

# Evaluation under REACH Progress Report 2016

Executive summary and recommendations to registrants

**Disclaimer:**

The report includes recommendations to potential registrants to improve the quality of future registrations. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not represent the position that the European Chemicals Agency may adopt in a particular case.

To correct any errors or inaccuracies that may appear in the text, the European Chemicals Agency is entitled to modify or revise the document at any time.

**Evaluation under REACH: progress report 2016 – Executive summary and recommendations to registrants**

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**This is an extract of ECHA's Evaluation under REACH progress report 2016. 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>**

## Executive summary

The report describes the results of ECHA's evaluation activities in 2016 and provides recommendations to registrants to foster improvement in the quality of registrations.

Registrants are encouraged to consider them and to be proactive in updating and improving their dossiers with any new and/or relevant information. Continuous improvement of the hazard, use and exposure information in the registration dossiers will lead to more accurate risk assessments and safer use of the chemicals.

### Implementation of ECHA's integrated regulatory strategy

In 2016, ECHA advanced the implementation of its integrated regulatory strategy, which has brought together all the processes under the REACH and CLP regulations. The strategy aims to contribute to achieving the ambitious goal of the United Nations on sustainable chemicals management: that chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment by 2020.

Both dossier and substance evaluation are essential in the implementation of the strategy. They are processes for ensuring that the data submitted by the registrants is adequate for correct classification and labelling, assessment of risks and for concluding whether regulatory risk management measures are needed. The prioritisation and selection of substances of potential concern for evaluation is now based on the common screening that also serves the identification of priority substances for regulatory risk management measures.

### Outcomes of compliance checks

In line with the strategy, ECHA reserved most of its evaluation capacity for compliance checks on the registrations of substances manufactured in or imported to Europe in volumes over 100 tonnes per year that may require substance evaluation or risk management measures.

Based on the regulatory strategy, the evaluations focused on the higher tier human health and environmental standard information requirements which are relevant for identifying CMR (carcinogenic, mutagenic and reprotoxic) and PBT/vPvB ((very) persistent, bioaccumulative and toxic) substances.

Of the evaluations concluded in 2016, 156 (85 %) were performed on the dossiers of such high-priority substances. This was a significant increase (over 50 %) in comparison to 2015, the first year of regulatory strategy implementation. The work involved the evaluation of over 1 200 higher-tier human health and environmental endpoints.

As a result of these evaluations, 805 standard information requests were made in the draft decisions, 550 of which addressed higher-tier human health and environmental endpoints. These results confirm that there are important data gaps in the dossiers of substances of potential concern.

A total of 184 new compliance checks were concluded by ECHA in 2016. Of these, 168 cases (91 %) led to a draft decision and 16 (9 %) were concluded with no further action. This result merely reflects the effectiveness of the screening and selection of dossiers and cannot directly be used to assess the overall rate of compliance of all registration dossiers.

For 152 dossiers, ECHA adopted decisions, mainly based on the draft decisions issued in the previous year. These decisions contained 597 standard information requests. The non-compliances most commonly addressed in these decisions were prenatal developmental toxicity, short- and long-term aquatic toxicity, substance identification and composition, mutagenicity or genotoxicity and issues relating to the chemical safety reporting including DNELs, PNECs and PBT assessment.

### **Testing proposals**

An important milestone in REACH and ECHA's Work Programme 2016 was achieved when all testing proposals submitted in the 2013 registrations were examined by 1 June 2016, as required by the REACH Regulation. During the past year, ECHA examined 164 testing proposals and issued 133 testing proposal draft decisions containing 325 standard information requests. ECHA adopted 116 decisions containing 260 standard information requests.

### **Follow-up evaluation of compliance check and testing proposal decisions**

In 2016, ECHA concluded 355 follow-up evaluations of compliance checks and testing proposals. In addition, a milestone of 1 000 completed follow-up evaluations under the REACH Regulation was achieved. This is an important contribution to improved safety of chemicals.

Regarding the outcome of the follow-up evaluations in 2016, 92 % (565) of the endpoints originally identified as not complying with the REACH information requirements are now compliant.

During the past year, ECHA issued 33 statements of non-compliance (SONCs) following a dossier evaluation decision and inviting Member States to consider enforcement action.

Furthermore, ECHA was able to close 37 SONCs with an Article 42(2) notification following a dossier update by the registrants after the national enforcement authorities had been involved in the cases. At the end of 2016, there were 65 unresolved SONCs notified to the Member State authorities since 2012.

### **Progress in substance evaluation**

Following the earlier annual rounds of substance evaluations, ECHA adopted 26 decisions containing 84 information requests to verify the suspected concerns. Of the 48 substances evaluated during 2015, the evaluating Member States concluded that 32 required further information to clarify the suspected concerns. Consequently, ECHA sent draft decisions to the registrants of these substances.

In 2016, ECHA published 20 substance evaluation conclusion documents prepared by the evaluating Member States, hence completing the substance evaluation process and concluding on whether the risks are sufficiently controlled with existing measures, or proposing EU-wide risk management measures. In 9 cases, the evaluating Member State concluded that EU-wide risk management measures were needed.

