ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH: Progress Report 2017

Executive summary and recommendations to registrants

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This is an extract of ECHA's Evaluation under REACH progress report 2017. This document covers the Executive summary and the recommendations to registrants.

The complete report is available in English under https://echa.europa.eu/regulations/reach/evaluation

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EXECUTIVE SUMMARY

This is ECHA's tenth progress report on evaluation under the REACH Regulation. It summarises 10 years of experience from the evaluation activities carried out so far, and gives a more detailed account of ECHA's evaluation activities in 2017. It also provides recommendations to new and existing registrants deriving from this experience.

Trends in ECHA's evaluation activities since 2008

During the first years of evaluation, from 2008 to 2010, the ECHA Secretariat picked dossiers for compliance check based on random selection, IT screening and manual prioritisation. During these years, 105 dossiers were checked and 12 decisions were adopted. Altogether these decisions addressed compliance deficiencies on 23 information requirements, mainly on physico-chemical properties, screening for reproductive/developmental toxicity and the quality of the chemical safety report. At the same time ECHA, its Member State Committee and the Member States gained important experience on all aspects of the dossier evaluation process and built the capacity and skills necessary for addressing a higher volume of cases.

Over the three years following the first registration deadline of 2010, ECHA focused compliance checks increasingly on dossiers picked up by systematic IT screening. Selected information requirements were addressed in a standardised manner. This led to total of 1 464 targeted[1] and overall checks and 329 adopted decisions, each often containing one or two information requests. The first 5 % target[2] on 2010 dossiers was thereby also met at the end of 2013.

In 2014, ECHA moved to addressing also dossiers from the second phase-in deadline. With the help of improved screening tools, the Agency started selecting dossiers of substances of potential concern, i.e. those substances for which (i) the hazard profile for higher-tier (eco)toxicity information requirements[3,4] indicates a potential concern (or the hazard profile is unclear and needs to be further examined) and (ii) there is significant exposure potential. The focus was put on the key information requirements that could help to clarify if the substance is likely to be carcinogenic, mutagenic and reprotoxic (CMR) and/or (very) persistent, bioaccumulative and toxic (PBT/vPvB). Those information requirements are key in enabling the identification of a substance as being of very high concern. Since 2015, this approach has formed a core part of ECHA's Integrated Regulatory Strategy[5]. Compared to the previous approach, the number of compliance checks and decisions is lower, but the number of information requests has increased to an average of five requests per decision taken in 2017.

Overall, during the 10 years of evaluation, ECHA checked, to various degrees, the compliance of 1 350 (7.33 %) dossiers in the >1000 tn/a tonnage band and 430 (3.79 %) of the dossiers in the 100-1000 tn/a tonnage band. Due to the selection based on screening of suspected data gaps, in the vast majority of the cases (69 % and 77 % respectively), the compliance checks have confirmed one or more non-compliances and resulted in ECHA (draft) decisions.

By the end of 2017, altogether 2 586 information requests were made in the compliance check decisions. Of these requests, 420 (16 %) have targeted substance identification, 178 (7 %) physico-chemical properties, 955 (37 %) human health hazards, 662 (26 %) ecotoxicity and fate, and 367 (14 %) the quality of the chemical safety reporting. The most common non-compliances related to human health have been found in pre-natal developmental toxicity (first

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[1] For same registration more than one compliance check could have been opened to address different targeted concern scenarios or incompliances.

2 The 5% target is calculated by using number of unique registration dossiers checked for compliance (see Table 1.)

[3] Genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

[4] https://echa.europa.eu/documents/10162/17208/echa_cch_strategy_en.pdf/607b157b-a35d-4d1c-8e62-ce8668324b1a

[5] https://echa.europa.eu/documents/10162/22837330/mb_44_2016_regulatory_strategy_en.pdf/

and second species), sub-chronic toxicity (90-day study), *in vitro* studies for gene mutation and/or cytogenicity in mammalian cells and in the *in vitro* gene mutation study in bacteria. For the environmental information requirements, the most commonly found non-compliances have been in the long-term toxicity in fish, identification of degradation products, growth inhibition in the aquatic plants, bioaccumulation and effects in terrestrial organisms. In relation to physico-chemical properties, the partition coefficient, water solubility, vapour pressure and the dissociation constant were the most often requested information requirements in the decisions.

In parallel to the work on compliance checks, ECHA successfully met the two deadlines set in REACH, 2012 and 2016, for the examination of the phase-in substances' testing proposals and issued 806 decisions. The total number of requests made in the testing proposal decisions over the years is 1 588 – 964 (61 %) regarding toxicological testing, 494 (31 %) testing on ecotoxicology and environmental fate, and 130 (8 %) regarding physico-chemical testing. Registrants proposed testing mostly for pre-natal developmental toxicity, the 90-day sub-chronic toxicity study and the long-term toxicity testing on invertebrates.

The first cases in follow-up to dossier evaluation were processed in 2012, and a structured approach was fully established in 2013. Currently, the number of follow-up evaluations carried out annually is between 300 and 350, with approximately 55 % originating from compliance check decisions and 45 % from testing proposal decisions. Since 2013, ECHA has notified the Member States competent authorities and the Commission of 73 cases where substances are possible candidates for harmonised classification and labelling, and flagged 11 cases for substance evaluation. After setting the Integrated Regulatory Strategy to focus on substances of potential concern, ECHA has also considered more systematically whether further regulatory risk management processes are needed based on the follow-up evaluation.

