

Forum Final Report on the Pilot Project on Intermediates

Reporting period: December 2012 – June 2013



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Reference: ECHA-13-R-10-EN

Publ.date: October 2013

Language: EN

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Executive summary

The Forum for Exchange of Information on Enforcement (The Forum) conducted a pilot project on the enforcement of intermediates. 10 Member States¹ participated in the project, which was limited to follow-up actions on ECHA's letters that had been sent out to registrants in September 2011 according to Article 36 of REACH. In these letters, ECHA had asked registrants of intermediates to provide additional information on the handling of intermediates both at the registrants' and downstream users' sites. Through an evaluation of the registrants' responses, ECHA identified 15 cases that required enforcement actions, which were then followed-up by national enforcement authorities (NEAs) in six Member States. No other participating countries received cases from ECHA.

The NEAs started enforcement actions including desktop studies and onsite visits in June 2012. Inspectors detected one case of severe non-compliance with REACH, in which the intermediate was not handled under strictly controlled conditions (SCCs). In other cases, inspectors asked registrants to update their dossiers with additional information as requested by ECHA. The participants of the project reported that, in most cases, companies were willing to cooperate with enforcement authorities and that the requested information was often available onsite.

The pilot project has been a successful first step towards the harmonised enforcement of intermediate registrations under REACH. To ensure that the correct registration and handling of intermediates remains in the focus of both industry and authorities, enforcement efforts need to continue, especially in those cases where registrants are unwilling to provide information to ECHA. Furthermore, it is recommended for inspectors to be trained in this area of REACH. Industry is called upon to act responsibly and to ensure that intermediates are handled safely.

¹ AT, BE, DE, FR, IT, NL, NO, PL, SE and UK.

A. Introduction

REACH defines an intermediate as a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. When substances used as intermediates are manufactured, transported and used under strictly controlled conditions at chemical manufacturing sites, the exposure to humans and the environment is considered to be minimised.

On this basis, REACH allows for a reduction in the information requirements for the registration of intermediates manufactured, transported and used under strictly controlled conditions as set out in Articles 17 and 18 of the REACH Regulation. These intermediates may thus be registered with limited information on the substances' hazardous properties and without a chemical safety assessment.

Substances not used in accordance with the definition of intermediates in Article 3 (15) of REACH as well as intermediates that are not manufactured and used under strictly controlled conditions during their whole lifecycle may not benefit from reduced information requirements and may have to be registered in accordance with Article 10 of REACH.

Substances registered as intermediates under strictly controlled conditions, which are not manufactured and used under strictly controlled conditions, can pose a threat to human health or the environment, as the risk to humans and the environment arising from the exposure of these substances cannot be assessed due to the lack of information on their hazards and risks in the registration dossiers.

For this reason, the Forum in close collaboration with ECHA decided to conduct a pilot project on the enforcement of intermediates.

B. Objectives and participants of the project

The objectives of the project were to:

1. Define the status quo of intermediates with regard to the Article 36 letters of the ECHA Secretariat through coordinated enforcement actions, and to
2. Collect information on the outcome of the enforcement actions and prepare a document identifying best practice.

10 Member States² participated in the project, which was conducted from October 2011 to June 2013.

² AT, BE, DE, FR, IT, NL, NO, PL, SE and UK.

C. Background information

1. Project history and background

a. Article 36 letters and assessment of registrants' responses

In the second half of 2011, the ECHA Secretariat sent out 40 letters to registrants in 14 Member States³, according to Article 36 of REACH. The letters were related to intermediate dossiers of substances with different hazard profiles, including three cases of substances of very high concern (SVHC).

In these letters, ECHA asked registrants for detailed information on the use of the substance as an intermediate, on strictly controlled conditions, and the implementation of strictly controlled conditions by downstream users. Registrants were requested to provide details on the synthesis process for manufacturing another substance, a description of the technical role of the intermediate in this process, and the chemical identity of the substance manufactured from the intermediate.

ECHA received 35 responses from registrants within the two-month deadline set in the letters. The Agency proceeded to assess these responses in its Dossier Evaluation Group (DEG) on intermediates. The group verified whether the information requested in the letters had been provided by the registrants, and it prepared conclusions on the registrants' responses.