The interplay between compliance check and substance evaluation was further clarified in 2016 with the aim to prevent postponement of the substance evaluation, and consequent delays in the identification of regulatory risk management. Whenever possible, a compliance check is performed well before substance evaluation starts. This practice is in line with the Board of Appeal finding that dossier evaluation should normally come before substance evaluation (Case A-005-2014). However, there are situations where the performance of the two processes in parallel is feasible and is the preferred fastest route.

### **Extended one-generation reproductive toxicity study (EOGRTS)**

Following the changes in the information requirement for reproduction toxicity adopted by the Commission in 2015, ECHA continued systematically addressing the data gaps in this endpoint.

During 2016, ECHA sent 63 draft decisions on testing proposals and compliance checks with details on study designs of EOGRTS to registrants for their comments. Fifty (50) draft decisions were referred to the Member State competent authorities (MSCAs) for commenting.

Out of these, the vast majority (33) received proposals for amendments and were referred to the Member State Committee (MSC). Only one (1) draft decision was subsequently referred to the Commission for decision making due to differing views on the EOGRT study design whereas the other decisions were or are being adopted by ECHA.

This indicates progress in aligning views between ECHA and the MSCAs on the application of this important and complex study guideline under REACH. It is now expected that the majority of the 216 cases referred earlier to the Commission for decision making will be re-submitted as testing proposals to ECHA at the end of 2017 or in early 2018.

### **Avoiding unnecessary animal testing**

In 2016 ECHA consolidated the implementation of the European Ombudsman friendly solution from 2015 in its process and now requests all registrants submitting new testing proposals involving testing on vertebrate animals to provide their considerations on alternatives as part of the dossier. These considerations are published together with the testing proposals when the third party consultation on a testing proposal is launched.

New supporting material on alternative methods was published: a practical guide, updated guidance on various information requirements where new methods have become available, new web pages and a webinar.

### **Use of other measures**

The use of other measures than dossier and substance evaluation plays an important role in improving the overall dossier quality under the integrated regulatory strategy.

Besides providing general advice and communication to registrants, ECHA uses targeted campaigns to registrants with potential deficiencies in their dossiers. Overall, the results show that complementary measures can stimulate registrants to be more proactive, and update their dossiers on the key information requirements.

In 2016, ECHA launched a targeted letter campaign on 270 shortlisted substances, informing registrants that their substance is shortlisted, i.e. the substance is under Member States competent authorities' scrutiny. The letters invited registrants to improve

the dossier quality in advance of any compliance checks or other regulatory process that may follow the common screening. These letter campaigns have proven to be quite efficient. For example, the dossiers within the scope of the 2016 shortlist, 40 % were updated within four months of the letters being sent. Based on the common screening, ECHA regularly publishes a list of substances that may be subject to compliance check.

During 2016, new actions were launched on already submitted dossiers, to ensure the 'one substance, one registration' principle, and to re-open the completeness check for previously submitted dossiers in certain circumstances.

Important other measures supporting the integrated regulatory strategy were the release of IUCLID 6 and REACH-IT 3 in mid-2016. This enabled an enhanced completeness check on both initial and update dossiers to be implemented, bringing a number of improvements to the structure and availability of information in the dossier, which will also facilitate dissemination. In particular, this included manual checks by ECHA that improve among other things elements of the substance identity and robustness of data waivers.

### **Ensuring availability of key information on priority chemicals**

All in all, significant progress was made in the implementation of ECHA's integrated regulatory strategy. The REACH evaluation processes are the regulatory instruments assigned to ECHA for ensuring that registrants comply with the information requirements, that unnecessary testing on animals is avoided and that any concerns on risks caused by chemicals to human health or environment are effectively clarified.

They work in conjunction with other REACH and CLP processes and complementary measures, towards the common objectives set for the strategy.

This report explains how data gaps in priority substances are being closed by legally-binding decisions and other measures. As a result, the missing data is being generated, ultimately allowing authorities to draw conclusions on whether further action by authorities is required.

## Key recommendations to registrants

### ENSURE THE SAFE USE OF YOUR SUBSTANCE BY KEEPING YOUR DOSSIER UPDATED

- Regularly review your registration dossiers and update them with any new and/or relevant information including, where applicable, an update of the chemical safety report and/or tonnage band change.
- If you are informed that your substance will be under scrutiny for any evaluation or regulatory process in ECHA (you received communication or you see it on ECHA's website), try to address the identified concern by revising related information in the registration dossier, that it is compliant with the information requirements.

### EXPOSURE ASSESSMENT AND RISK CHARACTERISATION MUST COVER ALL HAZARDS

- Exposure assessment and subsequent risk characterisation must be performed for substances subject to registration (>10 tonnes/year), where the registrant concludes that the substance meets any of the criteria to be classified hazardous, i.e. for human health effects, or for environmental effects, or for physicochemical hazards listed under Article 14(4) of REACH.
- This means that once triggered by the conditions of Article 14, exposure assessment and risk characterisation must cover all hazards identified based on information requirements laid down in Annexes VII to XI, and is not limited only to classified hazards.<sup>1</sup>
- "Identified hazards" go beyond "classifiable hazards"<sup>2</sup>. The term also covers
  - hazards for which currently no classification criteria exist, but where there is evidence that the substance can cause adverse effects (e.g. typically relevant for soil and sediment).
  - hazards for endpoints for which there are classification criteria, but where the dose/concentration triggering effects in the test is lower than the threshold for classification, and so the substance is not classified for the endpoint.
- The safety data sheet must include information on all hazards identified and not only those leading to classification under the CLP Regulation.