The other main evaluation process, substance evaluation, started effectively with the publication of the Community rolling action plan (CoRAP) in February 2012. ECHA coordinates the work and collaborates with the evaluating Member States throughout the substance evaluation process, aiming to achieve consistent and scientifically robust decisions and to ensure that the necessary information is requested using the most viable route to clarify the concerns and inform regulatory risk management.

Between 2012 and 2017, a total of 221 substances were evaluated by Member States, who considered that 159 (72 %) of these required further information to clarify the suspected concerns; the remaining 62 substances could be concluded on without the need for further information. Of the 159 substances requiring further information to clarify the concern, 147 are currently at the process stage of either further information being requested (decision-making) or newly submitted information being evaluated (follow-up). The remaining 12 substances were concluded on following the submission and evaluation of requested information. Consequently, a total of 74 substances have been concluded on, and in 43 % of these cases the evaluating Member States considered that further regulatory risk management may be needed.

ECHA's evaluation activities in 2017

In line with the Integrated Regulatory Strategy set in 2015, ECHA continued to check the compliance of dossiers for registering substances in amounts of more than 100 tonnes per annum, addressing relevant higher-tier hazard endpoints for substances of potential concern. In addition, ECHA started a pilot focusing on selected groups of priority substances on which registrants are using read-across or grouping approaches for the key endpoints, and initiated informal interaction to more effectively ensure that such a grouping approach is in compliance with the information requirements. In addition, ECHA continued to use other measures – including letter campaigns and sector-specific approaches – to work together with industry to help to increase the overall compliance of the registration dossiers and improve the quality of chemical safety reports.

Outcome of compliance checks

In 2017, 185 (83 %) out of the 222 compliance checks concluded were done on substances of potential concern. ECHA issued 151 new draft decisions addressing non-compliances; the most common information requests were in relation to pre-natal developmental toxicity, mutagenicity/genotoxicity, reproduction toxicity, and long-term aquatic toxicity. In addition, ECHA adopted 139 compliance check decisions. Altogether, 679 standard information requests were made in ECHA decisions, with an average of five information requests per decision. The most common non-compliances addressed in the compliance check decisions were: pre-natal developmental toxicity, mutagenicity/genotoxicity, simulation testing (water, soil and sediment), long-term aquatic toxicity, reproduction toxicity, and repeated dose toxicity. These information requirements enable the identification of a substances of very high concern.

Testing proposal examination

Overall, 58 testing proposal decisions were adopted in 2017, comprising 127 requests for testing. The most common human health-related testing proposals were for pre-natal developmental toxicity and the sub-chronic 90-day toxicity study. On the environmental side, the most frequent information gaps identified by the registrants were on short- and long-term effects on terrestrial organisms and long-term aquatic toxicity. The results of these tests will inform the identification of substances of very high concern, but will also complete the information on the hazards of a substance to enable its safe use.

Follow-up evaluation of compliance check and testing proposal decisions

In 2017, 327 dossier follow-up evaluations were concluded. The outcome of the follow-up evaluations shows that of the endpoints originally identified as being non-compliant with the information requirements or where a testing proposal was submitted, 639 (85 %) are now compliant as a consequence of dossier evaluation. For the remaining 117 (15 %) endpoints, the ECHA Secretariat sent a statement of non-compliance (SONC) for 109 endpoints and launched a new decision-making process according to Article 42(1) for 8 endpoints.

Of the concluded follow-up evaluations, 67 cases were flagged as candidates for further regulatory processes, i.e. classification and labelling, substance evaluation or a new compliance check. As the first decisions based on ECHA's Integrated Regulatory Strategy's focus on selected key endpoints were made only in 2015, the first of such cases reached the follow-up stage at the end of 2017.

Progress in substance evaluation

The 2017-2019 CoRAP update, adopted on 21 March 2017, consists of 115 substances, of which 22 were scheduled for evaluation in 2017. Following the common screening round in 2017, ECHA proposed to include 107 substances in the draft CoRAP for 2018-2020 to be evaluated by the Member States.

From the previous round of substance evaluations, the evaluating Member States prepared draft decisions for 27 substances to request further information to clarify suspected concerns. For the remaining 12 substances, the evaluating Member States considered the available information sufficient to conclude on the identified concerns.

The substance evaluation process is shifting more towards follow-up assessment, and the timing depends on the deadlines set in the decisions for the registrants to submit the data. In 2017, 26 substances were at the stage where new information should have been submitted following an initial request for further information. The responsible evaluating Member State competent authorities are currently reviewing the newly submitted information to conclude on its suitability.

ECHA adopted 31 substance evaluation decisions and published 25 substance evaluation conclusions: for 13 substances it was concluded that the risks are sufficiently controlled with existing measures, and for 12 substances it was concluded that EU-wide risk management measures are necessary.

KEY RECOMMENDATIONS TO REGISTRANTS

The following are ECHA's key recommendations to registrants based on the evaluations carried out in 2017. All recommendations and advice are available in chapter 5 of this report and on ECHA's web pages on evaluation[6].

