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Evaluation under REACH Progress Report 2013

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The report includes recommendations to (potential) registrants in order 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 constitute legal advice and does not represent the position that the European Chemicals Agency may adopt in a particular case.

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Evaluation under REACH
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Foreword from the Executive Director

Dear reader,

This is ECHA's sixth annual report on evaluation, covering the experience of evaluating dossiers in 2013 and providing recommendations to current and future registrants. It shows how the Agency can improve the quality of Europe's chemical knowledge and safety information, and how registrants can help in this cause.

Maximising the availability of high-quality data is one of ECHA's strategic objectives for the coming years. The annual evaluation reports allow us to see where improvements can be made. Through better information in registration dossiers, registrants and authorities can work together for the safer manufacture and use of chemicals in Europe.

In 2013, ECHA started activities in new operational areas that follow through the whole REACH evaluation process. The first substance evaluation decisions were taken with agreement from the Member States, while the Community rolling action plan for such evaluation was updated for the first time. The Agency continued to follow up evaluation decisions under REACH and sustained communication with Member State authorities to enforce these decisions where necessary, leading to first results. ECHA plans to consolidate and strengthen all these processes in the coming years to make REACH work even more effectively.

Under testing proposal examination, ECHA continued to make decisions so that registrants could receive permission to test where appropriate. When evaluating the dossiers, the Agency assessed all read-across and category arguments consistently.

ECHA checked 5 % of the dossiers above 100 tonnes received for the 2010 registration deadline. To reach that goal efficiently, an intelligent strategy with both "overall" and "targeted" checks was used: some randomly selected dossiers were checked extensively and others because of multiple concerns. ECHA also chose some endpoints throughout the dossier database to select dossiers that merited targeted intervention. The Agency's capacity for concluding dossier evaluations has more than doubled every year since 2009. Altogether, ECHA checked all or parts of about one third of the substances covered by the registrations submitted for the 2010 deadline.

The findings of this report show that the information quality and consistency of registration data still need to improve. With this in mind, I want to remind registrants that the registration process does not stop with a registration number. You can update and improve your dossiers at any time. Please be proactive.

My sincere thanks go to all involved staff in the Member States and at ECHA – and to registrants for their work on improving registration dossiers so far. Please take the time to carefully read the recommendations of this report.

Geert Dancet
Executive Director
European Chemicals Agency

Executive summary

This report explains ECHA's evaluation activities under the REACH Regulation in 2013, highlighting the most frequently observed shortcomings found in registration dossiers and providing recommendations to registrants. These recommendations serve as a yearly reminder for registrants of how to improve the quality of their registrations. All registrants are encouraged to consider these recommendations and to be proactive in updating and improving their dossiers.

REACH aims to support competitiveness and innovation and to protect human health and the environment while enabling the free movement of chemicals on the internal market. It places the responsibility for establishing the safe use of chemicals on the companies manufacturing and importing chemicals in the EU. They must examine the potential hazards of their chemicals and show how they are being used safely. In addition, REACH promotes the use of alternatives to testing on animals. The safe use of chemical substances can only be ascertained by reliable test results or by alternative information that is scientifically justified, along with rigorous risk assessment that reflects the real conditions of use and exposure. Continuous improvement of the hazard, use and exposure information in the registration dossiers will lead to a better assessment of risks and the safer use of chemicals.

Compliance checks are a major instrument in promoting such improvement. In 2013, ECHA reached the target of checking 5 % of the high-tonnage dossiers submitted for the 2010 registration deadline for compliance. The number of substances covered by these dossier checks is 35 % and thus much higher than 5 %. This means that ECHA has checked all or parts of about one third of the substances registered for that deadline. ECHA chose which dossiers to check using an intelligent strategy that aims to maximise the availability of high-quality data in the registered dossiers: some dossiers are picked at random and checked extensively; some others are checked extensively because of multiple concerns; yet others are picked from the whole dossier database for checking targeted endpoints that are most relevant for safe use.

ECHA has started activities in new operational areas of REACH: the evaluation of 36 substances included in the first year of the Community rolling action plan was concluded by the evaluating Member States. The first substance evaluation decisions have been taken with agreement from the Member States, several of which have been sent to the registrants concerned. The Community rolling action plan for future substance evaluation was updated for the first time. Member States have also started to enforce REACH evaluation decisions that ECHA found not to have been properly implemented by registrants.

KEY RECOMMENDATIONS TO REGISTRANTS

ECHA's recommendations are relevant both to future registrants preparing their registration dossiers for the first time and to existing registrants who plan to update. These recommendations shift the focus somewhat from those of previous years: while reminding registrants to keep registrations consistent and up-to-date, ECHA urges them to robustly substantiate any adaptation of the standard testing regime. This time, specific attention is also paid to the chemical safety reports. As more cases will go through the decision-making stage in 2014, there is also advice about how best to plan in order to react when receiving a (draft) decision.

☐ Low-tonnage registrants (one to 10 tonnes/year) – pay attention to the following recommendations on the yellow background.

1. Keep your dossier up-to-date

Relevant for low-tonnage registrants

It is your duty to submit and maintain a compliant registration, so be proactive: Integrate REACH compliance into your quality management system.

Your registration dossier must be consistent and reflect the reality of your business.

Keep talking in the SIEF (substance information exchange forum) and in your supply chain, even after receiving your registration number.

Check REACH-IT regularly: This is ECHA's way of contacting you about issues found in your dossier. If you receive a message, you need to respond promptly.

When you prepare your dossier, use all available support material from ECHA, including guidance, IUCLID plug-ins (particularly the Validation Assistant) and Chesar.

ECHA's webinars are an easy and interactive way to learn about common pitfalls and how to avoid them.

2. Know how to react if you get a (draft) decision

Relevant for low-tonnage registrants

Start to think carefully about how you will respond immediately after receiving a draft decision. The 30-day commenting period is your chance to give your views and bring your dossier into compliance.

It is even more important to keep talking in the SIEF if you receive a (draft) decision because it may impact on many registrants with the same substance: Endeavour to coordinate and respond to ECHA with one voice.

Understand the REACH decision-making procedure: The room for manoeuvre and the strict timing gets tighter as the process rolls on.

Remember ECHA and the Member States take regulatory action to help you and your customers to use the substance safely.

3. Substantiate your reasoning if you adapt the standard testing regime

Relevant for low-tonnage registrants

Be specific on the legal basis for any adaptations you make and state it clearly at each endpoint; then justify and document how you have fulfilled the conditions that allow such an adaptation.

The adaptation needs to be adequate for the risk assessment, with a comparable level of confidence as the test it aims to replace.

For QSAR (quantitative structure–activity relationship), this means attaching the documentation in the right format in the right place, justifying fully why the model is valid and how it was applied to the substance. Just providing a number from an unspecified model will not do.

For read-across and category approaches, this means showing that the substances are very likely to be similar (eco-)toxicologically, preferably with a data matrix. A read-across hypothesis without a proper justification and supporting data will not be accepted.

If you need to propose a new test after all, do so explicitly by selecting "experimental study planned" at the endpoint in your IUCLID file.

4. The chemical safety report should reflect the actual uses and risks

If your substance is PBT (persistent, bioaccumulative and toxic) after careful assessment and checking the Candidate List, show clearly in the chemical safety report how you are minimising its release.

When you derive the DNEL (derived no-effect level), justify and document any deviation from the default assessment factors presented in REACH Guidance R.8 with scientific arguments that are specific to your substance.

When assessing the exposure, consider the scope of exposure assessment based on the hazards identified for the substance.

When using a model for estimating exposure, consider the domain of applicability of the model, use appropriate modelling parameters and justify their selection.

The exposure scenarios in the report must be transparent, have exhaustive coverage and each must be specific. The operational conditions and the risk management measures have to be provided in sufficient detail and should ensure safe use.

1. Introduction to the evaluation process

To keep Europe's people and environment safe from the improper use of chemicals, ECHA endeavours to improve the understanding of risks from chemicals marketed in the EU. This report shows how ECHA improves the quality of Europe's knowledge on chemical safety, and how the registrants can help in this cause. It is compiled and published every year under Article 54 of the REACH Regulation. The recommendations in this report serve as a yearly reminder for registrants on how to improve the quality of their registrations.

ECHA's evaluation work is divided into **dossier evaluation** and **substance evaluation**. In turn, dossier evaluation consists of two types: **compliance check** (CCh) and **testing proposal examination** (TPE). The outline of an evaluation is shown in Figure 1. These processes have been developed in line with the provisions in Title VI of REACH.

After registration, ECHA pre-processes the dossiers to pick the ones to be evaluated using selection criteria depending on the type of evaluation. In substance evaluation, these result in the Community rolling action plan (CoRAP). In dossier evaluation, this may be driven by concern, or the dossiers may be randomly selected.

The main player of the scientific and legal processing is ECHA in the case of dossier evaluation. In substance evaluation, a Member State competent authority (MSCA) takes on this role for each substance, with the coordination of ECHA. The outcome of this stage may be a conclusion of the evaluation if no further information request is considered necessary, or a draft decision.

The draft decision becomes a decision taken by ECHA through the decision-making process. The registrant is entitled to comment on the draft decision. If the registrant responds and updates the dossier in a way that makes the requests in the draft decision no longer necessary, there is no need to continue the process. Otherwise, the process involves the MSCAs, and sometimes ECHA's Member State Committee (MSC) as well. The registrant is entitled to comment on the proposals for amendment submitted by the MSCAs. If the MSC cannot reach a unanimous agreement, the decision has to be taken by the European Commission instead of ECHA.

ECHA follows up all decisions in dossier evaluation. The follow-up of a decision under substance evaluation is the responsibility of the evaluating Member State. The consequences of such follow-up are explained in sections 2.3 and 2.4.4.

Previous evaluation reports[1] presented the processes in detail. On the ECHA website, there is a description of the dossier evaluation process.[2] Non-confidential versions of evaluation decisions are also published on the website.[3]

1 http://echa.europa.eu/regulations/reach/evaluation

2 http://echa.europa.eu/documents/10162/13607/pro_0017_03_dossier_evaluation_en.pdf

3 http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions

Figure 1: The process of an evaluation

2. ECHA's progress in 2013

In 2013, ECHA's drive was to evaluate substances registered in 2010 to ensure their safe use. One main achievement for ECHA in 2013 was reaching the target of compliance checking 5 % of the dossiers in the two highest tonnage levels (100 to 1000 tonnes per year and above 1000 tonnes per year) received for the 2010 registration deadline. Under testing proposal examination, ECHA continued to draft and take decisions so registrants could promptly receive permission to test where appropriate. In addition, ECHA started to take the first decisions in substance evaluation. In 2013, ECHA followed up dossier evaluation decisions in earnest and boosted its cooperation with the Member States to help them enforce decisions where necessary.