### FAMILIARISE YOURSELF WITH THE REACH REQUIREMENTS FOR SKIN CORROSION OR SKIN IRRITATION, SERIOUS EYE DAMAGE OR EYE IRRITATION, ACUTE DERMAL TOXICITY AND SKIN SENSITISATION

- Consider and use alternative methods whenever possible. Due to the sequential nature of the REACH revised standard information requirements, and irrespective of the annual tonnage of the substance, new data for skin and eye irritation must be generated with *in vitro* testing. If the *in vitro* results are adequate for classification and labelling or risk assessment, no further *in vivo* testing is needed.
- Ensure that the chosen test method is suitable for the substance to obtain adequate information from the *in vitro* studies.
- For further advice on how to use *in vitro* methods and other alternatives, check the updated *Chapter R.7a of ECHA Guidance on information requirements and chemical safety assessment* related to skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity.

<sup>1</sup> Decision of the Board of Appeal of 28 June 2016 in Case A-015-2014, *BASF SE*.

<sup>2</sup> See also ECHA Guidance part B and part D

[https://echa.europa.eu/documents/10162/13643/information\\_requirements\\_part\\_b\\_en.pdf/7e6bf845-e1a3-4518-8705-c64b17cecae8](https://echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf/7e6bf845-e1a3-4518-8705-c64b17cecae8)

[https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_part\\_d\\_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df](https://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df)



#### **PREPARE YOURSELF FOR THE REACH 2018 REGISTRATION**

- If you have pre-registered substances that you manufacture or import from outside the EU above one tonne but not more than 100 tonnes per year and have not already registered them, the REACH registration deadline of 31 May 2018 concerns you.
- Consult the information and advice ECHA developed especially targeting inexperienced registrants preparing for 2018 registration, through the REACH 2018 one-stop-shop web page: <https://echa.europa.eu/reach-2018>.
- Review Phase 4 of ECHA's information<sup>3</sup> more specifically, which will guide you step-by-step through the process of assessing hazard and risk, and refer to the available practical guides<sup>4</sup>.
- Allow sufficient time to understand your requirements, to get organised with your co-registrants, to determine if you need to generate data.
- Remember to consider testing on animals only as a last resort, once you can ascertain that alternatives are not suitable for a property of your substance.
- Before submitting the dossier, use the validation assistant in IUCLID to do a preliminary check of the completeness of your registration.
- If you and your co-registrants conclude that no test needs to be undertaken for certain endpoints, make sure to provide a scientific justification based on the Guidance documents.

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<sup>3</sup> <https://echa.europa.eu/-/reach-2018-assess-your-substance-to-show-safe-use>

<sup>4</sup> <https://echa.europa.eu/practical-guides>

## 1. Recommendations to registrants

We advise all existing and future registrants to read this section carefully.

ECHA's recommendations are based on the most frequent shortcomings observed when evaluating dossiers and aim to provide advice on how to improve the quality of registration dossiers. They contain technical and scientific information that is of most use when preparing or planning to update the technical dossier and/or chemical safety report.

In 2016, to support future registrants, ECHA has published practical advice on information requirements and how to avoid unnecessary testing on animals as well as on ways to gather information, as part of ECHA's REACH 2018 Roadmap<sup>5</sup>. For an overall picture on the information requirements, we recommend reading the *Practical guide for SME managers and REACH coordinators*<sup>6</sup>. It covers the information requirements for registering substances from 1 to 100 tonnes per year. This guide aims to support small and medium-sized enterprises with their obligations. The content of the guide is also relevant for registrants regardless of their deadline and is available in 23 EU languages.

In addition to the advice provided in this report, the shortcomings observed in previous years of evaluation have already been highlighted in the previous evaluation reports. These reports, practical guides and illustrative practical examples are available on ECHA's website<sup>7</sup>. All of the advice given on the previous evaluation progress reports are still relevant, even though not repeated here.

### 1.1. Communication with ECHA during evaluation

Below are some recommendations on how to communicate with ECHA<sup>8</sup> and the Member States during the different phases of the dossier and substance evaluation processes.

#### **Cease of manufacture after a (draft) decision does not relieve you from all obligations**

If you indicate the cease of manufacture or import in REACH-IT after a draft decision has been notified to you, but before the decision is adopted, Article 50(3) of the REACH Regulation applies. This means that the registration will no longer be valid, the ongoing decision-making procedure will be terminated and no further information will be requested. In all cases that fall under Article 50(3), ECHA confirms with the registrants that they understand the consequences before invalidating the registration.

In contrast, if you inform ECHA of a cease of manufacture after a dossier evaluation decision has been adopted, you still have to fulfil the requests in the decision. Cease of manufacture or import after a decision has been adopted falls under Article 50(2) of the REACH Regulation. This means that the tonnage is set to zero, the registration stays valid but becomes inactive, and no further information will be requested on that substance unless the manufacture or import restarts. However, any decisions adopted before the cease of manufacture still apply.