UPDATE YOUR REGISTRATION DOSSIER WITHOUT UNDUE DELAY WHEN RELEVANT NEW INFORMATION IS AVAILABLE

- According to Article 22 of the REACH Regulation, you are responsible for updating your registration with relevant new information on your own initiative and without undue delay and submitting it to ECHA, for example in the following cases:
  - there are changes in your status as registrant;
  - there are changes in the composition of your registered substance;
  - there are changes in the annual or total quantities manufactured or imported, resulting in a change of tonnage band;
  - you have identified new uses or new uses advised against;
  - you have new knowledge of the risks of substance to human health and/or the environment;
  - there are changes in the classification and labelling of the substance;
  - you have updated or amended the chemical safety report or guidance on safe use;
  - you have identifed the need to perform a new test listed in Annex IX or Annex X to the REACH Regulation;
  - there is a change in the access granted to information in your registration.
- The new information may have an impact on the protection of human health and the environment.

JUSTIFY AND DOCUMENT YOUR WEIGHT OF EVIDENCE APPROACH

- If you propose an adaptation based on weight of evidence, the individual lines of evidence and the justification should provide a sufficient confidence level when compared to information expected with the default test. Documentation of the weight-of-evidence adaptation should be transparent and conclusions justified.
- You need to document the quality and relevance of the pieces of evidence, as well as their consistency and completeness, in relation to the standard information requirements.
- You should also address the associated uncertainties and their impact in a way that allows ECHA to assess and verify all the pieces of evidence provided in the technical dossier.

[6] https://echa.europa.eu/regulations/reach/evaluation

PROVIDE ROBUST GROUPING AND READ-ACROSS ARGUMENTS

- Use ECHA's Read-Across Assessment Framework (RAAF[7]) to check the robustness of your read-across adaptation. The RAAF describes the aspects of grouping and read-across justifications that ECHA considers to be crucial for both human health and environmental endpoints.
- In March 2017, a technical document[8] was published on ECHA's website on assessing the complexity of grouping and read-across for multi-constituent and UVCB substances. It describes the additional key issues proposed to be considered when predictions based on grouping and read-across cases involving multi-constituent substances and/or UVCBs are used to adapt standard information requirements.
- Justify the grouping and read-across approach by showing how structural similarity and dissimilarity are connected to the prediction and create a data matrix, allowing side-by-side comparison of properties of the source(s) and target substance(s).

[7] ECHA Read-Across Assessment Framework (RAAF): https://echa.europa.eu/documents/10162/13628/raaf_en.pdf.

[8] Read-Across Assessment Framework (RAAF) - Considerations on multi-constituent substances and UVCBs: https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316.

1. RECOMMENDATIONS TO REGISTRANTS

This chapter contains advice to all existing and future registrants under REACH.

The recommendations are based on the most frequent shortcomings observed during dossier and substance evaluation, or their follow-up, and includes also information on the guidance and tools made available to the registrants during the year.

1.1 Report the identity of your substance and representative test material correctly

Report clearly what you have registered

Check that your reported legal entity composition information is within the boundaries of the substance identity profile compositional information as reported in the boundary composition record in the lead registrant dossier. More information can be found in "*Guidance for identification and naming of substances under REACH and CLP*" [9].

Make full use of the available IUCLID reporting fields

Proactively update the lead registrant dossier to make use of the new reporting functionalities for the joint compositional profile and the test material records.

ECHA encourages you to take action to correct substance identification mistakes not only during dossier evaluation but also on your own initiative. More information on how to prepare a registration can be found in the manual "*How to prepare registration and PPORD dossiers*" [10].

Ensure that you can demonstrate you are in the correct joint registration

Check that your compositional information is within the boundaries agreed by your co-registrants and that the jointly reported REACH Annex VII-XI information is relevant for your composition.

A broadly defined substance identity means broad Annex VII-XI reporting

If you and your co-registrants have defined your substance identity broadly, ensure that you also clearly report in your registration file how you have fulfilled your REACH Annex VII-XI information requirements for all that is registered and covered by the registration.

Ensure you can demonstrate the relevance of your test materials

Report the constituent identities and concentration values of each test material and study used to generate your reported REACH Annex VII-XI data in the fields available in the Test Material Record.

Registering nanomaterials? Consult ECHA's Guidance

Consult the available ECHA Guidance on how to address the specific properties of the nanomaterials you register when generating or collecting REACH Annex VII-XI information for your registration file. Make use of the IUCLID 6 reporting fields available in the composition records to document what you have registered and what your REACH Annex VII-XI data refers to[11].

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[9] https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d

[10] https://echa.europa.eu/manuals

[11] https://echa.europa.eu/documents/10162/13643/appendix_r14_05-2012_en.pdf/7b2ee1ff-3dc7-4eab-bdc8-6afd8ddf5c8d

1.2 Provide information on GLP compliance of the whole study

When you report results of a toxicocological or ecotoxicological study, identify unambiguously the test facility in which the study was conducted by providing the complete name and address of the facility so that a good laboratory practise (GLP) compliance claim can be verifified.
If parts of a GLP study were not conducted in line with GLP principles, indicate which parts of the study were affected in the remarks field of the GLP compliance section in the IUCLID.

1.3 Make sure your registration dossier is complete

The experience gained so far with the manual verifications on incoming dossiers has enabled ECHA to identify several recommendations for registrants to successfully prepare and submit a registration dossier. ECHA has published an information document on the manual verification that describes the different areas of the manual verification checks and provides useful instructions on how to prepare a complete registration dossier[12]. You should take into account the information document and the following recommendations when preparing a registration dossier.

