

Update on the collaborative approach (COLLA) pilot projects and their review

50th Meeting of the Management Board 20-21 June 2018

Key messages

Addressing substances in groups, intensifying collaboration between authorities and initiating early interaction with registrants when addressing the groups can all be seen as useful elements during the manual screening stage of the regulatory strategy.

After consultation of the REACH Competent Authorities (CARACAL) (document expected to be available at the time of the Management Board June meeting), the Secretariat will conclude whether and how the learnings could be reflected in the SPD 2019-2021, which the Management Board is invited to discuss and adopt at its meeting in September.

Background

At its 44th meeting in December 2016, the Management Board discussed, in the context of adoption of the SPD 2017-2019, the proposed new initiative on piloting a collaborative approach with Member States and industry for improving the quality of REACH registration dossiers (see the minutes of the meeting and Annex 4 of document AP 5.1 – MB/43/2016 – Single Programming document 2017-2019). Whilst the specific references to the pilots were removed from the SPD, the Management Board found merit in a number of elements of the collaborative approach. In particular, *“the collaboration between ECHA, industry, and Member States to improve compliance and addressing groups of substances found support. These elements were identified as valuable additional means of improving the quality and compliance of existing registrations. It was further noted that the proposed pilot project would fit within the Integrated Regulatory Strategy”*¹. The concerns raised in relation to the implementation of the proposed project were agreed to be further discussed by the Working Group on Planning and Reporting and the proposal was also submitted to the competent authorities for REACH and CLP (CARACAL).

As outlined in the document referred to above presented to the Management Board in December 2016, the pilots were initiated in March 2017 after several Member States had volunteered for the project and identified groups of substances to work on. Altogether five pilots were conducted and brought to closure after 12 months, in March 2018. As planned, the Secretariat conducted an ‘ex post’ review of the project and for that purpose it collected information and detailed feedback from the participants in the pilots.

A dedicated Workshop was organised 7-8 May 2018 to discuss the draft review report and draw conclusions and recommendations for the future. The conclusions were then also brought to RIME+-meeting held 14-15 May 2018 and the feedback from that meeting is being taken into account in finalising the review report and in preparing the discussion document to the June 2018 CARACAL-meeting.

¹ Minutes MB-44.

Conclusions

The collaborative approach ('COLLA') pilot projects are now finished and reviewed by the ECHA Secretariat. The Secretariat's findings and learnings are:

- The collaborative approach is an extension of the regular manual screening to cover groups of substances and an interaction with industry. The manual screening is currently performed by MSCAs in annual rounds to verify concerns on substances and to identify the best actions to address them.
- The five pilot projects helped clarifying if and how a grouping approach can be used to clarify and address the identified concerns, and what type of supporting information is required to clarify the concern and to justify the grouping. The pilots also allowed to verify the concerns that merit further action and to conclude with more informed basis and higher level of confidence what next action, if any (dossier/substance evaluation, risk management measures) is needed.
- Regarding one of the general objectives, to test out the efficiency and effectiveness of the collaborative approach, in order to see if it is worthwhile to continue or even intensify the approach from 2018 onwards, the Secretariat notes that it cannot draw firm conclusions.
 - The pilots were generally considered as providing added value in addressing the groups and they allowed action plans to be defined, including actions by the registrants, or action under dossier or substance evaluation. However, the efficiency and effectiveness of the plans could even in principle only be evaluated once the industry actions and REACH processes have been completed.
 - Furthermore, the pilots were testing two different elements, addressing substances by groups and an early interaction with registrants, and their impact on the efficiency or effectiveness would be difficult to differentiate.
 - It is noted that the resources reported being spent by ECHA and Member States authorities in the pilots were significant: in total 62 and 123 person days per group, respectively, i.e. 6.2 and 12.3 person days per substance. There is no evident point for comparison as there is yet little experience on addressing groups of substances in manual screening or interacting with industry on groups at this early phase of the process but to put the resources into perspective, ECHA recommends to use for the manual screening maximum 2 person days per substance. As another comparison, the current transfer of funds for substance evaluation is at the maximum 65 person days of work per substance.

Based on the experience of the pilots it is possible to better define what should be the scope of and objectives for early interaction with registrants at the manual screening stage of the integrated regulatory strategy. The pilots also gave insights to when and when not such early interaction could achieve the expected benefits and considerations of required resources and time.

In summary, addressing substances in groups, intensifying collaboration between authorities and initiating early interaction with registrants when addressing the groups can all be seen as useful elements. However, the ECHA Secretariat does not recommend formalising these aspects under a specific process of "collaborative approach". Instead, the Secretariat invites the MSCAs to consider the option of an early interaction at the phase of the manual screening process. The Secretariat will propose certain "best practice" recommendations on the timing, practical organisation and documentation of applying the elements. These will aim to ensure the necessary level of consistency and clear focus (both in terms of time, resources and scope) and to ensure that the expectations of all actors are clear.

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