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<sup>5</sup> <https://echa.europa.eu/-/reach-2018-assess-your-substance-to-show-safe-use>

<sup>6</sup> <https://echa.europa.eu/practical-guides>

<sup>7</sup> How to improve your dossier and lessons learned from dossier evaluation  
<https://echa.europa.eu/support/how-to-improve-your-dossier/lessons-learned-from-dossier-evaluation>

<sup>8</sup> More details in practical guide How to communicate with ECHA in dossier evaluation:  
<https://echa.europa.eu/practical-guides>

## Dossier evaluation

If you have received a draft decision for your comments:

- Upon receipt, share the relevant requirements and reasoning of the draft decision with the members of your joint submission;
- Discuss and coordinate the response with the members of the joint submission;
- Send your consolidated comments to ECHA within the given deadline.

ECHA offers lead registrants an informal opportunity to clarify the content of draft decisions and the decision-making process. If you receive such an offer, inform your member registrants to explore how to make the best use of it.

If you think the time ECHA gives in the draft decision is not enough for performing the tests requested, you should discuss with your member registrants and the testing laboratories. After the discussion, you may consider asking ECHA for more time. If you do so, make sure you explain why extra time is needed, and provide written evidence from the laboratories.

## Substance evaluation

During substance evaluation, maintain good communication with ECHA and the evaluating Member State, as well as within your SIEF.

- Coordinate your comments with co-registrants during the relevant steps of the decision-making process and provide a single set of consolidated comments. Registrants' coordination to speak in one voice is appreciated, as has mostly been the case so far.
- Registrants should update their dossiers with detailed information on exposure before the substance evaluation is started i.e. at the stage when the draft CoRAP update is published.
- Be in contact with your downstream user or relevant downstream user association to gather the relevant exposure and use condition information. The evaluating Member State normally talks with the lead registrant to clarify the exposure and risk assessment.
- Because the draft decision commenting period is only 30 days, make sure you are prepared to receive the draft decision.
- Registrants must make every effort to reach an agreement on who will perform testing on behalf of the other registrants. They must also inform ECHA accordingly within 90 days from the date of the decision under Article 53(1) of the REACH Regulation (for requests suspended as a consequence of an appeal filed against a decision, the 90-day timeline for informing ECHA begins from the date of the decision of the Board of Appeal).
- Inform the evaluating Member State and ECHA of the relevant update when the requested information is submitted.

Further guidance is provided in the factsheet on substance evaluation.<sup>9</sup>

## Decision making

If the Member States have not proposed any amendments on the draft decision, you will receive a public (redacted) version of the adopted decision to check for any remaining confidential information a few months after the commenting period is over. Make sure you inform ECHA within the given deadline, so that there is no confidential information left in the decision before it is published. The decision is then published by the Agency.

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<sup>9</sup> [https://echa.europa.eu/documents/10162/13628/fs\\_substance\\_evaluation\\_en.pdf](https://echa.europa.eu/documents/10162/13628/fs_substance_evaluation_en.pdf)

If Member States propose some amendments, you will receive them from ECHA for your comments. At this stage, only your comments on the proposals for amendment will be considered. If ECHA and the Member State Committee (MSC) puts your case for the Committee discussion, you as the case owner (i.e. a concerned registrant or a representative of a group of concerned registrants for joint submissions) may be invited to participate in the discussion as an observer when your case is addressed by the Committee. Should you accept such an invitation, you must conform to the *ECHA Code of Conduct for Case Owner Observers at MSC meetings*.<sup>10</sup>

You can influence and help the MSC's decision making by being well-prepared. This means understanding the science required to show how your substance can be safely used. At the MSC meeting, you should focus on clarifying your written comments to the proposal for amendments. If your comments do not address the amendments but refer to the draft decision as a whole, they will not be considered because they fall outside the MSC's scope.

You can review recent decisions (available on ECHA's website) which may help you explain your own dossier to the Committee. You may want to talk with your consortium or other accredited stakeholders who have observed MSC discussions before. They might have something to teach you about how to improve your dossier, and for getting the most out of the decision-making process.

### **After the decision is taken, provide the requested information by the deadline**

This will ensure a smooth follow-up process, and minimise the risk of any enforcement action.

- Make sure that you use the contact channel provided in the communication, along with any keyword suggested. This allows for a timely and efficient handling of your reply. ECHA cannot extend the deadline in the decision.
- Any adaptation to the requests in the decision is the registrant's responsibility and ECHA will assess the validity of any such adaptations only after the deadline has expired.
- Studies should be reported comprehensively, to enable ECHA to make an independent assessment.

Further guidance is provided in the factsheet on follow-up to dossier evaluation decisions.<sup>11</sup>

## **1.2. Registration and updates**

### **Make sure that your studies and data are ready before you submit your dossier**

Set out your plan for registration. Make sure that the information needed to fulfil your information requirements will be available for entering into IUCLID. Submit it on time.

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<sup>10</sup>

[https://echa.europa.eu/documents/10162/13578/code\\_of\\_conduct\\_msc\\_case\\_owners\\_en.pdf](https://echa.europa.eu/documents/10162/13578/code_of_conduct_msc_case_owners_en.pdf)

<sup>11</sup>

[https://echa.europa.eu/documents/10162/13628/factsheet\\_dossier\\_evaluation\\_decisions\\_followup\\_en.pdf](https://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf)

Carefully check your information requirements and possibilities for adaptations. The adaptation should be chosen from picklists in IUCLID 6. It is not possible to state reasons for not having the data or not wanting to generate data for the substance.