2.1 COMPLIANCE CHECKS

The 5 % compliance check target, as set out in Article 41(5) of REACH, is not only there to instil confidence in REACH by ensuring the checks cover a definite proportion of the registration database. It also contributes to achieving ECHA's strategic objective of maximising the availability of high-quality data to enable the safe manufacture and use of chemicals. Indeed, ECHA looks at dossiers already in the priority setting and preliminary examination before a check is officially opened, so in reality ECHA has scrutinised – to various extents – far more than 5 % of the dossiers.

ECHA picks dossiers for "overall" compliance checks that cover elements necessary for safe use throughout a dossier. For these extensive checks, ECHA either picks dossiers randomly or selects them using concern-driven criteria. In addition, ECHA carries out concern-driven "targeted" checks. For targeted checking, ECHA uses intelligent selection strategies to screen the whole database, with the focus on the endpoints most relevant for safe use. As the hazard information of a substance is shared by all registrants in the joint submission and is pivotal for risk assessment, ECHA has chosen to check this information first. Then, for each joint submission, ECHA may select dossiers to check from both lead and member registrants.

Ideally, an **overall compliance check** of a dossier occurs in one single assessment and decision making. In practice, every overall check occurs in stages, starting with assessing the substance identity (SID) information. If the information provided is sufficiently clear and allows ECHA to interpret the scope of the registration, the check continues with the next phase of addressing REACH information requirements on hazard data in the technical dossier. Once the hazard data is found to comply with REACH requirements, the chemical safety report (CSR) is addressed. However, the evaluation may result in more than one decision, as clarity of the SID data is a prerequisite for ensuring the dossier complies with the information requirements.

Some of these overall checks are on dossiers that are randomly selected. The rest are on dossiers that have been selected because of particular concerns: for example, dossiers that use a large number of

adaptations, including those using many read-across approaches for higher-tier endpoints.

In a **targeted compliance check**, ECHA focuses only on specific parts of the selected dossier. Here the focus is on particular concerns, for example:

- substance identity issues (often necessary to clarify during testing proposal examination),
- areas of concern: endpoints that are considered highly relevant to risk management and chemical safety (see section 2.1.2),
- chemicals that may soon be subject to substance evaluation (CoRAP substances, see section 2.4), and
- dossiers submitted outside the joint submission with many adaptations for higher-tier toxicological endpoints, even though reliable data exist in the joint submission (data-sharing concern).

For the last of these, ECHA noticed that after it took action, many registrants of such individual submissions eventually chose to submit dossiers jointly with other registrants in the substance information exchange forum (SIEF): In 17 out of 24 cases where ECHA took decisions, the registrants joined existing joint submissions; in seven other cases the registrants improved their dossier without submitting jointly. Additionally, one registrant joined an existing joint submission after a draft decision was sent.

After finding a non-compliance in a targeted check, ECHA immediately sends a draft decision to the registrant in order for the non-compliance to be addressed. When many non-compliances are found in the dossier, ECHA may escalate such a targeted check to an overall check because the dossier deserves a wider assessment.

If ECHA is not in a position to identify a specific substance covered by a registration due to the unclear substance identity information in the dossier, the Agency cannot sensibly evaluate the hazard and risk information of the substance purported to have been registered. If the identity of the substance remains unclear even after the follow-up to a decision requesting information to clarify substance identity, ECHA may invalidate the registration and withdraw the registration number.

The Agency continued the work on nanomaterials and played an active role in implementing the regulatory actions on nanomaterials stemming from REACH and CLP. In 2013, ECHA took three compliance check decisions on registered nanomaterials, requesting information on substance identity and/or granulometry. Within the context of capacity building, ECHA continued to organise training in the field of nanomaterials for its staff as well as for stakeholders. ECHA organised the two meetings of the Group Assessing Already Registered Nanomaterials (GAARN). The best-practice recommendations for registrants resulting from GAARN meetings are published on the ECHA website.[4] ECHA has convened a Nanomaterial Working Group, which is an informal advisory group consisting of experts from Member States, the European Commission, ECHA and accredited stakeholders organisations. Its purpose is to discuss scientific and technical questions relevant to REACH and CLP processes dealing with nanomaterials and provide recommendations on strategic issues. The two first meetings were organised in 2013.

Below is more detail about how ECHA achieved the 5 % check target for the 2010-deadline registrations, how ECHA continues and enhances concern-driven targeted checks, and the decisions ECHA took in 2013.

2.1.1 Checking beyond the 5 % target

ECHA has checked more than 5 % of the dossiers on the two highest tonnage bands submitted for the 2010 deadline (those where Article 23(1) of REACH applied); see Table 1. This fulfils ECHA's commitment in the Multi-Annual Work Programme 2013–2015. It also contributes to the statutory target to check at least 5 % of dossiers in each tonnage band, provided in Article 41(5) of REACH. The proportion of substances covered by these checks is much higher than 5 %: ECHA has checked all or parts of **more than a third (957 out of 2 700) of the substances** registered for the 2010 deadline.

In the table, the total number of registration dossiers in each tonnage band represents the number of complete registrations submitted by the registration deadline of 1 December

4 http://echa.europa.eu/regulations/nanomaterials

TABLE 1: REGISTRATION DOSSIERS CHECKED BY TONNAGE BAND

Tonnage band	Total number of registrations submitted for the 2010 deadline (1 March 2011)	Registrations checked for compliance (31 December 2013)	Proportion checked
≥ 1000 t/a	17 551	1 063	6.0 %
100 to 1000 t/a	1 013	58	5.7 %
10 to 100 t/a	481	6	1.2 %
1 to 10 t/a	727	3	0.4 %
Total	19 772	1 130	5.7 %

2010, as established on 1 March 2011. This number includes all registration dossiers, no matter whether they were jointly or individually submitted; but it excludes registrations of on-site isolated intermediates that are not subject to the evaluation process.

When a dossier indicates the use of the substance covered both as a non-intermediate and as a (transported) intermediate, for the purpose of this report it counts as only one registration (non-intermediate) with the cumulative tonnage band of both uses. A registration is only counted once, regardless of the number of submitted updates, while the latest successful submission determines the tonnage information and status provided. Likewise, each dossier is counted only once in the column "registrations checked for compliance" regardless of how many times it has been subject to compliance check.

In 2013, ECHA concluded all compliance checks within the 12-month legal deadline. This means if the conclusion leads to a draft decision, it was sent to the registrant within 12 months of the start of the check. Table 2 shows the outcome of these checks.

Following 61 % of the compliance checks in 2013, ECHA concluded that the dossiers did not comply with the checked REACH information requirements and draft decisions were sent to the registrants. By the end of 2013, one fifth of these have become decisions taken.

TABLE 2: COMPLIANCE CHECKS CONCLUDED IN 2013, BY TONNAGE BAND

Tonnage band	Concluded with draft decisions	Concluded without action	Total
≥ 1000 t/a	500	323	823
100 to 1000 t/a	56	29	85
10 to 100 t/a	8	3	11
1 to 10 t/a	2	7	9
Total	566	362	928

Cumulatively since 2009, ECHA has had to take such action for 66 % of checked dossiers (888 out of 1 348) and 70 % of the randomly-selected dossiers checked (122 out of 175). Since the selection criteria are not entirely random – some are intended to find cases with high potential for compliance issues – this cannot be taken to be a representative sampling to indicate the overall quality of the whole registration database. However, it does show that for many dossiers, the information quality and overall consistency still need to be improved to achieve compliance.

ECHA expects that the registrants will continue to learn about REACH compliance, so dossiers will also continue to improve. With this in mind, ECHA reminds registrants again that they can update and improve their dossiers at any time.

More than 9 000 new registration dossiers came for the second registration deadline of 31 May 2013, covering nearly 3 000 additional substances. Continuing the strategy to maximise the availability of high-quality data for safe use, in 2014, ECHA will start to check this new batch of dossiers for compliance.

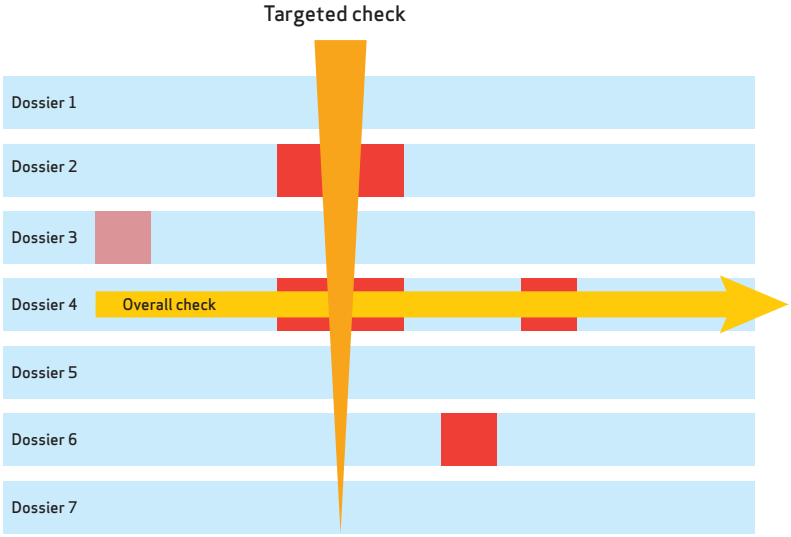
2.1.2 Enhancing concern-driven targeted checks

In 2013, ECHA enhanced the computer-assisted selection of registration dossiers for targeted compliance checks and continued implementing this approach to address severe non-compliances in all dossiers. For targeted checks, computers are used to filter the **whole registration database**, picking out dossiers with a higher potential to be deficient in priority endpoints called **areas of concern**; see Figure 2.

This is in contrast to the overall checks where substance identity information, all endpoints related to safe use of the substance and relevant parts of the CSR are evaluated in a single dossier. The endpoints of concern targeted in these checks relate especially to carcinogenicity, mutagenicity and reproduction toxicity (CMR) and environmental persistence, bioaccumulation and toxicity (PBT). ECHA also prioritises some other endpoints, such as those that influence predictions of environmental fate and exposure routes and those that can be used to adapt information requirements for other priority endpoints.

ECHA continued to expand and refine these concern-driven dossier selection criteria in collaboration

Figure 2: Comparing the coverage of "areas of concern" targeted compliance checks and that of overall checks. In this schematic pile of dossiers, an overall check examines all endpoints in a single dossier to find non-compliances (red spots). In contrast, targeted checking probes a chosen endpoint through all dossiers in the pile.



with MSCAs. The related compliance check decision-making process has been streamlined by identifying typical deficiencies and discussing beforehand with MSCA experts about how to proceed.

