

OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL UPDATE FOR THE YEARS 2018-2020

ADOPTED ON 8 FEBRUARY 2018

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 2018-2020, 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:

https://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf/67441c3c-75be-4ecd-992e-b90ab2041805

Draft CoRAP update for the years 2018-2020:

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 2017 screening process. Substances for which the MSs indicated an interest for evaluation were then included in the draft CoRAP update for 2018-2020 which was submitted on 12 October 2017 to the MSs. At the same time, the draft CoRAP update for years 2018-2020 was submitted also to the MSC for their opinion. In this draft CoRAP update 17 new substances were included and 2 substances were withdrawn.

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 2018-2020.

Process for adoption of the opinion

At its 55th meeting (14 September 2017) 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 2018-2020.

On 12 October 2017 the draft CoRAP update for years 2018-2020, including 108 substances with justifications, was submitted to the MSs and to the MSC. A non-confidential version of the draft CoRAP update with 107 substances was published on 24 October 2017 on the ECHA homepage as one new candidate was removed upon notification from the MS. The updated draft CoRAP update for 2018-2020 was then introduced to the Committee in its 56th meeting (24-26 October 2017), so the Committee could provide its first comments. Consequently, the CoRAP working group distributed among themselves for further scrutiny the 16 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 2018-2020 (confidential version), dated 12 October 2017
- Justification documents (JD) on each substance suggested for evaluation

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 29 November 2017. In this draft, 106 substances, 15 new and 91 existing, were included. Two substances were removed from the list on request of the evaluating MS before referral of the draft CoRAP and two new substances after referral of the draft CoRAP. This draft opinion and explanatory annex were discussed at the 57th MSC meeting on 11-15 December 2017. It was decided that the MSC members could further comment on the documents until 17 January 2018. After 29 November 2017, two new additional substances were proposed to be included in the CoRAP. After MSC-57, for 2 substances a delay in year of evaluation was also notified. No specific MSC comments were given on any of the other substances. An updated draft opinion with Annex with 108 substances was provided by the Rapporteur to the MSC on 24 January 2018, changed according to agreements in MSC-57, notifications received on the 2 new substances and delay of 2 additional substances or as result of justification documents being updated by MSs (by own initiative or after requests from the WG or ECHA). The documents were discussed at the 58th MSC meeting (6-9 February 2018) and some late changes introduced as after 24 January 2018 additional notifications were received to postpone the substance evaluations of EC 201-247-9 and EC 215-160-9 from 2018 to 2019. The (amended) opinion was adopted by the MSC on 8 February 2018.

The draft CoRAP update for years 2018-2020 and focus of the opinion

1. Existing CoRAP entries

The MSC used the previous MSC opinion on the final CoRAP update adopted in February 2017 and any new input from MSs to express its opinion on the substances already on the CoRAP update as adopted in March 2017.

Prior to the referral of the draft CoRAP update 2018-2020 to MSC the following changes took place to some of the existing CoRAP entries. The JDs were updated for four substances (EC 205-117-2, EC 701-057-0, EC 218-487-5 and EC 906-390-7) already on the CoRAP as adopted in March 2017. The changes cover adding and/or deleting some part(s) of the initial grounds of concern or a change in substance identity or tonnage band.

In addition, for Titanium dioxide (EC 236-675-5), the justification document was updated after referral of the draft CoRAP update 2018-2020 to reflect more recent information on the substance.

For 3 other substances (EC 701-160-0/EC 936-414-1, EC 701-029-8 and EC 911-815-4) the justification documents were updated after the referral of the draft CoRAP update 2018-2020 to reflect the change in substance identity. In addition, for EC 701-029-8 also the tonnage band changed and some of the initial grounds for concern were deleted.

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.

Two of the existing entries have been withdrawn upon justified requests of an eMSCA. These are N-butylbenzenesulphonamide (EC 222-823-6) and 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (EC 225-208-0).

For the other substances already in the CoRAP as adopted in March 2017, 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 49 changes were made in the year of evaluation at the time of referral of the draft CoRAP update 2018-2020. Only three were moved to an earlier year, while the rest were postponed mainly to wait for results of ongoing compliance checks/testing proposals or a few for results of substance evaluation of similar substances. In addition, after referral of the draft CoRAP update 2018-2020, Diuron tris(sulphate) (EC 233-072-9) was postponed to 2019 upon request of the eMSCA and oxydiethylene dibenzoate (EC 204-407-6) and Benzeneamine, reaction products with aniline hydrochloride and nitrobenzene (EC 309-912-6) to 2019 due to an ongoing CCH and/or grouping considerations. Moreover, on 22 January 2018, a notification was received to postpone EC 911-815-4 from 2018 to 2019 and on 29 January 2018, a notification was received to postpone EC 201-247-9 from 2018 to 2019.

2. New CoRAP entries

The MSC used the confidential draft CoRAP update for the years 2018-2020 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 document¹?
- Does the concern given in the justification document fulfil the selection criteria agreed on

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

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 (2018-2020). 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 REACH)
11. Tonnage band disseminated
12. Selection criteria met for the substance²
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 2018-2020

For some substances, the MSC working group requested updates of the justification documents mostly to solve some inconsistencies and for two substances, the year of evaluation needed to be postponed due to ongoing CCH/grouping considerations.

One new substance included in the published draft CoRAP, 2,4,6-triallyloxy-1,3,5-triazine (EC 202-936-7), was removed upon request of the evaluating Member State due to new information on the substance.

Two additional substances, Antimony trichloride (EC 233-047-2) and Diantimony tris (ethylene glycolate) (EC 249-820-2) were notified for inclusion in the CoRAP in December 2017. These substances are added to the CoRAP as part of a group of substances already present in CoRAP.

² 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.

For one of these substances, Antimony trichloride, the exposure selection criterion is not fulfilled as such, but due to the grouping approach it is considered an appropriate CoRAP candidate.

For one new substance, Chromium(III)Oxide (EC 215-160-9), the proposed year of evaluation was changed from 2018 to 2019.

For all substances on the draft CoRAP update for the years 2018-2020 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.

Due to ongoing compliance checks (CCH) and testing proposal examinations (TPE) however, evaluations may be postponed later or may not be needed due to the results of the CCH/TPE.

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 2018-2020 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 2018-2020 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.