If still you do not have some of the required information (e.g. if you have ordered tests in a timely manner but have not received the results in due time), follow the instructions provided by the Directors' Coordination Group.<sup>12</sup> Do not simply state that you will submit the information later.

### **Use the validation assistant plugin for IUCLID when preparing your registration**

The IUCLID 6 validation assistant is a tool that is available for you to check your IUCLID substance datasets and dossiers before submitting your registration dossiers to ECHA.

In addition to verifying business and completeness check rules relevant for a successful submission of the dossier in REACH-IT, the validation assistant also contains the quality checks module that warns you of deficiencies and inconsistencies found in your dossier.

You should run the plugin on your substance datasets and dossiers and correct all reported issues before submitting them to ECHA. The quality checks are updated regularly with experience from ECHA's evaluation.

### **When forming a joint submission, agree to allow the publication of the name of the lead registrant on ECHA's website**

This allows downstream users to see the information on ECHA's website. Otherwise, the joint submission information cannot be published if the substance identity has been declared confidential in already-existing registrations by the lead and all members.

If the lead registrant does not agree to the publication of its company information with the substance identity, the published list will only indicate "Available in REACH-IT". This is because REACH-IT will always display the contact details of the lead registrant or the assigned third-party representative to those who have registered, pre-registered or inquired for the substance in addition to the web page published information.

## **1.3. Substance identity and physico-chemical hazard data**

### **Provide clear information on your substance identification profile**

Substance identification is an obligation for each registrant, so it cannot be left to the lead of the substance information exchange forum (SIEF). The substance identity information in each registration dossier must be specific for the substance that is registered by a given legal entity.

The key elements of the substance identity information that must be included in the registration dossier consists of the substance name and related identifiers, molecular and structural formulae (if applicable), composition, and analytical data.

The current IUCLID version enables the substance identification profile (SIP) to be reported in the form of the boundary composition of a substance. Pay specific attention when reporting this information. In particular, you should ensure consistency with compositional information given in relation to each legal entity.

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<sup>12</sup> <https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues>

Make use of support and services for improvement of the data quality, including the substance identity information ECHA provides. Use the quality checks in the IUCLID 6 validation assistant to verify common shortcomings and inconsistencies in the substance identification information. By correcting these quality issues before submitting the dossier to ECHA, you may avoid follow-up actions at a later stage.

### **Provide precise information on the composition of the test material**

You should provide all compositional information of the material used when carrying out tests for meeting REACH information requirements. Such information has to be included in the appropriate fields available in IUCLID 6. The correctness of the information given on the specific composition of the tested substance is an essential element for assessing the properties of the substance jointly submitted.

You are responsible for ensuring the accuracy of the reported data.

### **Some tests need to be performed according to the methods set out in the CLP Regulation**

You need to perform all tests for physico-chemical hazards according to the methods set out in the CLP Regulation. You will thereby ensure that the results can be adequate for classification and labelling under the CLP Regulation and that they are consistent with the United Nations' Recommendations on the Transport of Dangerous Goods manual of tests and criteria.

Consult ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7a: endpoint specific guidance (version 5.0, December 2016)<sup>13</sup>, which has been updated to clarify this requirement.

## **1.4. Good laboratory practice must be complied with in (eco)toxicological test**

Make sure that your (eco)toxicological test are conducted by a test facility complying with the principles of good laboratory practice provided for in Directive 2004/10/EC.

ECHA will continue to verify compliance with the good laboratory practice and request GLP-study audits.

## **1.5. Testing on animals must only be undertaken as a last resort**

### **Actively explore all possibilities to use existing information and alternative methods in meeting information requirements**

Remember that the REACH annexes are applied sequentially. Therefore, Annex VII requirements for *in vitro* irritation testing should be fulfilled before considering the Annex VIII *in vivo* test methods. However, ECHA recommends that to fulfil the acute oral toxicity endpoint (Annex VII), you first perform an Annex VIII study (namely the sub-acute repeated-dose toxicity (28-day) study) and use, where applicable, the results within a weight-of-evidence approach.

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[https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r7a\\_en.pdf/](https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/)

Also, you have the obligation to share data as any other registrant under the REACH Regulation irrespective of the phase-in or non-phase-in status of their substance.

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

### **Testing proposals involving animal testing needs to be accompanied with your considerations on alternatives**

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. When your testing proposal involves testing on vertebrate animals, you have to include your considerations on alternatives methods in the dossier documentation. ECHA will publish this information together with the testing proposal and take your considerations into account when examining the case.

Testing proposal consultations provide an opportunity to submit any valid information that may address the hazard endpoints in question and may make animal testing unnecessary.

### **Start with *in vitro* tests for skin and eye irritation and for skin sensitisation**

If new data for skin and eye irritation and for skin sensitisation needs to be generated, you will have to perform them *in vitro* first. This is due to the sequential nature of the REACH standard information requirements, and irrespective of the annual tonnage of the substance.

For serious eye damage/eye irritation, *in vivo* testing is still needed in some cases, as there is no test method available currently that can be used for direct identification of category 2 eye irritants. The current test methods can identify substance causing serious eye damage (category 1) and substances not requiring classification.