As a result of the targeted checks, a registrant may receive several draft decisions at different times on the same dossier. This is because the dossier has more than one non-compliance, each found during a separate round of checks. Therefore, registrants would be wise to re-examine the overall quality of their dossiers – especially for typical shortcomings as highlighted in these annual evaluation reports – when they receive a targeted-check decision, so they can avoid more draft decisions coming for similar shortcomings.

To help registrants with such an overall review, ECHA provides guidance to registrants with a series of webinars on "How to bring your registration dossier in compliance with REACH – Tips and Hints".[5] ECHA invites registrants to review the past webinars for detailed, endpoint-specific recommendations on how to improve their dossier compliance for the priority endpoints. These webinars already address the scientific rationale behind the targeted-check draft decisions. So, ECHA does not offer informal discussions during the 30-day commenting period on draft decisions for targeted checks; informal communication is only available for overall compliance checks.

2.1.3 Decisions taken under compliance check

In 2013, ECHA took 159 decisions under compliance check. Among these, 150 decisions were taken without proposals for amendments from the MSCAs. These are mostly targeted checks focusing on areas of concern (83 cases). The remaining nine decisions were taken after the MSC reached unanimous agreement on proposals for amendments, either in a written procedure or by discussion in one of its meetings. In 2013, ECHA did not refer any compliance check draft decisions to the European Commission. Table 3 presents compliance check outcomes in 2013, for all types of dossiers selected for checking (draft decisions still in the decision-making process are not included).

The information requested from the registrants by the decisions is summarised in Table 4. A decision may contain more than one request.

5 http://echa.europa.eu/support/training-material/webinars

TABLE 3: OUTCOME OF COMPLIANCE CHECK IN 2013, BY SELECTION CRITERIA

	Outcome Type					
Reason for selection	Concluded without further action[6]	Closed after draft decision[7]	Decision taken without amendment: Article 51(3)	Decision taken after ECHA MSC agreement:[8] Article 51(6)	Commission to take the decision: Article 51(7)	Total
Concern-driven overall CCh	20	3	22	3	0	48
Random	10	3	7	2	0	22
CCh targeted at areas of concern	273	84	83	0	0	440
CCh targeted to SID	6	0	6	0	0	12
CCh triggered by the substance evaluation process	41	4	8	4	0	57
CCh targeted to SID issues found during TPE	0	27	19	0	0	46
CCh targeted to other issues[9]	12	0	5	0	0	17
Total	362	121	150	9	0	642

6 Including one quality observation letter in a concern-driven overall compliance check.

7 Cases closed after draft decision was sent to the registrant (the dossier being subsequently updated with the information requested).

8 Excluding decisions that have to be split to be referred in part to the European Commission.

9 Issues relating to chemical safety report, joint submission or both.

TABLE 4: INFORMATION REQUESTED BY COMPLIANCE CHECK DECISIONS (SORTED BY ANNEX)

Type of information requested	Number of decisions
Exposure assessment and risk characterisation: Annex I	19
Robust study summaries: Annex I, 1.1.4 and 3.1.5	3
Information regarding identification and verification of the composition of the substance: Annex VI, 2	43
Brief general description of the identified use: Annex VI, 3.5	2
C&L according to CLP: Annex VI, 4	5
Physicochemical properties: Annex VII, 7	61
Toxicological information: Annex VII, 8	4
Toxicological information: Annex VIII, 8	15
… of which: *In vitro* cytogenicity study in mammalian cells: Annex VIII, 8.4.2	8
… of which: *In vitro* gene mutation study in mammalian cells: Annex VIII, 8.4.3	9
…of which: Screening for reproductive/developmental toxicity: Annex VIII, 8.7.1	1
Sub-chronic toxicity study, 90-day: Annex IX, 8.6.2	20
Pre-natal developmental toxicity: Annex IX, 8.7.2	20
Two-generation reproduction toxicity study:[10] Annex IX and X, 8.7.3	6
Ecotoxicological information: Annex IX, 9	4
…of which: Aquatic toxicity: Annex IX, 9.1	4
…of which: Bioaccumulation in aquatic species: Annex IX, 9.3.2	1
…of which: Effects on terrestrial organisms: Annex IX, 9.4	1
Developmental toxicity study in the rabbit: Annex X, 8.7.2	11
Effects on terrestrial organisms: Annex X, 9.4	1
Long-term toxicity to sediment organisms: Annex X, 9.5.1	1

10 Requesting study results that already exist.

2.2 TESTING PROPOSAL EXAMINATION

In 2013, ECHA continued to examine testing proposals. The focus here has been the consistent examination and decision making for sets of dossiers relying on read-across and category approaches.

By the end of 2013, ECHA concluded 157 testing proposal examinations by sending a draft decision (37), by taking a decision (111) or by terminating the case (nine). An examination may be terminated because the registrant withdrew the proposal after ECHA started to examine it, or because the proposal is not admissible (e.g. the test is already complete or ongoing). The evaluation of a further 27 dossiers continues beyond 2013; for these, a draft decision has not yet been issued. This last number includes the four cases involving complex category approaches, where the substance identities need to be clarified with the help of enforcement authorities.

Among the dossiers submitted for the 2013 registration deadline, ECHA has so far identified 770 testing proposals in 376 dossiers. Of these, 563 proposed to test on vertebrate animals to fulfil the information requirements in Annex IX of REACH. ECHA will evaluate all dossiers that include testing proposals relevant to Annex IX by 1 June 2016. All tests proposed on vertebrate animals will be subject to third-party consultation.

The focus of evaluation in 2013 was on compliance check rather than testing proposal examination, so there were fewer third-party consultations than in previous years. Third parties frequently sent comments on ECHA's consultations of testing proposals in 2013. In several of the comments, third parties provided scientific reasoning with references to the specific adaptation possibilities provided in the REACH Regulation. The use of read-across was proposed in at least nine comments. For example, in five of these comments (which concerned similar substances) the third party proposed use of read-across to data on systemic bioavailability of the substance. Registrants were informed of these comments for consideration.

ECHA recognises that it is difficult for the third party to provide actual data that is so reliable and substance-specific that testing can be avoided without further effort. To illustrate: in a testing proposal examination, ECHA informed a registrant that third parties had identified the availability of a non-EU guideline study on the substance and endpoint in question. To use these data, the registrant must acquire access. Subsequently, the registrant agreed a letter of access with the study owner, included the data in the registration dossier and removed the testing proposal. Consequently, ECHA did not have to take a decision on the testing proposal. ECHA notes that in 2013, on at least two occasions third parties indicated a willingness of data owners to consider making the data available to the registrant.

2.2.1 Decisions taken under testing proposal examination

In 2013, ECHA took 111 decisions under testing proposal examination. In 71 decisions taken, ECHA accepted the tests proposed by the registrants,[11] while in 37 cases the Agency modified at least one of the tests proposed. In three cases, ECHA rejected the test proposed altogether. The information requested from the registrants is summarised in Table 5. In each decision, more than one testing proposal may have been examined.

Of these 111 decisions, 25 were taken without referral to the MSC because the MSCAs did not propose amendments. For the remaining 86 cases, the draft decisions received at least one proposal for amendment from the MSCAs. Among these, in 57 cases, the MSC unanimously agreed on the decisions and ECHA accordingly took them.

Twenty-nine cases also contained proposals for a two-generation reproduction toxicity study among the 108 cases where the other testing proposals were accepted or modified. The MSC handled these proposals separately from other information requests due to recent scientific developments that require further policy consideration before the testing can be decided. After the MSC established the absence of unanimous agreement on an appropriate study for this endpoint, these draft decisions were each split into two parts. ECHA referred the part about reproductive toxicity to the European Commission for them to decide. The other part was then taken as an ECHA decision, as the MSC had reached unanimous agreement on this part.

11 Except for two-generation reproduction toxicity studies, discussed below.

TABLE 5: INFORMATION REQUESTED IN TESTING PROPOSAL DECISIONS (SORTED BY ANNEX)

Type of testing requested	Number of decisions
Physicochemical properties: Annex IX, 7	17
Mutagenicity: Annex IX, 8.4	2
Sub-chronic toxicity study, 28-day: Annex IX, 8.6.1	2
Sub-chronic toxicity study, 90-day: Annex IX, 8.6.2	45
Pre-natal developmental toxicity study: Annex IX, 8.7.2	57
Extended one-generation reproductive toxicity study: Annex IX, 8.7.3	1
Long-term aquatic toxicity testing on invertebrates: Annex IX, 9.1.5	22
Long-term aquatic toxicity testing on fish: Annex IX, 9.1.6	9
Biotic degradation: Annex IX, 9.2.1	6
Fate and behaviour in the environment: Annex IX, 9.3	3
Effect on terrestrial organisms: Annex IX, 9.4	22
Mutagenicity: Annex X, 8.4	1
Pre-natal developmental toxicity study: Annex X, 8.7.2	6
Effect on terrestrial organisms: Annex X, 9.4	25
Long-term toxicity to sediment organisms: Annex X, 9.5.1	8

TABLE 6: OUTCOME OF FOLLOW-UP EVALUATIONS PERFORMED IN 2013

	Article 42(2) without SONC issued[12]	Article 42(2) after a SONC[13]	Article 42(1)[14]	SONC[15]
TPE decisions	71	1	0	10
CCh decisions	70	5	43	22

12 All requests in the decision have been compiled with, without a SONC having to be issued.

13 A SONC and subsequent Member State actions led to a dossier update now compliant with the requests in the decision.

14 Requests in the decision have been complied with, but new requests for data are needed. Article 42(2) notification has been put on hold.

15 A statement of non-compliance following a dossier evaluation decision, stating that some or all of the requested information in the decision has not been complied with, has been sent to Member State authorities for them to consider enforcement actions. Article 42(2) notification has been put on hold. As such, the statement is triggering a transient status in the dossier evaluation process.

2.3 FOLLOW-UP AND ENFORCEMENT OF DOSSIER EVALUATION DECISIONS

In follow-up, ECHA examines whether the information requested in the decision has been provided in the latest dossier update, under Article 42 of REACH. This happens after the deadline specified in the decision has passed. Three types of outcomes are possible:

1. If the registrant updates the dossier with information that is assessed by ECHA to comply with the information required in the decision, an Article 42(2) notification is sent to the MSCAs and to the European Commission. This is to inform them that the evaluation has completed, as well as the information obtained and the conclusions made. If the registrant deviated from the information requested in the decision, but still ensured compliance with the relevant requirements of REACH by a correctly applied alternative method or another valid adaptation argument (e.g. test not technically possible), ECHA may consider the deviation from the request to be acceptable.

2. If no update is received or the update is assessed as inadequate for any of the requests in the Agency's decision, a "statement of non-compliance following a dossier evaluation decision" (SONC) is sent to the Member State concerned and, for information, to the registrant.