- Before you submit the dossier to ECHA, use the IUCLID Validation assistant tool.
- If the Validation assistant does not indicate any failures, it is not an automatic confirmation of that the dossier is complete, since the manual verifications are not displayed in the Validation assistant report. Ensure that you have included all the required data for the areas that are described in the information document on manual verification.
- When preparing your dossier, consider that the registration dossier should not only be prepared to pass the completeness check – it should contain all the information on the substance as specified by REACH and should aim to demonstrate that the substance is used in a safe manner.
- Each registrant is responsible for ensuring that they register the substance as part of the correct joint submission, and that they provide the correct substance identification information in their registration dossier. Registrants should not rely on company-specific substance identification information provided by the lead registrant (such as analytical or compositional information).
- Use the available templates that exist to support registrants with the reporting of certain information requirements. For example, IUCLID has integrated templates for the manufacturing process description that is required for UVCB substances and for the considerations of alternative methods that need to be reported with testing proposals on vertebrate animals.
- When certain information is requested in a specific IUCLID field, this information must be included in the appropriate field. Reference to other parts of the IUCLID dossier is not considered complete.

1.4 Use the support available for REACH 2018 registrants

Follow the Directors' Contact Group

The Directors' Contact Group[13] restarted their activity in 2017. Their objectives are to monitor the overall preparedness of companies and to identify and resolve the priority issues of concern in meeting obligations relevant to the registration of chemical substances. They have decided to reopen four solutions designed already for the 2010 and 2013 deadlines for

[12] The document is published on ECHA's website:
https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf
[13] https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

companies in exceptional circumstances (solutions 10, 15, 20 and 21)[14] from 31 January 2018.

Consult the REACH 2018 web pages

The REACH 2018 website[15] remains the main information point for the registrants falling under the 31 May 2018 registration deadline. "*Practical guide for SME managers and REACH coordinators*"[16], published already in 2016, includes many tips on how to fulfil information requirements at tonnages 1-10 and 10-100 tonnes per year, as does ECHA's web page "*What information you need*".[17]

Check our practical examples

A new support web page bringing together practical examples[18] was published on 31 May 2017. Among others, one example relevant for information requirements was published, namely "*Steps to gather information for low tonnage substances*"[19]. In early 2018, more practical examples related to hazard and risk assessment were published:

- How to gather information to register an inorganic mono-constituent substance (including the chemical safety assessment);
- How to gather information to register a multi-constituent or a UVCB substance - toxicological information;
- How to decide whether a substance is a polymer or not and how to proceed with the relevant registration.

In addition, links to the existing examples related to assessing hazards and risks of substances were gathered on the practical examples web page. Note that the examples with the OECD QSAR Toolbox were developed with an older version of the Toolbox, but the reasoning described in the document is still valid.

If you are a SME, consider using ECHA Cloud Services

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications in a cloud environment. By using the services, you can work together in a more transparent and interactive way. The service allows SMEs and their consultants to work online with the latest version of IUCLID without having to install IUCLID on computers or company servers. It has a simple interface focusing on the REACH 2018 registration deadline tasks, and also offers a guided approach to help inexperienced SME registrants through the process of entering their IUCLID data. The service provides the user with up to 1 GB of data storage, fully managed backups and dedicated helpdesk support. More information on IUCLID Cloud is available on-line [20,21,22].

1.5 Avoid unnecessary testing on animals

Share data and use non-animal approaches where possible

Potential registrants of the same substance must collaborate to share the requested information and agree on the data to be submitted jointly.

If new data for skin corrosion/irritation, serious eye damage/eye irritation and/or for skin

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[14] https://echa.europa.eu/documents/10162/23556156/171219_dcg_four_solutions_en.pdf/9451fa44-266c-74d5-40d9-8beebd0e5c8b
[15] https://echa.europa.eu/reach-2018
[16] https://echa.europa.eu/practical-guides
[17] https://echa.europa.eu/support/registration/what-information-you-need
[18] https://echa.europa.eu/support/registration/practical-examples
[19] https://echa.europa.eu/documents/10162/23221373/example_low_info_reqs_en.pdf/3db4c47b-4ebf-1768-6350-e87b530a8f7e
[20] https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services
[21] https://www.linkedin.com/groups/12043483
[22] https://www.youtube.com/playlist?list=PLOPGDACSd6qyDkdXwPua1Fjb5bJksY75k

sensitisation needs to be generated, you will have to perform the *in vitro* studies first, irrespective of the annual tonnage of the substance. Unjustified *in vivo* testing when non-animal alternatives are available may lead to compliance check or direct enforcement action.

For substances expected to not be acutely toxic based on non-animal approaches (e.g. *in vitro* and QSAR data), consider conducting a sub-acute repeated-dose toxicity study (28-day study) first. The results from that study may be used within a weight-of-evidence approach to conclude on oral acute toxicity without conducting an acute oral toxicity study.

Information from non-animal approaches may also be used as supporting data for grouping and read-across adaptation. Results from several individual non-animal approaches (e.g. *in silico*, *in vitro*) may allow to adapt information requirements and avoid an animal test under weight-of-evidence adaptation.