For skin sensitisation, when the *in vitro* test will not enable the appropriate classification to be concluded on, or will not be suitable for the test substance, an *in vivo* test, the murine local lymph node assay (LLNA) must be performed only as the last resort.

Always justify any deviations from the sequential testing in your dossier. Unjustified *in vivo* testing when non-animal alternatives are available may lead to compliance check or direct enforcement action.

### **Grouping and read-across**

Use ECHA's Read-Across Assessment Framework (RAAF)<sup>14</sup> to check the robustness of your read-across adaptation. Familiarity with RAAF is essential for adapting standard information requirements by using grouping and read-across.

You can use the RAAF to identify the aspects of read-across justifications that ECHA considers to be crucial and can assess the robustness of read-across adaptations against these aspects. Expert advice is most likely needed.

Structural similarity is not sufficient on its own to establish a basis for prediction of properties between substances. Show how structural similarity and dissimilarity are connected to the prediction and create a data matrix, allowing side-by-side comparison of properties.

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<sup>14</sup> <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

- Justify the selection of the source substances proposed.
- Specify the identity of all substances involved. Consider impurities and potentially different substance compositions also when developing a read-across argument.
- Justify the prediction based on read-across adequately and provide supporting and credible information. Adequately document the scientific reasoning. Give a hypothesis-driven justification why the data from one substance can be used to fill the data gap for another substance. Do that for each property. The hypothesis must address why structural differences between the substances do not affect the prediction of the property under consideration.
- Make sure that the source studies used comply with the information requirement under consideration. Study results of source studies must be included in the dossier in the format of robust study summaries.
- Analyse experimental data to confirm the proposed hypothesis.
- Provide (toxico)kinetic information to make the read-across hypothesis more robust.
- Other substance-specific supporting information may be needed to support your arguments.

### Weight of evidence

Registrants are advised to explain why and how the individual lines of information for a substance lead to the assumption/conclusion that it has or has not a particular dangerous property. The associated uncertainties and their impact should be addressed, e.g. related to:

- Key parameters not covered in comparison with the default test method;
- Test duration covered in the lines of evidence not adequate to cover the information requirement;
- Missing quality assurance procedures;
- Unclear substance identity of the test material used for a piece of information;
- Insufficient reporting in the sources for the information.

If an adaptation based on weight of evidence is proposed, the individual lines of evidence and the justification should provide a sufficient confidence level when compared to information expected with the default test.

### Quantitative structure-activity relationships

The practical guide on how to use and report quantitative structure-activity relationships ((Q)SARs) is available on ECHA's website<sup>15</sup>. This updated version contains a recommended strategy for how to use (Q)SARs, how to check the validity of the (Q)SAR model and whether it falls in the model applicability domain.

Four examples are presented for endpoints where the mathematical models such as (Q)SARs can be used to derive the knowledge from available experimental data and can be applied to a substance in a relatively safe manner.

Despite the effort of ECHA to provide examples with different tools, there is a significant variation between the tools in terms of available databases and modelling approaches. The OECD QSAR Toolbox<sup>16</sup> is a good source to find experimental data and to relate it to chemical structure.

- Consult the manual "How to prepare registration and PPORD dossiers" for practical direction how to present their read-across information in IUCLID 6.

<sup>15</sup> <https://echa.europa.eu/practical-guides>

<sup>16</sup> <https://echa.europa.eu/support/oecd-qsar-toolbox>



- For statistical models, which are complex by the type and number of descriptors and/or modelling algorithm, follow the recommendation of ECHA's *Guidance (Chapter R.6)* on how to check validity.
- Provide information in the (Q)SAR prediction reporting format (QPRF). The (Q)SAR model reporting format (QMRF) alone is not sufficient.
- For complex health endpoints (e.g. reproductive and developmental toxicity, repeated dose toxicity), there is often no model to predict a result of a whole study. If such models are attempted, they can only be used for screening purposes.
- Present the prediction results accompanied by an estimated error of the prediction and description of any other possible uncertainty.

## 1.6. Extended one-generation reproductive toxicity study

Familiarise yourself with the technical report ECHA published in September 2016. It explains how ECHA identifies and concludes on the design of the extended one-generation reproductive toxicity study (EOGRTS) under dossier evaluation and discusses the crucial information sources for defining the EOGRTS design and triggering the study itself<sup>17</sup>.

When submitting a testing proposal on EOGRTS, you must document your justifications for the study design, following the criteria in column 2 of REACH Annex IX/X, Section 8.7.3. These are explained in detail in ECHA's *Guidance on information requirements and chemical safety assessment R.7a on reproductive toxicity (chapter R.7.6)*.

Furthermore, ensure that the proposed pre-mating exposure duration and dose selection is appropriate to meet risk assessment as well as classification and labelling purposes.

You must also document the existence/non-existence of the triggers justifying the need to include the expansions (extension of Cohort 1B, Cohorts 2A and 2B, and/or Cohort 3) for testing proposals. These also need to be included in the dossier update when reporting on the study results.