3. If the registrant complies with the Agency's decision but the updated data raises new concerns regarding the same information requirement, as identified by the registrant or the Agency, the Agency may issue a new dossier evaluation decision pursuant to Article 42(1) of REACH. In addition, if an update is received that complies with the Agency's decision but new concerns with other information requirements are identified as a result of the information received, the Agency may open a new compliance check procedure on the basis of Article 41 of REACH.

Enforcement is the sole responsibility of the Member States (REACH Title XIV). If the issues requested by a decision are not fully addressed by the deadline, ECHA informs the Member States of this through the SONC. Its purpose is to support national enforcement actions. Therefore, it is addressed to the relevant national enforcement authority and to the MSCA. The national authorities are asked to address the decision issues identified by ECHA within their own competence and, where appropriate, to adopt enforcement measures. The registrant receives a copy for information. Of course, ECHA expects registrants to provide the information requested in the decision after interacting with the Member State authorities. More details about follow-up and ECHA's cooperation with the Member States are available in an ECHA factsheet.[16]

In 2013, ECHA conducted 222 follow-up evaluations. Six of these were re-evaluations after an initial evaluation resulted in a SONC being issued and subsequently an updated dossier being received. The number of outcome types is summarised in Table 6. For comparison, nine SONCs (one on a TPE decision and eight on CCh decisions) were sent in 2012.

In addition, ECHA conducted follow-up evaluations on 80 quality observation letters (QObLs). In 57 cases, the QObLs resulted in an improvement of the dossier quality either by fully (38 cases) or partly (19 cases) meeting the information needs addressed. In 17 cases, the information needs were not addressed at all. In six cases, the registrants have ceased manufacture. The Member States have been informed on the results.

In view of the high costs often involved in conducting the requested tests, ECHA expects closer attention to be paid to the reporting of the results. In many cases, the robust study summaries do not comply with the specification and improvements needed to be requested. Registrants are recommended to provide clear robust study summaries, including tabular data, according to the criteria published in ECHA's *Practical Guide 3* and the relevant test guidelines. Consideration needs to be given to the inclusion of full study reports if the results need further documentation or interpretation. Also, the implications of new information on hazard endpoints for the chemical safety assessment need to be addressed, including revising the DNEL and PNEC derivation as necessary.

The factsheet mentioned above contains further advice for registrants about the follow-up process.

16 http://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf

2.4 SUBSTANCE EVALUATION

Substance evaluation aims to verify whether a substance constitutes a risk to human health or the environment from an EU-wide perspective. It contributes to achieving ECHA's strategic objective of mobilising authorities to use data intelligently to identify and address chemicals of concern. The substances prioritised for such evaluation are listed in the Community rolling action plan (CoRAP). Only registered substances can be subject to substance evaluation. MSCAs are in charge of evaluating the substances. After evaluating, they may propose to request further information from registrants if the available information does not fully address the potential risks. This request may include a test or data beyond the standard REACH information requirements.

ECHA coordinates and supports the work of Member States. ECHA is also in the position to propose amendments on the draft decisions made by the Member States. After consulting the registrants and all Member States, ECHA takes the decision on the information needed on a substance if no MSCA proposes any amendment. If amendments are proposed, ECHA takes the decision after the MSC reaches a unanimous agreement on the decision. If such an agreement cannot be reached, the case is referred to the European Commission. ECHA has published procedures describing the substance evaluation process, from updating the CoRAP to decision-making, on its website.[17]

ECHA's two priorities for substance evaluation in 2013 have been preparing the annual update of the CoRAP and supporting the decision making stemming from the evaluations performed in 2012.

2.4.1 The Community rolling action plan (CoRAP)

The CoRAP specifies the substances subject to evaluation over a period of three years. ECHA prepares the CoRAP update in close collaboration with the MSCAs, taking into account the criteria for selection of substances[18] and the opinion of the MSC. The Member States may also propose substances based on national priorities, under Article 45(5) of REACH. Each year, ECHA submits the updated draft CoRAP to the Member States by 28 February, as Article 44(2) of REACH requires. In practice, ECHA issues a draft for the CoRAP update in the preceding autumn to ensure the adoption of the CoRAP during the first quarter of the year.

For the development of the CoRAP, three sources are used for identification of potential CoRAP candidate substances:

1. MSCA notification (Article 45(5) of REACH),
2. dossier evaluation (prioritisation of a case),
3. the database of all registered substances: computer-assisted filtering and expert verification using selection criteria.

Adoption of the CoRAP 2013–2015. The first CoRAP was published in 2012, and the first update for 2013–2015 was adopted in March 2013. With this update, the CoRAP now contains 115 substances: 53 substances already published in the first CoRAP (2012–2014) and 62 newly allocated substances. The substances were distributed for evaluation in 2013, 2014 and 2015 among 22 Member States. According to the first CoRAP, 46 substances were to be evaluated in 2013. However, in 2013 there was an extra update to the CoRAP. This was because the MSC considered that one substance should be urgently evaluated, so it was added to the 2013 allocation. Thus, in total, 47 substances were subject to evaluation in 2013.

Preparing for the annual CoRAP update (2014–2016). The proposal for the CoRAP 2014–2016 update covered 125 substances, with 56 substances to be evaluated in 2014. The list contained 56 newly selected substances and 69 substances carried over from the existing CoRAP. ECHA forwarded the draft to the MSC in mid-October 2013 to collect opinions and posted a public version on its website on 4 November. Depending on the opinion of the MSC, the number and order of substances may change before the plan is adopted. In this update, the focus is on potential PBT properties, endocrine disruption,

17 http://www.echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures

18 Selection criteria to prioritise substances for substance evaluation http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

carcinogenicity, mutagenicity and reproductive toxicity, in combination with wide dispersive use, consumer exposure and high aggregated tonnage. ECHA anticipates the adoption of the CoRAP 2014–2016 update in March 2014.

2.4.2 Member States at work: evaluating the selected substances

Member States are responsible for evaluating the substances allocated to them from the CoRAP. According to REACH, the evaluation of substances listed for the **first** year starts on the day of publication of the CoRAP. From that date, the designated Member States have 12 months to evaluate substances and propose further testing. In 2013, 22 Member States contributed to the evaluation of 47 substances. The work on the substances for the years overlaps, in the sense that the Member States and ECHA are working in parallel. For example in 2013, while the decision making continues for the draft requests from the 2012 list, the Member States are already evaluating the new substances from the 2013 list.

The evaluation addresses at least the concerns originally identified in the justification documents for CoRAP listing, but this does not limit the scope of the Member States' evaluation. The Member States may also identify additional concerns during their evaluation, and propose to request further information to clarify any potential risk of the substance.

The registrants of CoRAP substances may interact with the evaluating Member State during the evaluation. This kind of communication is not mandatory under REACH, but Member States have agreed to communicate informally with the registrants at least once. The purpose is to discuss any technical issues about the information already available on the substance and to plan and agree on any dossier updates foreseen. Substance evaluation by itself should not be a reason to make a dossier update, but sometimes there can be mutual interest for having a dossier more up-to-date. However, unplanned dossier updates or those that come too late create problems for the evaluating Member State, since it is difficult to take into account updates arriving just before the deadline for sending the draft decision to ECHA.

TABLE 7: PROGRESS OF SUBSTANCE EVALUATION CASES (STATUS AT THE END OF 2013)

Evaluation year	2012	2013
Substances under evaluation	36	47
Substances with draft decisions	32	0
Substances with draft decisions unanimously agreed at the MSC	14	0
Substances with decisions taken by ECHA	2	0
Conclusion documents published	4	0
Substances whose draft decisions do not continue to decision making	1	0

As there may be multiple registrants per substance, it may not be possible for the evaluating Member State to have separate interactions with each registrant. So it is recommended that the registrants coordinate their responses, and select one registrant to speak for the others.

ECHA offered to screen the Member States' draft decisions for consistency before they are officially submitted to the Agency. With this service, ECHA aimed to ensure a harmonised approach to requesting further information. In January 2013, almost all Member States used this possibility. ECHA was able to give its feedback one month before the end of the 12-month evaluation period.

Already in 2012, tips for registrants and downstream users on how to interact during the substance evaluation process[19] were published on the ECHA website. In 2013, a working group including participants from the Member States, industry associations, the European Commission and ECHA was formed to propose the best way for evaluating MSCAs and registrants to interact. The conclusions have been published on the ECHA website.[20]

19 http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

20 http://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

2.4.3 In the pipeline: first substance evaluation decisions

For the 36 substances evaluated in 2012, the Member States submitted the substance evaluation reports, along with draft decisions where needed, to ECHA by 28 February 2013. By that deadline, ECHA received draft decisions on 32 substances. This means in four cases, the MSCA concluded that no further information on the substance was needed.

ECHA sent the draft decisions to the registrants concerned for their comments. In many cases, the registrants responded with a single, coordinated set of comments per substance. After this, the evaluating Member State referred the case for consultation, so both ECHA and other Member States could propose amendments to the draft decision. In 2013, 23 out of the 32 cases were referred. All these cases received proposals for amendments; see Table 7.

By the end of 2013, ECHA was able to take the decisions for two substances, namely isoheptane and 4,4'-isopropylidenediphenol. For one other substance, the evaluating Member State decided to conclude the substance evaluation with no further request for information after considering the registrants' comments and dossier updates that addressed the issues raised in the draft decision.

2.4.4 Follow-up of substance evaluation

After the information requested by the decision is submitted in the form of a dossier update, the MSCA responsible reviews it and decides whether further information is needed (Article 46 of REACH). The MSCA has to complete the assessment of the substance within 12 months of receipt of this new information. Then, the MSCA uses the information available to decide whether further regulatory actions on the substance are needed, and if so, which actions are most appropriate. For instance, the MSCA can propose:

- to harmonise the substance's classification and labelling,
- to identify it as a substance of very high concern for the Candidate List, or
- to restrict its use.

In 2013, no substance was at the stage when new information has been submitted following a request for further information. However, there were four substances for which the evaluating Member State did not request further information; see Table 7. For these cases, the Member States prepared conclusion documents. Out of these four cases, the evaluating Member States were satisfied of the risk management measures proposed by the registrants in two cases, whereas in the other two cases further regulatory options may be explored.

2.5 FURTHER ACTIVITIES

2.5.1 Intermediates

On-site isolated intermediates (Article 17 of REACH) and transported isolated intermediates (Article 18 of REACH) can be registered using reduced information requirements provided they meet the respective definitions and are used under strictly controlled conditions. Whether the reduced data requirements apply depends on these criteria being fulfilled.