Provide your considerations on non-animal approaches with your testing proposals

When you have concluded that generation of new information is necessary, verify whether the endpoint requires a testing proposal and prior authorisation of the testing by ECHA. Apart from information requirements listed in Annexes IX and X, some testing proposals may need to be submitted already at Annex VII or at Annex VIII level[23]. For example, the Annex VIII, Column 2 requires the registrant to consider appropriate mutagenicity *in vivo* studies in cases where positive results in *in vitro* genotoxicity studies have been obtained. It should be noted that where this involves tests mentioned in Annexes IX or X, such as *in vivo* somatic cell genotoxicity studies, testing proposals must be submitted by the registrant and accepted by ECHA in a formal decision before testing can be initiated.

When your testing proposal involves testing on vertebrate animals, you have to include your considerations on non-animal approaches for that information requirement in the dossier documentation.

Justify and document your weight-of-evidence approach

If you propose an adaptation based on weight of evidence, the individual lines of evidence and the justification should provide a sufficient confidence level when compared to information expected with the default test. Documentation of the weight-of-evidence adaptation should be transparent and conclusions justified.

You need to document the quality and relevance of the pieces of evidence, as well as their consistency and completeness, in relation to the standard information requirements. You should also address the associated uncertainties and their impact in a way that allows ECHA to assess and verify all the pieces of evidence provided in the technical dossier.

Provide robust grouping and read-across arguments

Use ECHA's Read-Across Assessment Framework (RAAF[24]) to check the robustness of your read-across adaptation. The RAAF describes the aspects of grouping and read-across justifications that ECHA considers to be crucial for both human health and environmental endpoints. A technical document[25] on the key issues for assessing the complexity of grouping and read-across for multi-constituent and UVCB substances was published on ECHA's website in March 2017. This document describes the additional key issues proposed to be considered when predictions based on grouping and read-across cases involving multi-constituent substances and/or UVCBs are used to adapt standard information requirements.

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[23] https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f

[24] ECHA Read-Across Assessment Framework (RAAF): https://echa.europa.eu/documents/10162/13628/raaf_en.pdf.

[25] Read-Across Assessment Framework (RAAF) - Considerations on multi-constituent substances and UVCBs: https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316.

Justify the grouping and read-across by showing how structural similarity and dissimilarity are connected to the prediction and create a data matrix, allowing side-by-side comparison of properties of the sources and target substances.

1.6 Your chemical safety report should reflect the actual uses and risks

Derive DNELs according to ECHA's Guidance

Derivation of DNEL (derived no-effect level) is a key element for the risk characterisation of a chemical substance. The DNEL is set by REACH as the threshold above which humans should not be exposed. Therefore, it is important that your DNEL is derived appropriately to make sure that your substance is manufactured and used in such a way that they do not adversely affect human health. A DNEL has to be derived based on the dose descriptor giving rise to the highest concern per route of exposure and type of effect. Usually it is the study with the lowest NOAEL/LOAEL (no/lowest observed adverse effect level).

A set of assessment factors should be applied to convert the dose descriptor into a DNEL. For an explanation on the background to these assessment factors, consult REACH Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health (version 2.1, November 2012)[26].

You need to justify and document any deviation from these default assessment factors with scientific arguments that are specific to your registered substance.

If it is not possible to derive a DNEL for a particular hazard, for example skin/eye irritation/corrosion, skin sensitisation, mutagenicity, you should carry out and report a qualitative assessment.

Use the DNEL and PNEC calculators in IUCLID 6

DNEL and PNEC calculators[27] are new features in IUCLID 6 (versions 1.2.0. and 1.3.0.).

The DNEL calculator was developed in collaboration with the State Secretariat for Economic Affairs (SECO) from the Swiss Confederation in order to support the derivation of worker and general population derived no-effect levels (DNELs) for long-term systemic effects for oral, dermal and inhalation routes based on ECHA's Guidance.

The PNEC calculator was developed to support the derivation of predicted no-effect concentrations (PNECs) for the aquatic, sediment and terrestrial environmental protection targets based on ECHA's Guidance.

Both DNEL and PNEC calculators use the information already provided in the endpoint study summaries of the IUCLID dossier and populate automatically the summary records in sections 6 (Ecotoxicological information) and 7 (Toxicological information) of IUCLID.

Your exposure assessment needs to cover all identified hazards

According to Section 5.0 of Annex I to REACH, when the exposure assessment is triggered, i.e. criteria given in Article 14(4) are met, it "shall consider all stages of the life-cycle of the substance" and "cover any exposures that may relate to the hazards identified". ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment (version 2.1, December 2011) clarifies that there are three types of identified hazards requiring exposure assessment:

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[26] REACH Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health: https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/.
[27] https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf

1. hazards leading to classification;
2. classifiable hazards where the severity of the effects is lower than the criteria for classification and so the substance is not classified;
3. hazards for which currently no classification criteria exist.

The three points above entail that exposure assessment is not limited to the classifiable hazards or adverse effects observed at doses or concentrations where classification is triggered, but should cover all hazards identified. It should be noted that hazard is considered as identified when adverse effects have been observed in studies at the highest recommended concentration or doses tested. The DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect, or protection target would be needed. For instance, when adverse effects have been observed in studies conducted at the highest practicable and biologically relevant concentration on environmental aquatic toxicity according to OECD and EU test guidelines (e.g. 100 mg/l as a limit test for acute aquatic toxicity in the OECD guideline), taking into account the properties of the substance determining the environmental fate, it would indicate that quantitative exposure assessment, i.e. derivation of predicted environmental concentrations (PECs), is mandatory for the water, sediment and soil environmental compartments.