After the evaluation, ECHA recommended follow-up actions for each individual case to the participants of the project. Out of a total of 40 cases, 19 were terminated without further action because the requested information had been provided by the registrant or the dossiers had been updated to a full standard registration according to Article 10 of REACH. In 15 cases, ECHA asked the participants of the pilot project to perform follow-up actions in the form of onsite verifications. Among those 15 registrants were nine manufacturers, four importers and two only representatives. For the remaining six cases, other follow-up actions were planned by ECHA.

b. Development of the Decision Support Document

ECHA provided the participants of the pilot project with background information on those 15 cases, for which it requested follow-up actions by the NEAs. In addition to the Article 36 letters, the information package contained a "Decision Support Document" (DSD) in the form of an evaluation template, which had been developed by ECHA in consultation with the Forum members. The DSDs included ECHA's conclusions drawn from the evaluation of the registrants' responses and listed open issues that were supposed to be inspected by enforcement authorities.

ECHA sent the DSDs to the participants of the pilot project at the end of June 2012, thus enabling them to start with follow-up actions as appropriate.

2. Legislative background

ECHA based its request for registrants to submit further information on Article 36 of REACH. According to paragraph 1 of this provision:

³ AT, BE, CY, CZ, DE, ES, FR, IR, IT, NL, PL, RO, SE and UK.

"Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation [...]. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency [...]".

In relation to the registration of intermediates under Articles 17 and 18 of REACH, registrants are required to hold information confirming that the substance is used as an intermediate, that strictly controlled conditions are met during the whole lifecycle of the substance, and that downstream users are implementing those conditions.

The wording of Article 36 can be interpreted in two ways: a registrant replying to an information request by ECHA or by a Member State competent authority may submit the information or make it available. Whereas the former option seems to indicate that the dutyholder has to actively submit the information to the enquirer, the latter seems to request the mere holding and making available of the information – possibly even at the dutyholder's site. The interpretation and practical implementation of these two options in Article 36 has proven to be a challenge during the pilot project on intermediates (see Chapter D. 4.).

D. Enforcement actions

1. Participating countries and number of inspections

Based on the registrants' responses, ECHA identified 15 cases for enforcement in seven Member States. Follow-up actions were conducted in 14 out of those 15 cases.

In the remaining case, the registrant had already been contacted prior to the project by the NEA due to other suspected shortcomings under REACH. The NEA consequently decided to pursue these potential violations first before enforcing ECHA's Article 36 letter.

Other participating countries of the pilot project did not receive cases from ECHA; however, some of them started additional national initiatives, including specialised trainings for inspectors, with regard to the enforcement of intermediates.

2. Coordination of the project

The pilot project on intermediates was based on a close cooperation between the ECHA Secretariat and the participating NEAs. The corresponding Forum members established and maintained the link between these parties and coordinated national enforcement activities.

In a workshop on intermediates and strictly controlled conditions organised by the ECHA Secretariat in May 2012, participants discussed views and strategies regarding the Article 36 letters.⁴ All parties exchanged valuable information on the enforcement of strictly controlled conditions and agreed to set up follow-up actions in the cases identified by the ECHA Secretariat.

The pilot project also served to test and establish communication and collaboration channels between all of the actors involved. During this process, participants of the project and ECHA relied on the principles and recommendations developed by the Forum Working Group on Interlinks. A secure messaging system within the REACH Information Portal for Enforcement (RIPE) was set up, through which the ECHA Secretariat and the participants of the pilot project were able to exchange confidential information such as inspection reports and DSDs.

3. Methods of enforcement

In all Member States, inspection activities began with desktop studies, during which inspectors often consulted the RIPE database for further information on the company, the intermediate dossier, and the substance in question. In some cases, inspectors also contacted their Member State competent authorities to access additional data from REACH-IT.

The desktop studies were followed by one or more onsite visits at the registrants' premises, in most cases. During both phases of the enforcement actions, inspectors were able to contact members of the ECHA Secretariat for specific questions related to their cases. Enforcement authorities from all participating Member States used this opportunity to exchange information with ECHA.

The results of the inspections were then fed back to the ECHA Secretariat and to the Chair of the pilot project for further evaluation.

⁴ Further information on the workshop can be found in the Workshop Summary Report on ECHA's website: http://www.echa.europa.eu/en/web/guest/view-article/-/journal_content/8ccfdae3-39ec-4c0f-bc1c-bdda01f25069.

4. Challenges

During the course of the project, the participants and the ECHA Secretariat encountered and addressed a number of practical and legal challenges.

The practical challenges mostly stemmed from the new processes for communication and collaboration that were set up between the ECHA Secretariat, Forum members and national authorities. Through good and effective cooperation, all parties involved managed to keep these practical issues to a minimum.