To verify the status of isolated intermediates, ECHA uses Article 36 of REACH to request information from registrants. This provision requires registrants to "*assemble and keep available all the information he requires to carry out his duties under this Regulation*" and to "*submit this information or make it available without delay upon request […] to the Agency*". ECHA started verifying intermediate status in this way in 2011 to ensure the appropriate registration and safe use of the substances. ECHA does so by requesting the registrant to provide the following information:

- to clarify the use of the substance and conditions applied during the full lifecycle of the substance;
- to provide documentary evidence that, before supplying an intermediate to the downstream user, the registrant was **certain** about downstream intermediate use and conditions of use of the substance.

For example, ECHA may ask the registrant to provide documentary evidence (such as a copy of confirmation signed by a downstream user) that the substance at the downstream user site is used as an intermediate under controlled conditions.

In 2012 and 2013, ECHA has continued the verification of intermediate status. Currently, priority is given to substances in Annex XIV and in the Candidate List of substances of very high concern. ECHA and the national enforcement authorities need to have this information on downstream users and uses, so that they can ascertain that the substances are indeed used as intermediates and that controlled conditions are applied throughout the supply chain. Otherwise, the substances cannot benefit from the reduced registration requirements for intermediates used under controlled conditions, let alone the exemption from the authorisation and restriction processes. ECHA is currently discussing enforcement action with the enforcement authorities, for the cases where the documentary evidence was not provided by the registrant in response to ECHA's request under Article 36.

Altogether, 79 requests under Article 36 were sent to registrants in 2012 and 2013. In 29 cases, the verification process has been terminated. This takes place after the registrant has:

- submitted a standard registration instead of registering as an intermediate,
- provided enough information to confirm the intermediate status, or

- ceased manufacture by formally putting the registration tonnage to zero.

Some responses received from registrants are still being evaluated.

Some registrants have provided information showing that the substance's use may not correspond to the definition of intermediate as given in Article 3(15) and/or the substance is not used under strictly controlled conditions. This can lead to a compliance check on these registrations: one check has been initiated in 2013 on a substance in Annex XIV of REACH.

ECHA asks for the requested information to be submitted in section 13 of IUCLID through a dossier update instead of separate communications. This ensures secure communication and guarantees that the information is protected by ECHA's strict security measures for storing dossiers.

2.5.2 Classification and labelling

Classification and labelling (C&L) is an important part of the information requirements for substances registered under REACH. The registrants are obliged to provide C&L information in their registration dossiers. The dossiers have to specify the hazard classes and, if no classification is provided, give reasons as to why.

Annex VI of CLP gives the harmonised classifications for substances, as individual or group entries. In their dossiers, registrants have to follow these harmonised classifications currently in force. For hazard classes not listed in the Annex VI entry, registrants are required to self-classify according to the CLP criteria. In addition, for non-harmonised endpoints, registrants of the same substance have to agree on its C&L unless there is a reasoned opt-out.

C&L plays a role in both dossier and substance evaluation. In compliance check decisions, ECHA has required registrants to respect the harmonised

classification and/or to justify deviations in a hazard class where appropriate. For certain endpoints, adaptations under column 2 of REACH Annexes VII to X are only allowed for substances with certain classifications. Comparing the classification with the related supporting information in the registration dossiers is one of the starting points in selecting substances for the CoRAP list. Substance evaluation can eventually lead to a proposal to change or introduce harmonised classification.

2.5.3 Evaluating read-across and categories

REACH provides a possibility for the standard information requirements to be met by means other than testing the registered substance using REACH's standard testing regime. One such approach is to predict the properties of a substance by grouping and read-across. These alternatives to the standard information requirements (referred to as adaptations of the standard testing regime in Annex XI of REACH) are often used by registrants to meet information requirements that may incur great costs and large numbers of experimental animals, for example, when submitting registration dossiers for chemically similar groups of substances.

The core of every grouping and read-across approach is a scientifically credible explanation as to why a data gap for a registered substance can be filled by means of grouping or read-across. In ECHA's evaluation, the acceptance or rejection of such an approach ultimately depends on the adequacy of its explanation. Authorities must be confident that the hazards of the substance are not underestimated and that a meaningful use of the result in the context of REACH is possible, in particular for the purposes of risk assessment and C&L. In other words, it has to be demonstrated that the test result of the alternative substance is equal in relevance with the result of the standard test on the registered substance that it replaces.

The evaluation of grouping and read-across within ECHA is necessarily focused on the quality of the explanation provided by the registrant. An adequate explanation is an absolute prerequisite for the acceptance of a grouping or read-across approach. If the explanation is manifestly inadequate, the registrant has not satisfactorily demonstrated how the information requirement has been or will be met. The Board of Appeal confirmed[21] that it is the registrant who is responsible for making the appropriate arguments; it is not the role of ECHA to develop these arguments for registrants. If there is an adequate explanation, ECHA then evaluates whether it is scientifically sound and adheres to the REACH requirements. In practice, an evaluator will also consider the extent to which the explanation considers all relevant aspects; the clarity of its formulation; as well as the presence, comprehensiveness and validity of supporting data. Then a decision is taken on scientific credibility and adequacy of the justifications in the context of REACH.

Often, some registrants make a testing proposal for a test to be performed on a different substance than the registered substance. They intend to use the obtained information in the future to adapt the information requirements of the registered substance. This means the read-across approach is based on information yet to be obtained by means of the proposed test. When examining such a proposal, ECHA first considers whether a test is necessary to fulfil the information requirements for the dossier. If the necessity of generating new data is confirmed, ECHA then considers whether the proposal to meet the information requirements of the registered substance by testing the analogue substance as part of read-across/grouping approach is plausible. If ECHA concludes that, based on the documentation and justification provided, the proposed approach is not plausible, ECHA rejects it and requires the testing to be performed on the registered substance.

Similarly during a compliance check, if ECHA finds that the adaptation of standard information requirements with the application of the read-across/grouping approach is not adequately justified, ECHA concludes that there is a data gap and issues a decision requesting the missing information on the registered substance.

Therefore, it is of great importance that registrants include adequate and scientifically sound explanations why the read-across approach is justified in their dossiers. In principle, many different

21 Decision of the Board of Appeal of 10 October 2013 in Case A-004-2012.

explanations can be made and supporting data provided, depending on the nature of the registered substance and its analogues, the availability of information, and the information requirement under consideration, etc. Different and varying scientific expertise may be involved, such as the determination of structural similarity of substances and the prediction of the relevant properties of the substance from the reference substance.

ECHA's experience has shown that, notwithstanding the available guidance, registrants still have difficulty in justifying their grouping and read-across cases in the context of the REACH information requirements. Often, seemingly promising cases fail in the first instance due to their incomplete or inadequate justification or the lack of supporting evidence of similarity or predictability.

To share ECHA's experience of good practice, an illustrative example of grouping and read-across has been published,[22] with two more to follow soon. They are based on ECHA's experience of evaluating real-world cases, and emphasise the crucial role of the existence of comprehensive explanation and supporting data in ECHA's evaluation. Further consideration of read-across and grouping approaches will be provided in the ECHA report: *The use of alternatives to testing on animals for REACH*, to be published in June 2014.

2.5.4 Publication of dossier evaluation decisions

ECHA has been publishing non-confidential versions of its dossier evaluation decisions on its website since December 2012.[23] Transparency is one of ECHA's core values. The purpose of publishing these decisions is to inform industry and the general public about the way ECHA works and to foster confidence in ECHA's decision making. By publishing these decisions, ECHA also provides guidance for future registrants on how best to fulfil their regulatory obligations.

Such publication is not intended to highlight that certain dossiers were once found to be non-compliant with REACH. Therefore, ECHA explains on the website that the decisions are published as such, without reflecting later updates to the registration dossiers, e.g. in response to a decision. Further, generally each decision is accompanied with a link to the corresponding entry on the registered substance website, to allow the latest data on the substance to be reviewed.

2.5.5 Appeals

Registrants can lodge an appeal against an ECHA evaluation decision before ECHA's Board of Appeal within three months of receiving notification of such a decision.

Since the entry into operation of the REACH Regulation until the end of 2013, a total of 11 appeal cases have been lodged against ECHA dossier evaluation decisions; see Table 8. In 2013, no appeal cases have been brought against substance evaluation decisions. Out of the 11 evaluation appeal cases so far, three were lodged in 2013. The subject matter of these appeal cases are varied and includes substance identity issues, the use of a read-across approach, information requirements requiring testing on vertebrate animals and procedural issues.

By 2013, the Board of Appeal has issued its first seven decisions on appeals against dossier evaluation decisions. The Board's decisions have provided useful information to ECHA, registrants and other stakeholders on the scope of certain REACH requirements.

Further information on the current status of appeal cases and the Board of Appeal's decisions can be obtained from the Board of Appeal's web pages.[24]

22 http://echa.europa.eu/support/grouping-of-substances-and-read-across

23 http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions

24 http://echa.europa.eu/about-us/who-we-are/board-of-appeal/

TABLE 8: APPEAL CASES RELATED TO EVALUATION

Appeal case number	Keywords	Date of Board of Appeal decision (if any)
A-005-2011	Compliance check Testing involving animals	29 April 2013
A-001-2012	Compliance check Rejection of suggested read-across ECHA's margin of discretion	19 June 2013
A-002-2012	Testing proposal Updated dossier Rectification	21 June 2012
A-003-2012	Compliance check Deadline for update of dossier Legal certainty	1 August 2013
A-004-2012	Compliance check Testing involving animals Developmental toxicity testing	10 October 2013
A-006-2012	Compliance check Use of read-across data	
A-007-2012	Compliance check Substance identity, UVCB Partial rectification Principle of good administration	25 September 2013
A-008-2012	Compliance check Substance identity	
A-001-2013	Compliance check Substance identity	
A-018-2013	Compliance check Request for further information Withdrawal	5 December 2013
A-019-2013	Notified substance Statement of non-compliance	

3. Recommendations to registrants

In this section, ECHA advises **you, the (potential) registrants**, about how you can improve the quality of your registration dossiers. The recommendations contain technical and scientific information so they can be most useful for you when you prepare or plan to update your technical dossier and/or chemical safety report. These recommendations are based on the most frequent shortcomings observed when evaluating dossiers.

This year, not as much space is devoted to substance identity and hazard endpoints as in previous reports. These reports, available on the ECHA evaluation web pages,[25] already described shortcomings previously observed and gave advice on how to avoid them. They are still relevant, even though they are not repeated here. Instead, ECHA would like to emphasise the need to keep your registration consistent and up-to-date without undue delay, and how to use adaptation possibilities correctly. More attention is also paid to the chemical safety reports.

3.1 THE REGISTRATION DOSSIER MUST BE UP-TO-DATE AND CONSISTENT

In the first instance, it is your duty to submit and maintain a compliant registration. When preparing your registration, make the most of the available support. The national helpdesks and ECHA Helpdesk[26] are here to help you meet your obligations. These can help you to solve problems and doubts that might arise along the submission process.