Use correct exposure scenarios and exposure estimations

The reliability of the exposure assessment highly depends on the reliability of the exposure scenarios and input parameters used in the exposure estimation. One of the main parameters affecting the outcome of the environmental exposure assessment are the release factors to the environment. ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation[28] suggests generic worst-case release factors for each environmental release category (ERC) that registrants can use without further justification. If non-default ERC release factors (site-specific or sector-proposed specific environmental release categories (SpERCs)) are available and used for exposure estimation, this should always be justified. This justification should be detailed enough, the source referenced (and retrievable) and linked to the related operational conditions or risk management measures, so ECHA can understand whether it covers the relevant scenarios for possible releases from substance processing according to the relevant exposure scenario. For example, SpERC developers and users should ensure that the description provided in the SpERC factsheet is detailed in a clear and accurate manner with sufficient justification, and covers all relevant activities or processes, operational conditions, and risk management measures claimed. In general, SpERCs include a definition of scope (applicability domain), information on conditions of use leading to a certain expected release factor, expected release factors, and an explanation of how the release factors were derived. If the SpERC factsheet does not contain sufficient background information on the release factor proposed, the registrant's CSR may not be convincing in demonstrating the control of risk.

The exposure assessment requires the estimation of the level of the substance to which humans and the environment may be exposed. It is another key element in assessing whether the risks are adequately controlled throughout the lifecycle of a substance. It consists of two clear steps: identifying exposure scenarios (as discussed above) and estimating the exposure in each scenario.

The exposure estimates give the level of exposure that is expected when manufacturing and using a chemical substance and they are compared with the derived DNELs to ensure that human health is not adversely affected. For estimating the level of exposure, an adequate or representative set of measured data can be used. In the absence of workplace exposure data, the exposures should be carefully estimated by using the exposure models that are

[28] https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af

appropriate for the physico-chemical properties of the substance and the route of exposure. When using a model to obtain exposure estimates, you should understand how it works and its limitations, so that it is fit for purpose and you can enter the parameters correctly. In other words, you should use the model within its domain of applicability, and you should not deviate from the underlying assumptions in the model. For exposure tools integrated into Chesar, users receive warnings when using the tool in a way that may conflict with the applicability domain.

Justify your exposure based adaptions

When you use Annex XI, section 3, substance-tailored exposure-driven testing by claiming implementation of strictly controlled conditions throughout the life-cycle of the substance, for confirmation of applied conditions during the whole lifecycle of the substance, you should also provide a description of the specific activities performed at each lifecycle stage and on each relevant site concerning the handling and use of the substance in the registration dossier. For each specific activity it should contain a brief description of the system and/or equipment that demonstrates how the substance is rigorously contained by technical means during its whole lifecycle and how other requirements of Article 18(4)(a) to (f) of REACH are implemented.

More information on what information and documentation is relevant and necessary to be submitted in the registration dossier to support a claim of strictly controlled conditions is given in ECHA's Practical Guide 16, "*How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID*"[29], and ECHA's Guidance on intermediates[30].

Improve use descriptions

The basis for prioritising substances for evaluation and regulatory risk management are their hazard properties and exposure potential. In order to assess the exposure potential of a substance, there needs to be sufficient information on how it is used. For example, the work on the plastic additives has demonstrated that insufficient information on uses has been provided in REACH registrations to allow (de)prioritisation of substances used as additives in plastics based on their exposure potential. The lack of such information means adequate safety assessments for substances in plastic articles cannot be performed. In order to be able to prioritise and deprioritise plastic additives, registrations should be updated so that they provide a clear picture on the use patterns of these substances and conditions of safe use.

Use maps are a tool which aim to improve the quality of information on use and conditions of use communicated up the supply chain and the efficiency of this communication process. Use maps are now available on ECHA's website for plastic compounding and conversion, which we recommend the registrants use. These use maps will be extended to cover article service life.

1.7 Familiarise yourself with new guidance on PBT/vPvB assessment

Take note that Chapter R.11 of the Guidance on Information Requirements and Chemical Safety Assessment[31] which covers PBT/vPvB assessment was updated in 2017. The integrated testing strategies for persistence and bioaccumulation were updated and there is further explanation on applying a weight-of-evidence approach, as required by REACH Annex XIII.

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[29] https://echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf/291b6e50-5598-42d3-8a2b-d63d50a68104

[30] https://echa.europa.eu/documents/10162/23036412/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641

[31] https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

1.8 Identify and address information of the degradation products

The identification of the degradation products is a standard information requirement of Annex IX, Section 9.2.3. of REACH. Information on degradation products should be provided if you do not have valid evidence showing that your substance is readily biodegradable.

It is necessary for the PBT/vPvB assessment, as Annex XIII to REACH specifies that "the identification [of PBT and vPvB substances] shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products". Information on degradation products should also be taken into account for the exposure assessment (Annex I 5.2.4. of REACH), when applicable, and for the hazard assessment (e.g. Column 2 of Annex X 9.4 and Annex X 9.5.1 to REACH). Finally, this information is required for the preparation of section 12 of the safety data sheet (Annex II to REACH), when applicable.

Information on degradation products is generally obtained from simulation tests. For further information see ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7.9.