If you are waiving the study for this endpoint and use alternative methods, you must consider all the expansions that are triggered for the substance e.g. if there is a particular concern for developmental neurotoxicity (Cohorts 2A and 2B), the adaptation must explain how this concern has been addressed:

- For a category approach, a plausible read-across hypothesis considers the properties and triggers from all category members and potentially other structurally similar substances;
- If weight of evidence is proposed, the adaptation must address reproductive toxicity to the extent that hazardous properties of the substance can be assumed/concluded at the sufficient confidence level compared to information expected from an EOGRTS design triggered for the substance;
- In all cases, adequate and reliable documentation to support your adaptation has to be provided.

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<sup>17</sup> How ECHA identifies the design for the extended one-generation reproductive toxicity study (EOGRTS) under dossier evaluation  
[https://echa.europa.eu/documents/10162/13630/eogrts\\_design\\_en.pdf/09123723-1df7-43cd-952b-21eb365a5d2c](https://echa.europa.eu/documents/10162/13630/eogrts_design_en.pdf/09123723-1df7-43cd-952b-21eb365a5d2c)

## 1.7. Registration and test data of substances with multiple constituents, impurities and additives

### The test method must be appropriate - also when the substance is UVCB

The test method regulation was amended<sup>18</sup> and the new provisions came into force in March 2016. It contains a new note relating to testing of multiconstituent, UVCB and mixtures:

*"Before using any of the following test methods to test a multi-constituent substance (MCS), a substance of unknown or variable composition, complex reaction product or biological material (UVCB), or a mixture and where its applicability for the testing of MCS, UVCB, or mixtures is not indicated in the respective test method, it should be considered whether the method is adequate for the intended regulatory purpose. If the test method is used for the testing of a MCS, UVCB or mixture, sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents".*

This note is applicable to testing under REACH Article 13(3).

### The chemical safety assessment must be meaningful for the UVCB substance

The main principles and elements of the chemical safety assessment (CSA) of mono-constituent substances are established and used across various pieces of legislation.

Due to the specific nature of UVCB substances, the specific considerations and non-standard approaches may need to be applied for the assessment of these substances. There is a degree of established practice on how to address UVCB substances under the REACH Regulation.

In principle, you need to ensure that the comparison of respective environmental exposure concentrations (PECs) with relevant effect concentrations (PNECs) is meaningful. ECHA's *Guidance on Information Requirements and Chemical Safety Assessment for substances requiring special considerations regarding testing and exposure, Chapter R.7.13* (Version 2.0, November 2014) specifies that "it is therefore necessary to develop a specific testing strategy to ensure that the composition of the sample to be tested in the laboratory reflects fully the composition of the likely human or environmental exposure".

Thus, even though the proper identification of UVCB substances might be challenging, it is a very important step of the CSA. This is necessary for the selection of an approach for the CSA of the UVCB substance (e.g. assessment could be based on fractions/blocks of a UVCB substance as applied for petroleum UVCB substances), which will affect the selection of relevant important endpoints and testing strategies for gathering information on those endpoints.

There are several ECHA Guidance documents and tools tailored to cater for the special nature of UVCB substances. If several complementary sets of information on substance properties may play a role in the exposure and assessment of a registered substance, "assessment entity" might be useful.

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<sup>18</sup> Commission Regulation 2016/266.

“Assessment entity”, a concept developed by ECHA together with industry, enables grouping of data within a IUCLID dataset for IT processing and transparent documentation of the safety assessment.

IUCLID 6 and Chesar 3 have been extended with the “assessment entity” concept, supporting transparent reporting of substance properties and their relationship to the assessment. This feature could be useful when the fate of (groups of) constituents differs substantially and parallel assessments may need to be carried out.

### **Characterise your substance, including the ‘unknown’ constituents, impurities and additives, to such a level that you can conclude whether the substance contains PBT/vPvB constituents or not**

A PBT/vPvB assessment is required for all substances for which a chemical safety assessment must be conducted and reported in the chemical safety report (CSR). In general, these are all substances that are registered in amounts of 10 or more tonnes per year.

A CSA can only contain negative or positive conclusions on PBT/vPvB properties of a registered substance<sup>19</sup> and its constituents, impurities and additives or testing proposals which propose testing to reach a conclusion on the PBT/vPvB properties. A CSA on a UVCB substance cannot conclude that there is insufficient information on PBT/vPvB properties of some constituents, impurities or additives, if no testing proposals are submitted.

You need to properly address the PBT properties of constituents of UVCB substances in the registration dossiers. You need to carry out the characterisation and assessment of properties of the registered substance to such a level of detail that it allows an unequivocal conclusion to be derived on the PBT properties for the registered substance as whole.

Carefully consider the constituents of UVCB substances in the PBT/vPvB assessment. The assessment does not mean that all constituents must be identified by their chemical structure, but the identity needs to be sufficiently analysed to enable the PBT/vPvB assessment to be concluded.

Only in cases where the constituents are similar with regard to fate properties, may it be sufficient to only provide data on the whole substance. In most cases, however, you need to assess the constituents either one-by-one or fraction wise.

Once available, consult the revised *REACH PBT assessment guidance Chapter R11*, which provides further advice on the issue. The publication of the revised guidance is expected by June 2017.

## **1.8. Chemical safety report**

### **Use map information can be valuable for your dossier**

Five harmonised templates to support downstream users to provide their use maps have been finalised and published on ECHA’s website.