One of the unknown factors before the start of the pilot project was how much and what type of information needed to be communicated from ECHA to national authorities and vice versa. In a number of cases, inspectors asked their MSCAs for access to data from REACH-IT to enforce the Article 36 letters or contacted ECHA about the registrants' responses to these letters. Both ECHA and the relevant MSCAs quickly adapted to these and other information needs by sending out the required information on request.

The participants of the pilot project informed ECHA that they would not be able to determine exact timelines for their inspections in advance due to the fact that the time needed for an enforcement action depended to a great extent on the case at hand and on factors outside of the inspector's control (such as the registrants' responses to the enforcement action or possible legal actions by one of the parties involved).

The participants and the ECHA Secretariat thus set up a regular reporting obligation for national authorities, through which the status of all open cases was transmitted to ECHA. During the course of the project, ECHA and the NEAs also discussed and agreed on the content of the responses the Agency expected from the NEAs after the conclusion of their enforcement actions.

Legal questions centered on the interpretation of Article 36 of REACH. The issue arose when ECHA asked registrants to update their dossiers with attestations from downstream users stating that they would implement strictly controlled conditions when handling the intermediate. Whereas all registrants were able to provide the attestations onsite, some of them refused to include them into their IUCLID dossiers.

Both ECHA and the participants agreed that they would continue to work together to develop a harmonised approach to the legal interpretation and objectives pursued in the Article 36 letters.

E. Results and conclusions

In the 14 cases enforced by the participants of the pilot project, ECHA mostly asked inspectors to check onsite whether the substance was handled under strictly controlled conditions at all times. Additionally, and in some cases solely, ECHA's information request focused on the availability and correctness of attestations from downstream users, in which the downstream users stated that they would use the substance under strictly controlled conditions.

With regard to the strictly controlled conditions, ECHA's questions specifically centered on the status of the intermediate. In some cases, the chemical reactions taking place when the intermediate was used to manufacture another substance, and the practical setup on the registrant's site to ensure strictly controlled conditions were in focus (with a special emphasis on the rigorous containment of the substance, control technologies, cleaning and maintenance procedures, substance handling and training of workers, and waste treatment).

Strictly controlled conditions were met by registrants in 13 out of the 14 cases. Inspectors found only one case of severe non-compliance, in which a transported isolated intermediate (TII) was not handled under strictly controlled conditions. In this case, the inspector reported that they could touch the substance. Consequently, the registrant was asked to either update the registration dossier to a full registration according to Article 10 of REACH or to commit, no later than one month after the inspection, to a schedule of technical means implementation to ensure the rigorous containment of the intermediate. The registrant agreed to submit a full registration and did so within the set deadline. In this case, the inspector noticed that there was a big gap of knowledge with regard to intermediates between the unit handling REACH registrations at group level and the local unit handling the manufacture of the substance.

Regarding the downstream user attestations, participants of the pilot project noted that in most cases the requested information was available onsite and that national authorities were able to easily access and check the attestations.

In a few other cases, the information required by ECHA was partly missing and the registrants were ordered by the enforcement authorities to update their registration dossiers with the missing information. Most of these updates have already been performed by the end of the project.

The participants of the pilot project concluded that registrants were generally willing to cooperate with inspectors. Some companies stated that they were surprised to be contacted by enforcement authorities before having received a reaction from ECHA regarding their responses to the Article 36 letter. Inspectors indicated that it would be beneficial if ECHA tried to contact registrants multiple times if they seemed willing to cooperate with authorities and tried to provide the missing information.

F. Outlook: ECHA's screening of intermediates

The conclusion of the pilot project does not draw an end to ECHA's and the Member State's initiatives regarding the examination of intermediate registrations.

During the course of the pilot project in September 2012, ECHA started a systematic IT-screening of all intermediates registration dossiers.⁵ The analysis of the uses described in these dossiers indicated that 2 388 of approximately 5 500 dossiers included uses that according to ECHA did not, or were unlikely to, fulfil the definition of intermediates and/or were used under SCCs.

ECHA sent letters to 574 registrants with potentially non-compliant registrations and asked them to review their reported uses and to update their registration dossiers within three months. In a news report⁶ in February 2013, ECHA reported on the outcome of its screening exercise: "In total, 1 844 dossiers were updated, of which 39 were updates into Article 10 registrations, meaning full registration dossiers. For 107 dossiers, registrants have indicated they were preparing an update of which approximately half will become a full registration. For approximately 437 dossiers that have not yet been updated or indicated as dossiers for which an update is imminent, ECHA is starting follow up actions. First, a final reminder was sent to the registrants of 183 dossiers, who failed to read the communication ECHA sent via REACH-IT."