It is also important to remember your industry sector associations, who are experienced with REACH and have sector-specific knowledge and know-how. Talk with other members of the SIEF – they may also be a good source of information, particularly for new registrants. Many are registrants that already have experience in preparing registrations. More experienced registrants may help other less experienced or smaller companies, who might become registrants for the 2018 registration deadline.

Make sure that appropriate communication channels are in place to ensure a good communication flow in the supply chain.

Extended safety data sheets, including exposure scenarios, are the key vehicle to communicate the outcome of the chemical safety assessment. So, make sure their quality is good enough so your customers and downstream users can consider the advice on safety seriously and apply it.

Exposure scenarios attached to the safety data sheet are only useful if the chemical safety assessment is meaningful and relevant,

25 http://echa.europa.eu/regulations/reach/evaluation

26 http://echa.europa.eu/support/helpdesks

the identified risk management measures are appropriate, and if the downstream user can understand them.

Be aware of the good practices being shared and developed on how to generate and communicate exposure scenarios. The Exchange Network on Exposure Scenarios is a good source of information.[27] This network aims to identify good practices on preparing and implementing exposure scenarios, and to develop an effective communication exchange between supply chain actors.

3.1.1 Use ECHA's guidance and tools

When preparing and maintaining your registration, consult the guidance material on the ECHA website. The Data Submission Manuals and the REACH-IT Industry User Manuals give definitive instructions for preparing and submitting dossiers.

Use the Validation Assistant plug-in for IUCLID when preparing your registration. It warns you of deficiencies and inconsistencies found in your dossier.

ECHA has continued to develop REACH guidance in 2013. These updated guidance appeared on the ECHA website during the year:

- An update of *Guidance on the compilation of safety data sheets* was published in December 2013, allowing Part G of the *Guidance on information requirements and chemical safety assessment* to be declared obsolete.
- An update of *Guidance for downstream users* was published in December 2013.
- Updates to *Guidance on the application of the CLP criteria, Part 2: physical hazards* and *Part 3: health hazards*, were published in November 2013.
- Two corrigenda of *Guidance on information requirements and chemical safety assessment, R.7.1: physicochemical properties*, were published in August and December 2013 respectively.

27 http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

ECHA made its guidance more accessible by publishing "lighter" versions of guidance documents. These included the updated *Guidance in a nutshell on registration* (September 2013), a new *Guidance in a nutshell on safety data sheets* and a new *Guidance in a nutshell for downstream users* (both December 2013). As these three documents are of particular interest to small and medium-sized enterprises, they have been published simultaneously in 23 official EU languages.

ECHA updated the **online Navigator tool** in 23 official EU languages on 25 September 2013. The Navigator is an interactive tool that helps manufacturers, importers, downstream users and distributors of chemical substances, either on their own or in mixtures, to identify their obligations under REACH. It also helps producers and suppliers of articles to clarify their role in the supply chain. It can be found on ECHA's website.

ECHA invites you to take note of these new resources and update the relevant parts of your dossiers accordingly where appropriate. ECHA will take into account the new approaches described in the guidance in on-going and future dossier evaluation.

3.1.2 Keep your dossier up-to-date

The registration dossier always has to reflect the current information and the real situation.

Receiving the registration number is not the end of the REACH process. Article 22(1) of REACH provides: "*Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information…*".

Example: If there is new information on a hazard or use, this needs to be included in the technical dossier. Such information may also have implications on the chemical safety assessment: e.g. the assessment factors may have to be revised. So, you need to review the chemical safety report at the same time.

Example: If no production or import takes place anymore, the tonnage of the registration has to be set to zero, using the "cease manufacture" functionality in REACH-IT.

Make REACH compliance part of your quality management system.

The best way to make sure your dossier is up-to-date is to be proactive and integrate REACH compliance into your quality management system, ensuring that there are processes in place to gather any new information relevant for REACH compliance like new uses that have to be included in the registration dossier through spontaneous updates.

It is also important to be prepared to react when your company is subject to any regulatory action under REACH. Some registrants underestimate the time it takes to prepare a dossier update and the number of issues that can arise during the preparation. This can become even more acute if you receive a decision with a deadline to update. Having REACH as part of your plan keeps it within your own scheduling and control.

You should log in to your REACH-IT accounts regularly to check the message box.

The typical way for ECHA to contact you or request information from you is through the REACH-IT message box. Some of these are linked with very specific deadlines for you to react, e.g. notifying you of a draft decision and informing you of your right to comment on it. Therefore, a regular check of REACH-IT should allow enough time for you to respond appropriately. Make it clear in your company who is in charge of such regular checks.

It is also important that you have your contact details updated in REACH-IT should ECHA need to contact you directly. If a consultant has been contracted to manage the REACH-IT account but now the contract is ending, plan for a smooth handover beforehand, ensuring that you receive all relevant data. A new person should then be made responsible for regularly monitoring your REACH-IT account.

Make sure that there is a process in place in your SIEF to deal with updates and to react in case of regulatory actions.

Often registrants of the same substance need to discuss among themselves first before providing comments on a draft decision or reacting to the authorities' requests.

3.1.3 Registering as an intermediate?

Is your substance really an intermediate under REACH?

If its lifecycle leads to a risk of emission and exposure, or if there is a need for personal protection equipment to avoid exposure, your substance cannot benefit from the special regime for intermediates under strictly controlled conditions. Submit a standard registration under Article 10 of REACH instead.

Example: Physicochemical properties can be taken into account in designing strictly controlled conditions, However, "risk-based" approaches – for example, comparing exposure levels with (no-)effect concentrations or national/international limits – is not acceptable as proof of strictly controlled conditions.

Example: Continuous releases of an intermediate from the process under strictly controlled conditions are not expected. So if such releases occur, the substance cannot be regarded as an intermediate under REACH.

Example: The substance cannot be considered as an intermediate if personal protective equipment is used to avoid exposure during normal operating conditions (except for accidents, incidents, maintenance, cleaning).

For intermediate registrations, show that the use of the substance fulfils the definition of the intermediate use and the conditions set out in REACH.

When considering an intermediate registration, in particular under the special regime of REACH Articles 17 and 18, you need to assess the conditions of use for a substance, keeping in mind these points:

- Consider what technical function your substance serves in a process. An intermediate is used in the manufacturing of another substance where it is itself transformed into that other substance.
  Example: Processing aids that are also reactive are not intermediates.
  Example: The production of waste cannot be considered as the main intention of a manufacturing process.

- Your registration should include details of risk management measures applied. This should prove that strictly controlled conditions have been applied during the lifecycle of your intermediate, especially in steps where breakage of the containment system is expected.
  Example: Loading, unloading, cleaning, maintenance and sampling activities need special attention when justifying strictly controlled conditions.

If ECHA has concerns about the use of your substance as an intermediate or the conditions applied during the lifecycle of your substance, the Agency may contact you asking for clarification.

3.1.4 The dossier should be consistent as a whole

It is important to check the consistency of the whole dossier across all the endpoints as well as between endpoints and read-across approaches. This ensures that the risk assessment of a substance is clear and robust. This is particularly important during an update, so you should verify that all parts of the dossier remain consistent after one part has been updated.

The result of the studies should be coherent across different endpoints and in the CSR.

Example: The value for Henry's constant needs to be coherent with the values for vapour pressure and water solubility.

Example: The hazard data reported in the technical dossier should be the same as the ones used in the CSR.

Consistency is even more important if you rely on adaptations at some of the endpoints. If you rely on an adaptation to omit a study, you must clearly state this fact and explain why you decided not to perform a study in the relevant IUCLID section, referring to the appropriate legal provision. This is essential to allow ECHA to assess whether the adaptation is acceptable. ECHA is not obliged to compile adaptation arguments on your behalf from the information set out in other parts of the registration dossier.

Adaptations based on properties of the substance should be supported by valid studies regarding those properties.

It is often possible to adapt and omit a study based on the results from another endpoint. However, for such an adaptation to be acceptable, the information on the related endpoint needs to be consistent with the adaptation applied.

Example: If adaptations are based on the value of the vapour pressure or melting point, valid studies on these properties must be included.

Example: If the hydrolysis study is omitted based on very low water solubility, a valid study for water solubility showing very poor water solubility must be included in the dossier.

All the reported values for different properties should be consistent with one another.

Example: Octanol/water partition coefficient must be consistent with the adsorption coefficient.

As mentioned in section 3.1.2, if there is a change in the hazard or use/exposure information, this may have an impact on the risk assessment. So the CSR should also be reviewed accordingly.

3.2 REPORT HAZARD INFORMATION CLEARLY

Provide clear and complete robust study summaries including tabular data according to the criteria in ECHA's *Practical Guide 3*. Consider including full study reports if the results need interpretation to define the adverse effect levels.

ECHA noticed that some studies were reported more than once within the same dossier. Normally, one study covers only one information requirement, so this should be avoided.

When selecting values from a pick-list in IUCLID, it is strongly recommended to choose one of the valid values from the pick-list, and use the option "other:" only in exceptional situations.

3.2.1 Classification and labelling

Check carefully that the harmonised classification reported for your substance in the dossier is in line with the latest Annex VI of CLP in force, as amended, including all the adaptations to technical progress. Be aware that it may fall under a group entry.

3.2.2 Physicochemical properties

Check that the result from a physicochemical test falls within the test method's applicability range. If this is not the case, the result should not be used on its own to fulfil an information requirement.

Example: There are several possible methods to measure the vapour pressure of a substance, each with a different applicability range. The applicability range of the methods should be checked by consulting ECHA guidance, and the right method should be chosen for its range.

3.2.3 Toxicological information

Skin and eye irritation and corrosion. Several new *in vitro* test guidelines have recently been approved by the OECD. These test guidelines can be used for REACH purposes within the testing strategies that have been detailed in ECHA's chemical safety assessment guidance. ECHA will soon publish instructions on the use of these *in vitro* methods, addressing their scope and limitations.

Mutagenicity – comet assay. The comet assay is listed as a recognised test method in the guidance. However, the OECD test guideline for the comet assay has not yet been adopted. In the meantime, ECHA can consider a testing proposal with the comet assay for mutagenicity testing *in vivo* if the registrant has specified a detailed and scientifically sound protocol to be used for the test and scientific justification of its appropriateness to fulfil the information requirement. If ECHA comes to the conclusion that the proposed test will produce appropriate results, the Agency can accept the comet assay to be performed. This practice does not mean that ECHA would recognise a comet assay test guideline in general, but only that ECHA will consider testing proposals with specific protocols on a case-by-case basis.

Pre-natal developmental toxicity. For substances manufactured or produced in quantities of 1 000 tonnes or more per year, providing studies in two species for the endpoint pre-natal developmental toxicity is a REACH information requirement. The default species in the relevant guidelines (EU B.31, OECD 414) are rats and rabbits. ECHA's decisions normally request the studies to be performed in these species, and leave it up to the registrant which species to test first.