Use maps are generated by downstream user sector organisations by collecting information on the uses and the conditions of use of chemicals in a harmonised and

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[https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r11\\_en.pdf/](https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/)

structured way. Therefore, use maps document information on uses in a sector and the associated exposure assessment input datasets for workers, consumers and the environment.

The information fields in the use maps template is aligned with input fields on use and exposure in IUCLID 6. As a service, ECHA has set up a new web page where available use map information from sectors can be made available to registrants as a single point of access.

Five sector organisations (cleaning products [A.I.S.E], adhesives [FEICA], construction products [EFCC], cosmetics [Cosmetics Europe] and imaging and printing products [I&P Europe]) have published updated/new use map information in the harmonised format, and made their files available for the ECHA web page<sup>20</sup>. ECHA gives support by providing comments on the draft use maps.

You should request realistic and up-to-date information on uses and conditions of use from your downstream user sector organisation covering the market of your registered substances. Sector organisations or single customers should provide the information in the harmonised use map format.

You should apply the information available from use maps to make a better registration dossier, i.e. basing the assessment on realistic and representative conditions relevant in their market. This will also enable you to communicate the risk management advice through the supply chain in a form that is helpful for downstream users.

Remember that you should perform an exposure assessment and risk characterisation for substances registered over 10 tonnes per year if the substance meets the classification criteria according to Article 14(4) of the REACH Regulation and must cover all hazards identified by a registrant even if they do not lead to classification under the CLP Regulation.

## Chesar

In 2016, ECHA released a new version of ECHA's Chemical Safety Assessment and Reporting Tool (Chesar)<sup>21</sup> (Chesar 3), enabling the transparent documentation of assessments for substances with a more complex behaviour (e.g. UVCBs, substances reacting on use, substances with different composition requiring different risk management) and with improved user-friendliness.

The new version allows the generation of use maps in Chesar formats, including all exposure assessment inputs so that these can be used later by registrants in their CSA.

## 1.9. Publication of chemical information

Upon request of consultation of a non-confidential version of a decision, you should carefully check the content of the decisions, to ensure that no confidential content will be published by ECHA. Instructions are provided in the accompanying notification letter.

You are advised to regularly check the (draft) CoRAP and the list of substances potentially subject to compliance check.

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<sup>20</sup> Use maps from sectors are continuously updated on ECHA's website <https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>

<sup>21</sup> <https://chesar.echa.europa.eu>

During 2016, the list of substances potentially subject to compliance check has been updated six times. This list is only indicative as ECHA may at any time open a compliance check on any dossier to verify if the information submitted by registrants is compliant with the legal requirements. You should update your respective registration dossiers with any new and/or relevant information including, where applicable, an update of the chemical safety report (CSR).

### 1.10. ECHA's guidance updates

ECHA has continued to develop and update REACH Guidance in 2016. The following updated Guidance documents were published on ECHA's website during the year:

- *Guidance on Registration* (November 2016);
- *Guidance on Identification and naming of substances under REACH and CLP* (corrigendum in June 2016 and update in December 2016);
- *Guidance on data sharing* (January 2017);
- *Guidance on information requirements and chemical safety assessment:*
  - Part D: Exposure Scenario Building - Framework for exposure assessment (August 2016);
  - Part E: Risk Characterisation (May 2016);
  - Endpoint Specific Guidance, Chapter R.7.a, Sections R.7.2 – Skin corrosion/irritation and serious eye damage/eye irritation, R.7.3 - Sensitisation and R.7.4 - Acute Toxicity (December 2016);
  - Endpoint Specific Guidance, Chapter R.7.b (February 2016);
  - Chapter R.14: Occupational exposure estimation (August 2016);
  - Chapter R.15: Consumer exposure assessment (July 2016);
  - Chapter R.16: Environmental exposure estimation (February 2016).
- *Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008* (September 2016).

ECHA has applied a two-year moratorium on updates before the 31 May 2018 deadline to any guidance that explains the registration requirements for REACH. The moratorium began on 31 May 2016, although some Guidance documents are still under review, such as the *Guidance on Nanoforms/Nanomaterials*; final versions are expected to be published in 2017. Drafts and consultation processes can be followed here: <http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach>

ECHA published a list of the REACH guidance documents still under consultation in June 2016. The list (which is updated occasionally with changes of status) shows the status of the documents and when the final version is expected to be published<sup>22</sup>.

The purpose of this stand-still period is to provide a sufficiently long period of stability for 2018 deadline registrants to undertake their preparations and negotiations in the substance information exchange forums (SIEFs) without further changes to address. Guidance documents will only be updated during the moratorium in rare cases, such as when REACH legislation has been modified or IT tools updated.

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<sup>22</sup> REACH Guidance updates relevant to the 31 May 2018 registration deadline not finalised before 31 May 2016:  
[http://echa.europa.eu/documents/10162/13564/list\\_of\\_reach\\_guidance\\_under\\_consultation\\_en.pdf](http://echa.europa.eu/documents/10162/13564/list_of_reach_guidance_under_consultation_en.pdf)

Take note of these updated Guidance documents (and, where appropriate, draft document updates) and the two-year moratorium on Guidance related to registration requirements for REACH. You are invited to prepare dossiers according to this advice and, if appropriate, to update the relevant parts of their dossiers accordingly. ECHA will take into account the new approaches described in the guidance in on-going and future dossier evaluation.

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