1.9 Classify multi-constituent and UVCB substances correctly

The classification of a substance containing impurities, additives or multiple constituents (multi-constituent, UVCB) should, similar to mixtures, primarily be based on available relevant information (including test data) on the substance. However, when classifying for CMR properties or when evaluating the bioaccumulation and degradation properties within the hazardous to the aquatic environment hazard class, it is strongly recommended that the classification of the substance, similar to mixtures, should be based on information of the known individual constituent(s), as there is no toxicological difference between a mixture and a substance containing other constituent substances.

In exceptional cases, data on the substance itself might show more severe effects for classification for CMR or relevant effects on the bioaccumulation or degradation properties, which have not been identified from the information on the constituent substances. These data should then be used, if available. For non-CMR hazard classes, data on the constituents should be used for classification in accordance with the mixture rules where data on the substance is not available. The testing of a complex substance for classification purposes is strongly discouraged if there are data on the constituents.

1.10 Familiarise yourself with new documents on nanomaterials

ECHA invites you to familiarise yourself with the following five documents that provide advice to registrants preparing registration dossiers that cover nanoforms in 2017.

ECHA has published two completely new publications: the nano-specific Appendix R.6-1 to Chapter R.6: QSARs and grouping of chemicals of the Guidance on information requirements and chemical safety assessesment[32], and a document proposing best practices for registration of nanomaterials, "*How to prepare registration dossiers that cover nanoforms: best practices*"[33].

The best practices document provides recommendations for distinguishing between different nanoforms of a substance. Following the recommendations provided in the document will

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[32] Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals: https://echa.europa.eu/documents/10162/23036412/appendix_r6_nanomaterials_en.pdf/.
[33] How to prepare registration dossiers that cover nanomaterials: best practices: https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/.

ensure consistent reporting of information on nanoforms in registration dossiers and facilitate registrants in clearly demonstrating that they fulfil their registration obligations for nanomaterials. Furthermore, Appendix R.6-1 provides an approach on how to justify the use of hazard data between nanoforms (and the non-nanoforms) and within groups of nanoforms of the same substance.

In addition, ECHA published updates to three of its existing guidance documents on nanomaterials: the Appendices[34] for nanomaterials to Chapters R.7a, R.7b and R.7c of the Guidance on information requirements and chemical safety assessesment (endpoint-specific guidances). These Appendices provide nano-specific guidance on how to meet the information requirements set out in Annexes VI-X to REACH.

1.11 Respond to ECHA's evaluation decisions

Respect the deadlines set in the decision

You are reminded to respect the deadline to update the registration dossier. Even in cases where the information may be late, it is in your own interest to communicate to ECHA in a dossier update with justifications and to provide all the requested information according to the expected timeline.

Report the new information correctly

You are requested to pay attention to detail when reporting the requested information in the technical dossier. ECHA must be able to assess the studies independently and form its opinion about the study validity and the significance of the results.

Information about the test material composition is crucial for ECHA to be able to conclude on the relevance of the study results to the registered substance.

You must also take all the new hazard information into account in the chemical safety assessment and reflect this in the CSR.

When updating your dossier, if you decide to adapt the information requirement (i.e. you do not perform the requested experimental test), any such adaptations must meet the conditions described in Column 2 of the respective REACH Annex, or you should follow the rules set out in Annex XI to REACH. Such adaptations must be fully justified and documented in order to allow ECHA to properly assess and verify the adaptation used.

1.12 Recommendations related to substance evaluation

When your registered substance is included in the CoRAP, review and update your dossier as early as possible

Perform a thorough check of your registration dossier and submit a dossier update, if needed, to facilitate the future evaluation process.

It is crucial to:

- Update your dossier in a timely manner before the start of the evaluation process;
- Ensure that the identitification of your registered substance is clear and appropriately documented;
- Make sure that your use and exposure scenarios are accurate and up-to-date, and that your exposure estimations are correct.

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[34] https://echa.europa.eu/documents/10162/13632/appendix_r7a_nanomaterials_en.pdf/, https://echa.europa.eu/documents/10162/13632/appendix_r7b_nanomaterials_en.pdf/ and https://echa.europa.eu/documents/10162/13632/appendix_r7c_nanomaterials_en.pdf/.

Ensure a good communication up and down the supply chain to gather the necessary information on the intended uses of your registered substance.

- Contact your downstream users as early as possible to have all the relevant information in place and also consider being in contact with specific downstream user organisations.
- Downstream users of a substance included in the CoRAP who own or have access to useful information should consider informing the lead registrant[35] or the evaluating MSCA[36].

Whenever possible, avoid submitting dossier updates once the substance evaluation has started, unless in agreement with the evaluating MSCA.

Use the opportunity to interact with the evaluating Member State competent authority

ECHA has published recommendations on best practice for informal interactions, as Member State competent authorities have agreed on a common approach on interaction with registrants during substance evaluation[37].

Discuss with your co-registrants and decide who could be nominated as a representative for interacting with the evaluating MSCA.

The evaluating MSCA may approach you in writing to request further clarifications before preparing a draft decision. Ensure your responses are timely and discuss with the evaluating MSCA on the need or timing of any update of the registration dossier.

Interact with ECHA where necessary

While the evaluating MSCA performs the evaluation, ECHA coordinates the overall substance evaluation process. You can contact ECHA for clarification on issues of more administrative nature using the ECHA contact form[38].

- Ensure that your REACH-IT contact information is kept up to date.