3.2.4 Ecotoxicological and environmental fate information

Avoid using the equilibrium partitioning method if no effects are seen in aquatic tests.

For terrestrial toxicity, only when effects are observed in the aquatic tests can the equilibrium partitioning method be used to derive a terrestrial effect value. If a substance does not show effects in the aquatic toxicity tests, this method cannot be used.

The fact that a substance is readily biodegradable does not mean that it decomposes rapidly, so a test for ready biodegradability cannot be used to omit an adsorption/desorption study.

The fact that a substance is readily biodegradable does not constitute a valid basis to omit an adsorption/desorption study. Judging from the justifications provided in the dossiers, there seems to be confusion regarding the meaning of the term "rapid decomposition" in the context of adapting the information requirement for adsorption/desorption studies. A substance (and its degradation products) can be considered to decompose quickly if they are very unstable in the environment e.g. if they hydrolyse within seconds.

Consider potential degradation products and report accordingly.

Report the degradation products if they can be identified. Identifying the degradation products is sometimes not enough for the risk assessment, though. Additional testing for these products should be conducted if they can pose a risk. If such tests are carried out, the results of the testing should be reported correctly, too.

3.3 ADAPT ACCORDING TO REACH RULES

Clear reporting of QSAR, read-across and categories can prevent a long process of discussions to clarify the approach used. ECHA has, very often, faced situations where read-across/category approaches or QSAR predictions might be scientifically plausible but could not accept the adaptation due to missing or improper documentation that justifies it. In those cases, the only option left for ECHA is to consider the adaptation as not justified and to request data to be generated on the registered substance to fulfil standard information requirements. To help you avoid such a situation, ECHA published an illustrative example of a grouping of substances and read-across approach in April 2013, which can be found on the ECHA website.[28]

In 2013, ECHA found that more dossiers contained a sufficient level of documentation of hypothesis and justifications for read-across approaches and quantitative structure–activity relationships (QSAR). ECHA identified more and more documentation in QSAR Model Reporting Format (QMRF) and QSAR Prediction Reporting Format (QPRF) for QSAR estimations, especially after recent dossier updates. It should be noted that this observation mostly concerns physicochemical properties, such as octanol/water partition coefficient and vapour pressure, as well as aquatic toxicity.

For other environmental endpoints, one-to-one read-across is widely used rather than category approaches. In such an approach, trends might be overlooked and the approach might be vulnerable to inconsistencies. It is important to consider possible relationships between environmental properties and fate parameters to make the assessment more coherent both for a single substance and between substances. If you propose a category, it is recommended that you present a detailed data matrix indicating the experimental data that exist, and which data gaps have to be filled. The approach for data gap filling should be explained and justified.

For human health endpoints, read-across seems to remain the main alternative for addressing missing information. ECHA noted a positive trend towards building testing strategies with the use of different types of information, including non-standard tests and computational methods. Yet, the suitability of such alternative approaches has to be judged on a case-by-case basis, depending on the nature of the substance.

28 http://echa.europa.eu/support/grouping-of-substances-and-read-across

Below are further hints on specific adaptation possibilities for the different adaptation routes.

3.3.1 Reporting adaptations or proposing to test

Providing a solid legal basis in the adaptation statement and reporting it correctly is extremely important. ECHA can then assess the statement as fast as possible and contact you as swiftly as possible if the adaptation turns out to be unacceptable. By providing a sound legal basis, you can avoid a lengthy decision-making procedure just to clarify the nature of your adaptation. If you cannot clearly find which part of REACH provides for the possibility of using an adaptation, reconsider whether it is the right way to fulfil an information requirement.

Clearly state the legal basis for the adaptation, quoting the specific provision in REACH that allows this adaptation.

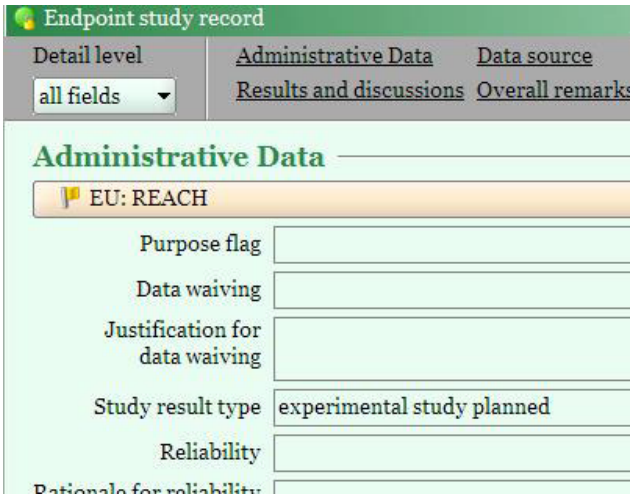
ECHA has observed that the dossiers frequently fail to clarify the legal basis for the adaptation. The adaptation needs to be based on the provisions mentioned either in column 2 of Annexes VII to X or in Annex XI, so you should always clearly indicate in your justification which of these constitutes the legal basis for the adaptation.

The "Justification for data waiving" field should be filled in only when an adaptation is reported, i.e. no adequate experimental data available.

Use the "Justification for data waiving" field exclusively when an adaptation is reported. On a number of occasions, ECHA observed that the reporting of studies is mixed with adaptations.

Explicitly propose a new test by selecting "experimental study planned" in an endpoint study record created for the relevant endpoint. When you propose to conduct a new test, this must be explicitly mentioned in the relevant endpoint. Vague expressions of intent to carry out new tests are occasionally found in the wrong places within the dossier.

A testing proposal for an Annex IX or X endpoint should always be reported by creating an endpoint study record for the relevant endpoint and selecting "experimental study planned" in the "study result type" (see example, below). If another (read-across) substance is proposed to be tested, this needs to be marked in the "test materials" section further down in the same endpoint study record. This recommendation is in line with the format specified by ECHA under Article 111 of REACH.



In contrast, reporting the intention to conduct a test only in, for example, the CSR or a free text field of an endpoint study record is not acceptable as a testing proposal under REACH. If such an ambiguity is detected in your dossier, ECHA will not examine it as a testing proposal. Instead, you will be asked to express your intention more clearly. If a test is to be proposed, then you must update the IUCLID dossier to say "experimental study planned" under the relevant endpoint. Otherwise, the ambiguous statements should be clarified or removed from the dossier.

3.3.2 Read-across and category approaches

If you use grouping and read-across approaches, the available experimental data (assuming that they are reliable) should be carefully analysed for contradictions against the proposed hypothesis. Advice on how to report such approaches is in ECHA's *Practical Guide 6*.

Example: It is not acceptable to conclude that all category members are not toxic due to a lack

of absorption, when experimental studies show that some category members produce adverse effects at concentrations lower than the maximum concentration tested.

Example: It is not acceptable to consider the toxicity of a common metabolic product alone as the basis for grouping if the metabolism has a moderate to low rate, and the parent molecules co-exist with the metabolic product in the organism. There might be other potentially toxic metabolites that may not have been considered in the assessment.

Remember when using read-across and category approaches:

- Consider impurities and potentially different substance compositions when developing a read-across argument.
- The read-across approach should always be done from a source (e.g. a substance, a substance form, or a set of substances) with its own experimental data. It is not valid to read-across from a QSAR prediction, or from another read-across.
- Usually, chemical categories are based on structural similarity. Nevertheless, structural similarity itself does not afford enough justification for toxicological similarity between the substances. Thus, for every endpoint, and for every substance a hypothesis-driven justification has to be elaborated to explain why the data from one substance can be used to fill the data gap for another substance.
- To make the approach plausible, a category should contain a reasonable amount of data covering the edges of observed or hypothesised trends.

3.3.3 Adapting with QSAR results

General advice on how to report QSAR results is available in ECHA's *Practical Guide 5*. Here are some recommendations about how to avoid common pitfalls.

QSARs should be reported including all the necessary documentation to assess the reliability of the prediction.

One endpoint study record should be created for each chemical structure that has been subject to a QSAR prediction. The QMRF describing the scientific validity of the model should be attached to the endpoint study record, and a QPRF should be provided for each structure that has been predicted with the model to show that the model is applicable to the query structure.

Example: If two constituents of a multiconstituent substance are predicted for vapour pressure by the same model, the vapour pressure section should contain two endpoint study records, one for each constituent. The QMRF could be attached only once (since the model is the same in both cases), but each endpoint study record should have its own QPRF attached. Advisably, the QPRF could contain structured, measured and predicted activity similar to the target substances from the training set of the model as proof that the model is applicable to the chemical structure in question.

Toxicological information taken from the training set of a QSAR model is not a QSAR result, because the values used in the training sets of the QSAR models are usually experimental results.

Since there is typically not enough summary information for such data, you should treat them in the same way as handbook data. These data points should be reported as "Weight of evidence" in the field "Purpose flag" and as "Experimental study" in the field "Study result type". The field in the "Reference" section can be used to indicate that it comes from a training set of a model. Any available information on the test method, route, duration, species, etc. should be reported in the endpoint study record.

Using QSAR predictions to fulfil an information requirement is not a justification for data waiving. Predictions should be reported as study results.

It is not appropriate to report a QSAR in the "Justification for data waiving", for example: "The study for BCF is not submitted because there is a QSAR calculation". If experimental data are not submitted because a QSAR prediction is used, an endpoint study record should be created indicating "QSAR" in "Study result type". Then, the prediction

should be reported as the result, and the necessary documentation (QMRF and QPRF) should be attached.

The fact that a model is mentioned in ECHA guidance does not eliminate the need for proper documentation of a model and the predictions from it.

However in some cases, when the documentation for the model is exhaustive and publicly available, this documentation might be used as part (or even instead) of the QMRF, but the QPRF is nevertheless necessary, since it contains the assessment of the applicability of a model to the specific substance.

3.3.4 Exposure-based adaptations

Exposure-based adaptations are often incorrectly used or inconsistently reported.

When using exposure-based adaptations, check that the uses described in IUCLID section 3.5 and the exposure assessment in the CSR are consistent with the premise of the adaptation.

Example: If IUCLID section 3.5 describes wide-dispersive or consumer use, explain why the assumption that there is no exposure for a relevant endpoint still holds. Otherwise, you should not use exposure-based adaptations.

3.4 CHEMICAL SAFETY REPORT SHOULD REFLECT ACTUAL USES AND RISKS

To support you in developing your chemical safety reports, ECHA recommends using the **Chesar** software as much as possible. ECHA welcomes that industry organisations are developing resources to help registrants assess chemical safety and prepare the report. These resources include use maps, specific environmental release categories (SpERCs), specific consumer exposure determinants (SCEDs) and generic exposure scenarios (GES). ECHA recommends organisations to continue to improve these, which may consequently also improve the quality of the dossiers.

