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32nd Meeting of Competent Authorities for REACH and CLP

6-7 November 2019

Concerns:	**Revision of completeness check**
Agenda Point:	**Point 9.2**
Action requested:	**Member State Competent Authorities and observers are invited to discuss the planned revision of the completeness check process to include the verification of the chemical safety report.**

This paper informs the REACH and CLP Competent Authorities of ECHA's proposal to revise the completeness check following the strategic priorities outlined in its Multiannual work programme.

1. Introduction

The completeness check implements ECHA's obligation under Article 20(2) to check that all the required elements have been provided in a REACH registration dossier. Each registration dossier must pass the completeness check before a registration number can be issued, or in the case of an update of a registration, before the new information can be associated with the registration.

After acquiring experience with the two first registration phases, ECHA undertook a revision of the completeness check in 2016. The revision, which was presented to the CARACAL meetings 15/2014 and 17/2015, encompassed the update of the completeness check rules to the new IUCLID formats and regulatory developments[1], and implemented improvements to checks where experience had shown that the prevailing rules did not fulfil their aim to ensure that the required elements were provided. In addition, the revision resulted in the enhancement of the completeness check with a manual verification component: information that does not lend itself well to computerised checks, such as free-format justifications, is verified by ECHA staff.

ECHA recently reviewed the impact of the 2016 completeness check revision and observed positive results, in particular related to the manual verification aspect. In most cases, the manual checks of substance identification information clearly improved the understanding of the substance identity and reduced the need for clarification via other processes. In the area of data waiving of Annex VII-X information requirements, manual checks resulted in that a significant amount of studies and testing proposals were submitted to replace incomplete waiving approaches, in particular in the human health endpoints.

After the final registration phase, ECHA has taken a new look to the completeness check in view of the strategic priorities of its Multiannual programme[2]. The review suggests that the current completeness check implementation does not fully ensure that all the elements required are present in the dossier and that it could be improved to better support ECHA's integrated regulatory strategy through two routes: by improving the starting point for the evaluation of hazard information and by addressing the shortcomings in use and exposure information already at the completeness check level, as presented at CARACAL 29/2019[3].

We note here that this document does not cover the specific revision of the completeness check that was undertaken this year to implement the new REACH requirements for nanomaterials[4].

2. Proposed revisions

Based on the above, the revision is focussed on the two following work streams:

1. Ensure that the standard information requirements under REACH Articles VII-X have been met through implementing more explicit completeness check rules on the key endpoints.

[1] Such as, the streamlining of the OECD harmonised templates for physical hazards with the GHS and the CLP Regulation; the harmonisation at the OECD level of the formats for use and exposure information; the development of the information requirements on reproductive toxicity.
[2] https://echa.europa.eu/documents/10162/13609/programming_document_2019-2022_en.pdf
[3] ECHA presented the document "Use and Exposure Information in the Regulatory Strategy" (CACS/03/2019) in the closed session on 19 March 2019.
[4] Please refer to agenda point 4.1 of the open session: "Update of ECHA preparedness for the implementation of the amendments of the REACH Annexes for nanoforms".

2. Strengthen the completeness check of the substance life cycle reporting and extend the completeness check to the chemical safety report.

2.1 Improving the completeness check of the key endpoints

Analysis of the current completeness check implementation on the key endpoints[5] revealed that the current rules do not sufficiently well ensure that the registrants have addressed the specific information requirements in the relevant Annex. The following improvement needs were identified:

- Mutagenicity
  - 8.4.1: The endpoint *in vitro gene mutation study in bacteria* is addressed (Annex VII and above).
  - 8.4.2: At least one of the endpoints *in vitro cytogenicity study in mammalian cells* or *in vitro micronucleus study* is addressed (Annex VIII and above).
  - 8.4.3: The endpoint *in vitro gene mutation study in mammalian cells* is addressed (Annex VIII and above). The requirement can be addressed with a standard waiver if there are no negative results in the studies required by 8.4.1 and 8.4.2.
  - 8.4: At least one endpoint for *in vivo genotoxicity* is addressed in case of a positive result in any of the genotoxicity studies required by 8.4.1, 8.4.2 and 8.4.1 (Annex VIII and above).

- Reproductive toxicity
  - 8.7: Data waiving of the reproductive toxicity endpoints must follow the appropriate Annex provisions.
  - 8.7.2: The endpoint *developmental toxicity* must be addressed with a different species than at Annex IX (Annex X).

- Degradation
  - 9.2.1.2/9.2.1.4: The endpoints *simulation testing on ultimate degradation in surface water* and *sediment simulation testing* must be addressed by separate records in the dossier (Annex IX and above).
  - 9.2.3: The endpoint *identification of degradation products* must be more explicitly addressed (Annex IX and above).

The changes listed above will all take place by modification of the computer-based completeness check rules, and will be included in the IUCLID Validation assistant tool that is also available to registrants to be able to verify the completeness of their dossiers ahead of the submission.

2.2 Enhancing the completeness check of the use and exposure information

Use and exposure information is critical as input to many regulatory processes, and is the basis for the risk management measures put in place by companies and communicated in the supply chain. Moreover, correct and complete use information provides significant added value to dissemination. As outlined in the document presented to the CARACAL meeting 29/2019[3] , ECHA proposes to limit requests on exposure information under dossier and substance evaluation. In parallel, it has

[5] https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

started to explore tools which are better suited to obtain this information. One of these tools is the completeness check, which is performed on all registration dossiers submitted to ECHA.

