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.

One new substance, potassium permanganate (EC 231-760-3), was notified by France after MSC-51, based on Article 45(5), for evaluation in 2017. The inclusion is supported by the MSC.

One new proposed substance was evaluated under the ESR programme. The Risk Assessment Report (RAR) was concluded in 2008, and justification for re-evaluation was given.

For six new and five old entries the initial grounds of concern were changed after the referral of the draft CoRAP update to the MSC. Following these changes, the substances still met the selection criteria.

For all substances on the draft CoRAP update for the years 2017-2019 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, based on the outcome of the assessment of the justification documents with the selection criteria as explained above, the MSC supports the draft CoRAP update for the years 2017-2019 and agrees that all the substances included shall be evaluated by the MSCAs in the next three years.

## **Annex**

Table of substances on the draft CoRAP update for years 2017-2019 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria. This table reflects the changes described in this opinion.