When you receive a substance evaluation draft decision, review it and provide your coordinated comments

Upon receipt of the draft decision from ECHA via the REACH-IT tool, review its content to understand the requests (including the test methods and/or the testing strategy).

Whenever possible, coordinate responses and submit a single set of consolidated comments within 30 days. The deadline for comments as well as the link to the webform are specified in the notification letter.

- All relevant registration numbers are listed in an appendix to the draft decision.
- Alternatively, you can consult the Co-registrants page in REACH-IT, which displays the contact details and roles of the existing registrants of the substance.

Similarly to the comments on the draft decision, coordinate responses to the proposals for amendment (PfAs) and submit a single set of consolidated comments within 30 days.

- Only comments on the PfAs are accepted, whereas comments on the (amended) draft decision *per se* are not taken into consideration at this stage of the process.

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[35] ECHA publishes the name of the lead registrants if permitted by the companies. For more information, check the "Lead registrant list" at: https://echa.europa.eu/regulations/reach/registration/registration-statistics.

[36] In the CoRAP list, ECHA publishes the Member State and contact details of the respective competent authority responsible for the evaluation of each substance.

[37] https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

[38] https://www.echa.europa.eu/contact/helpdesk-contact-form

- Also, at this stage it is not possible to extend the deadline to submit comments, due to the strict timelines of the decision-making process imposed by REACH.

Start discussing with testing laboratories to explore their capacity for new testing, so as to prepare a smooth start of activities once the final decision is received.

- This information can also be used to inform the evaluating MSCA on realistic deadlines to be included in the decision.
- No testing may be conducted until the decision-making process is completed, as there may be changes to the requests.

When you receive a substance evaluation decision, agree with your co-registrants who performs the study

After the agreement by Member State competent authorities or the Member State Committee members, ECHA adopts the decision and communicates it to the concerned registrants using REACH-IT.

Within 90 days of receipt of the decision, you need to inform ECHA of the agreed legal entity which is to perform the requested tests on behalf of the other registrants who are addressees of the decision and/or impacted by it.

- If ECHA is not informed of such agreement within 90 days, it has the obligation to designate one of the addressees of the decision to perform the tests on behalf of all concerned registrants.

Any issues regarding data and cost sharing among the registrants need to be solved within the SIEF or consortia. The substance evaluation decision is not setting rules on how to share data and costs among the registrants of the same substance. The data and cost sharing should happen in accordance with the data-sharing obligation set out in REACH and in the Commission Implementing Regulation 2016/9.

Inform ECHA and the evaluating MSCA once all information requested in the decision has been submitted

Once all the requested information has been provided by an updated registration dossier, inform ECHA about this using the webform indicated in the notification letter[39].

Inform the evaluating MSCA by e-mail.

- The evaluating MSCAs' contact information is provided in the CoRAP list published on ECHA's website[40].

If all requested information cannot be submitted according to the deadlines specified in the decision, complete the ECHA webform and include any relevant explanations and supporting evidence concerning the status of any pending information requirements.

- At the same time, inform the evaluating MSCA about the dossier update situation. This interaction should enable the evaluating MSCA to have a fully informed view for deciding whether to propose specific actions.

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[39] https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx
[40] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

1.13 Take note of ECHA's Guidance updates

ECHA has continued to develop and update REACH Guidance in 2017. The following updated Guidance documents were published on ECHA's website during the year.

- Corrigendum to the Guidance on data sharing (version 3.1), published 13 January 2017.
- New and updated appendices on nanomaterials to Chapters R.6, R.7a, R.7b and R.7c of the Guidance on Information Requirements and Chemical Safety Assessment, published 24 May 2017.
- How to prepare registration dossiers that cover nanoforms: best practices (version 1.0), published 24 May 2017.
- Corrigendum to the Guidance for identification and naming of substances under REACH and CLP (version 2.1), published 1 June 2017 in all EU languages.
- Update to the Guidance on requirements for substances in articles (version 4.0), published 28 June 2017.
- Update to the Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.11, Part C and specific sections of Chapters R.7b and R.7c (related to PBT/vPvB assessment) (versions 3.0/4.0), published 28 June 2017.
- Update to the Guidance in a nutshell on registration (version 3.0), published 5 July 2017.
- Update to the Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.7a, Sections R.7.5 on Repeated dose toxicity (version 6.0), published 19 July 2017.
- Update to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (version 3.0), published 4 July 2017.
- Update to the Guidance on the application of the CLP criteria (version 5.0), published 4 July 2017.

ECHA invites you to take note of these new or updated resources[41] and to update the relevant parts of your dossiers, where appropriate. ECHA will consider the new approaches described in the Guidance in ongoing and future dossier evaluations.

1.14 Consider the impact of the United Kingdom's withdrawal from the EU on your registration

As of September 2017, ECHA has been providing companies with advice to help them prepare for the expected impact of the UK's withdrawal from the EU. This is published in the Q&A section of ECHA's web pages on the matter[42]. ECHA is continually updating the information it provides on these pages as the withdrawal process develops.

ECHA recommends that you consult this information and its updates over the coming months and beyond, until the UK's withdrawal takes effect. The ongoing negotiation process underlines the importance of the recommendation to keep yourself up to date on ECHA's evolving advice on the probable impact of the United Kingdom's withdrawal from the EU.

[41] ECHA's Guidance web pages https://echa.europa.eu/support/guidance
[42] https://echa.europa.eu/uk-withdrawal-from-the-eu

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