ECHA announced that it would initiate legally binding actions including a formal request for information leading to compliance check decisions and the submission of complete datasets in the months following the conclusion of the pilot project. ECHA also plans on starting discussions with national authorities on possible actions that they could take in support of ECHA's measures.

In 2013, ECHA decided to continue with the systematic verification of registration dossiers of intermediates, focusing on substances included in Annex XIV of REACH and on other SVHCs. ECHA sees the outcome of the intermediate verification process as becoming more and more crucial in light of the approaching deadlines for authorisation and the corresponding task to determine whether registered uses are truly exempted.

⁵ For further information access:

http://echa.europa.eu/documents/10162/5174810/na_12_41_intermediates+screening_en.pdf.

⁶ Source: http://echa.europa.eu/view-article/-/journal_content/title/echa-receives-updates-for-intermediate-dossiers-and-announces-further-follow-up-actions.

G. Recommendations

Continue with the harmonised enforcement of intermediates ...

The pilot project has been a successful first step towards the enforcement of intermediate registrations under REACH. To ensure that the correct registration and handling of intermediates remains in the focus of both industry and authorities, enforcement efforts need to continue.

→ It is therefore recommended for the Forum to consider including the enforcement of intermediates in one of their upcoming enforcement projects.

... in those cases where the registrant is not willing to provide information

During the course of the pilot project it was found that there is a general willingness of registrants to cooperate with both ECHA and national authorities to reach compliance with the obligations under REACH. Enforcement should be seen as a last resort (*ultima ratio*) in order to enable national enforcement authorities to focus on those cases and those registrants that are not willing to comply with REACH.

→ It is therefore recommended to ECHA that inquiries for enforcement activities should be limited to those cases where ECHA cannot remedy the lack of information in cooperation with the registrant.

... after harmonising the approach to the interpretation of Article 36

In light of the ongoing screening exercise for intermediates by ECHA (see Chapter F.), it seems essential to harmonise the approach regarding the scope and legal basis of Article 36 of REACH before the start of further enforcement actions.

→ It is recommended that ECHA and the national authorities of the Member States work towards finding a harmonised approach on this issue in the near future.

... with ECHA providing sufficient information on the enforcement cases

In those cases that are passed on to national enforcement authorities, their information needs should be taken into account. During the pilot project, inspectors found that the documents provided by ECHA in general and the Decision Support Document in particular were helpful. Inspectors also welcomed the opportunity to contact a member of the ECHA Secretariat if they had questions on a particular aspect of a case.

→ It is therefore recommended that the ECHA Secretariat continues to prepare Decision Support Documents and to provide contact persons for all cases that are passed on to national authorities.

... and training for inspectors on this issue

During the workshop on strictly controlled conditions it was discussed that the enforcement of intermediates will be a challenging task for inspectors in the Member States. Practical experiences during the pilot project show that this issue is highly technical and that the ability of inspectors to address these cases without additional support depends to a large extent on their background knowledge and their training in this particular field.

→ The Forum and the ECHA Secretariat are therefore asked to consider organising a training event for inspectors focused on the enforcement of intermediates. Intermediates could for example be chosen as a topic for the annual Forum event "Training for enforcement trainers".

... while calling on industry to act responsibly

Enforcement actions can only aim to identify and address a limited number of cases of non-compliance. The pilot project with its relatively small number of cases (40 cases total, 15 cases identified for enforcement actions, 14 cases⁷ enforced in the Member States) was no exception

⁷ Cf. Chapter D.1.

to this principle. Therefore, companies that deal with intermediates are first and foremost responsible for the safe handling of intermediates.

→ It is recommended for companies to act responsibly and to ensure safety for human health and the environment when dealing with intermediates.

... and to provide detailed answers to ECHA.

The cases in the scope of the pilot project showed that ECHA was often unable to determine from the registrants' responses to the Article 36 letters whether or not strictly controlled conditions were met onsite. In some cases, the responses were simply not detailed enough to give precise information for determining the actual conditions on the registrants' premises.

→ It is recommended that companies, in response to the Article 36 letters, give a very detailed description of the actual conditions onsite to ECHA so that the Agency can decide from the information provided whether strictly controlled conditions are met.