The provision of a chemical safety report is required for registrations above 10 tonnes per year. The current completeness check ensures that registrants have provided a document declared as a chemical safety report, or provided a justification falling under Article 14(2) to explain why the safety assessment was not necessary to perform. To better fulfil its obligation under Article 20(2), and to support ECHA's regulatory strategy, ECHA plans to verify that the requirement to submit a complete CSR is met as part of the completeness check.

The chemical safety report is provided to ECHA in the form of a text document attached to the IUCLID dossier. The absence of a defined data format means that the information cannot be verified by computerised completeness check rules. ECHA plans therefore to manually verify that the CSR contains the required elements. The verification will contain the following items:

- All substances classified as hazardous or with PBT properties[6] must have a chemical safety report with exposure assessment and risk characterisation.

- All uses reported in the IUCLID dossier must have corresponding exposure scenarios in the chemical safety report.

- Each exposure scenario must contain contributing scenarios corresponding to the contributing activities (and the assigned process categories and environmental release categories) reported in the IUCLID dossier.

- Each contributing scenario must contain: operational conditions and risk management measures, emission estimates (for environment) exposure estimates, risk characterisation ratios, corresponding to the hazards identified.

- If elements are missing the presence of a justification that is relevant for its purpose is checked.

It is noted here that the foreseen manual checks on the chemical safety report information do not include a check of the adequacy of the information and will thereby stay within the limits of completeness checks under Article 20. For example, the checks will not assess whether the proposed operational conditions and risk management measures are appropriate for the substance, but they will verify that the expected information is provided in the dossier. ECHA's experience with the manual verification at completeness check suggests that most registrants tend to amend incomplete elements by providing information that goes beyond merely passing the completeness check.

In addition to the manual checks on the chemical safety report, ECHA also foresees to strengthen the computerised check of the completeness of the substance life cycle. In particular, the planned improvements aim to detect cases where the article service life has been omitted from the registration dossier, although the descriptions of the uses and the technical function of the substance clearly indicate that the substance is incorporated into an article.

3. Implementation

[6] This refers to registrants' self-classification and own PBT assessment.

The revised completeness check is planned to be implemented with the IUCLID release of April 2020. It will apply equally to existing and new registrations. This means that a dossier that was successfully submitted under the previous completeness check may no longer pass the revised completeness check with the same information. However, as with the previous revision in 2016, the implementation does not prejudice acquired rights of registrants (e.g. right to manufacture/import the substance) as failure to update does not lead to the revocation of the registration number.

We note here that the implementation approach is the same that was adopted for the completeness check revision in 2016. The approach was analysed and discussed for the previous revision, and it was then concluded that in addition to ensuring equal treatment of registrants, this was the only approach that would enable clear communication on the expected content of a complete dossier.

4. Support

ECHA recognises the implications of modifying the completeness check and foresees to support industry through different channels to mitigate unwanted impact in the registration process. Several initiatives are foreseen between now and May 2020, including awareness raising and the update of existing manuals and support materials. More targeted advice will be provided via a dedicated webinar in early 2020, which will also be made available as a recording for registrants to consult when preparing their dossiers. In addition, companies can approach ECHA's completeness check experts for case-specific support via the contact form[7]. ECHA already followed this approach in the previous revision of the completeness checks in 2016 and no substantial increase in the completeness check rejection rate was observed.

For the enhancement of the computerised completeness check on key endpoints (see chapter 2.1), an important piece of support will be the IUCLID Validation assistant. The updated tool will be published as part of the April 2020 IUCLID release, and allows companies to detect failures in the computer-based rules before submitting their dossiers to ECHA.

For the manual verification of the completeness of the chemical safety report, the IUCLID Validation assistant will not be able to indicate completeness issues to registrants. For this area, the need for support depends on the methodology and tools that companies have used to perform the safety assessment and prepare the report. Companies that have used the Chesar software[8] and followed its default workflow can expect that their chemical safety reports contain all the required elements under REACH, and thereby would pass the completeness check. The tool is nowadays widely used by the registrant community and is therefore expected to effectively limit the need for support following the completeness check update.

Registrants using other approaches/tools for preparing their chemical safety reports, will have support available in the form of an update of the manual verification document[9] with advice concerning this area, as well as the above-mentioned webinar.

[7] https://echa.europa.eu/contact
[8] This statement assumes that the tool has been used according to instructions and for the entire chemical safety assessment as opposed to parts of it.
[9] The document, which is regularly updated with new advice related to the manual verification at completeness check, is available on ECHA's website, next to the manual for preparing registration and PPORD dossiers: https://echa.europa.eu/manuals

In summary, ECHA is committed to supporting companies in addressing the areas of the completeness check revision and preparing successful submissions of their registrations.

5. Conclusions

Following the strategic priorities in its Multiannual programming, ECHA has reviewed the current completeness check implementation and proposes two types of improvements: more specific computerised rules to ensure that registrants have addressed the specific information requirements in key hazard endpoints, and an extension of the completeness check to the use and exposure information in the chemical safety report.

Ensuring that the information in registration dossiers is clear, consistent and understandable by all relevant parties will contribute to safer use of chemicals: substances of concern are more easily identified and management of risks arising from the use of such substances is properly communicated throughout the supply chain. Furthermore, through dissemination this will help increasing the public confidence in the operation of REACH. ECHA has prepared a plan to raise awareness and to support companies in adapting to the revised completeness check to minimise any unwanted impact on registrants.