3.4.1 PBT assessment

The PBT assessment is one of the main elements in the chemical safety assessment of substances. The fact that a substance is PBT triggers specific requirements. For these substances, minimisation of releases should be ensured because a quantitative assessment is not reliable enough to ensure chemical safety. Therefore, it is important that you have a good understanding of the properties of your substances to be able to ensure the safety of the chemical.

You should carefully assess whether your substance is PBT/vPvB, taking into account its constituents, impurities and additives also. If it turns out to be PBT/vPvB, assess and document how to minimise its emission. ECHA has noticed that the PBT assessment of the substance in some dossiers disregarded conclusions of the MSC, even though the substance has been included in the Candidate List of substances of very high concern due to its PBT properties. Moreover, in most cases where the substance is PBT/vPvB (or considered as PBT/vPvB by the registrant), the minimisation of releases has not been clearly demonstrated in the chemical safety report. A quantitative assessment (a risk characterisation ratio such as PEC/PNEC) is not appropriate for such a substance. You are advised to follow REACH Guidance R.11.

During the PBT assessment, remember these points:

- REACH requires you to use all available information to determine whether your substance is PBT/vPvB. If the available information does not allow this, you must either generate the necessary information or treat the substance as if it were PBT.
- Consider the properties of the substance taking into account its relevant constituents, impurities and additives.
- Check if the substance has already been agreed to be PBT/vPvB and included in the Candidate List of substances of very high concern[29] or the list of substances subject to authorisation (Annex XIV of REACH).
- Demonstrate clearly and document how you minimise releases of PBT substances. Do not assess the risks with a quantitative risk assessment only.

29 http://echa.europa.eu/candidate-list-table

3.4.2 Derivation of DNEL

DNEL derivation is a key element for the risk characterisation of a chemical substance. The derived no-effect level (DNEL) is set by REACH as the threshold above which humans should not be exposed. Therefore, it has to be derived appropriately to make sure that substances are manufactured and used in such a way that they do not adversely affect human health.

REACH Guidance R.8 describes in detail how to derive a DNEL. It specifically provides default assessment factors that should be applied to account for the uncertainty arising from the variability in the experimental data, the nature and severity of the effect and the sensitivity of the human population. Deviating from the use of these default assessment factors has to be justified and documented with scientific arguments explaining why such a deviation applies to that specific substance.

You should derive DNELs appropriately and follow the recommendations in REACH Guidance R.8. Registrants do not always select the correct key study for the derivation of DNELs. In addition, registrants do not always apply the assessment factors given in the guidance when deriving DNELs and the deviations are not justified adequately as they often do not include substance-specific justifications.

When deriving DNELs, consider:

- 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 R.8.
- Deviating from those default assessment factors needs to be justified and well-documented with scientific arguments that are specific to the substance. A generic statement is not sufficient.
- If for some identified hazard it is not possible to derive a DNEL (for example skin/eye irritation/corrosion, skin sensitisation, mutagenicity), you should carry out and report a qualitative assessment.

3.4.3 Exposure assessment

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. Therefore, the exposure assessment has to be carefully done. It consists of two clear steps: identifying exposure scenarios and estimating the exposure in each scenario.

First, the exposure scenarios describe how the substance is manufactured and used and how exposures to humans and the environment are controlled. This description includes both the operational conditions and the risk management measures implemented. It is very important that the description of the exposure scenarios is detailed enough, so ECHA can understand how the substance is manufactured and used and can subsequently assess whether the exposures have been correctly estimated. Otherwise, the credibility of the exposure assessment might be jeopardised. There are practical examples of exposure scenarios on the ECHA website.[30]

Then, the exposure estimates give the level of exposure that is expected when manufacturing and/or using a chemical substance and they are compared with the derived DNELs to ensure that human health is not adversely affected. Therefore, in the absence of real exposure data, the exposures have to be carefully estimated, using exposure models that are appropriate for the physicochemical 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 you know it is the right one to use and can enter parameters correctly. When evaluating the CSR, ECHA has sometimes found models used outside of their scope of applicability or that incorrect parameters are entered into the models. You have to show whether your risk management measures are the same as expected in the model; and if there are deviations, justify why these are acceptable.

30 http://echa.europa.eu/support/practical-examples-of-exposure-scenarios

You should provide a detailed exposure assessment for your substance. The process descriptions provided in the dossiers are often too vague and difficult to understand. As already mentioned, the operational conditions and applied risk management measures should be provided in sufficient detail for a credible exposure assessment. There is a practical example of a chemical safety report on the ECHA website.[31]

When assessing the exposure, remember these points:

- Consider the scope of exposure assessment based on the hazards identified for the substance. ECHA's *Guidance on information requirements and chemical safety assessment* in section B.8.4 advises on whether an exposure assessment is needed and what its scope is, given the available hazard information. For instance, if a substance is classified other than for the environment but fulfils the criteria set out in Article 14(4) of REACH, an environmental exposure assessment is needed if an adverse effect (even if not leading to classification) is observed at a concentration/dose below the highest recommended concentration/dose tested in an ecotoxicological study. An analogous reasoning applies to human health and physicochemical endpoints.
- The exposure scenarios should have a level of detail that allows a clear understanding on how the substance is manufactured and used. Thus, you should avoid generic descriptions of the operational conditions and the risk management measures implemented.
- Always think about the domain of applicability of the models used for estimating exposures. The physicochemical properties of the substance, its use and the routes of exposure should all be considered when choosing a model to ensure they are within the applicability domain.
- You should think about what the modelling parameters mean before entering them. For instance, using local exhaust ventilation modifiers for dermal exposure is not correct.
- For the environmental exposure assessment to be credible, non-default ERC release factors should always be justified, the source referenced (and retrievable) and linked to the related operational conditions or risk management measures.
- If internal, site-specific release measurements are available and used for exposure estimation, the summary of their results should be provided. This summary should be detailed enough. This is so ECHA can understand whether it covers the relevant scenarios for possible releases from substance processing according to the relevant exposure scenario.

Below are two particular topics in exposure assessment that warrant special attention, namely dermal exposure and assessment of consumer products or articles.

Dermal exposure assessment. Protecting against dermal exposure really matters when the substance either affects the skin or is readily absorbed by the skin and is systemically toxic. Dermal exposures are often poorly understood and real-world experience shows that the exposure distribution can be very wide and highly unpredictable; in these cases, relying on modelling alone may not be enough. Instead, worker protection relies on a sound assessment of what might happen in practice. So, it is important for you to specify the appropriate risk management measures to cover all intended uses.

When assessing dermal exposure, consider these points:

- Specify the appropriate risk management measures to cover all intended uses. Protective clothing and gloves are very important in this, so you should identify in the CSR what is needed to protect against exposures that can often fall well outside the predicted range from modelling.
- Information on dermal absorption may help in determining the right risk management measures.
- If the worker can get wet, personal protective equipment might be needed regardless of the modelling outcome.
- For low volatility substances, reducing dermal exposure estimates through applying a local exhaust ventilation modifier is not justified – and in many cases it leads to wrong or incomplete advice on risk management measures.

Assessment of consumer products or articles. Consumer exposure is one of the main elements in the chemical safety assessment. It is important that

31 http://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

you have a full picture on how consumer products or articles containing your substance are actually used.

Make sure the consumer exposure scenarios are closely aligned with what happens in practice.

You also need to understand the models you use to estimate consumer exposure. Default values in some models require careful consideration. The key aspects are the concentration in products, the quantity used, the duration and frequency of exposure. If these are not realistic, safe use is difficult to demonstrate.

When assessing consumer products or articles, remember these points:

- Always think about whether your substance ends up in an article. In particular, some use descriptors (e.g. ERC 5, ERC 8c/f, ERC 3 referring to inclusion into matrices or materials) strongly suggest that article service life is a relevant stage for the assessment. If so, you need to assess the exposure during the service life and add the necessary exposure scenarios. Failing this, you need to at least explain why you do not think the exposure assessment of the service life is relevant or why the service life is not described. Report the evidence and/or justification in the CSR.
- Consider all possible products or article types in which your substance ends up. If one particular product/article is then selected for assessment, you should provide evidence of how this product and its assessment is representative of the wide range of (sub)products or articles.
- Carefully consider the exposure and hazard identified for the substance. In particular, if acute effects have been identified and an acute DNEL has been provided, you should compare the event exposure concentration or dose with the acute DNEL.
- Always check the domain of applicability and the underlying assumptions of the exposure tools you use. Even simple algorithms (e.g. Tier 1 models) have assumptions that you have to verify. In particular, when Tier 1 exposure tools are modified (such as those offered by some sector organisations), the following aspects should be considered:
  - If the tool allows for averaging the event concentration or dose over the year for assessing long-term effects, you should provide strong evidence that the product is used infrequently.
  - If the tool skips some route of exposure for some product or article, you should always check the reliability of assumptions with the reference of product type and substance properties.
- When using Tier 2 tools, you should be aware of their domain of applicability and whether they suit your substance, product or article. Since Tier 2 tools are not generally designed for REACH, it is crucial that the CSR explicitly sets out the conversion of input parameters into conditions of use, the justification of such parameters and the assessment's coverage.

3.5 IF YOU RECEIVE A (DRAFT) DECISION FROM ECHA…

If ECHA decides to take regulatory action after evaluating your dossier, it is to help you improve your dossier by pointing out the non-compliances found in your dossier. Sending the draft decision to you first gives you a chance to comment on it, before ECHA starts to seek agreement among all Member States and moves towards taking the decision.

Immediately after receiving the draft decision, start to fully consider your strategy to respond, taking into account the deadlines.

ECHA only considers comments that are received within the 30-day commenting period. The webform for commenting is specific to your case; the link to the form is in the cover letter sent to you. If you plan to submit an update within these 30 days, notify ECHA of this intention as soon as possible.

Keep in mind that the decision is based on the dossier available when the notification to the MSCAs is prepared. Once the case is set to be notified to the MSCAs for consultation, dossier updates can no longer be taken into account. So, for example,

you will not be able to withdraw a testing proposal when your representative is presenting your case at the MSC meeting. You should not plan to bring new information to the MSC expecting that it would be considered in the decision making.

Aim to respond to ECHA with one voice during decision making. Keep the communication channels open and working within your SIEF and joint submission, especially during the evaluation process.

This is because some (draft) decisions have implications for many registrants with the same substance. For example, if you receive a draft decision under substance evaluation, it is also addressed to other registrants in place on the date of sending the draft decision (excluding registrants with only on-site isolated intermediate registrations). Since the decision-making process involves you all, aim to speak with one voice. So at all stages, endeavour to submit one single, joint comment through the lead registrant. A single contribution on behalf of the whole group makes the decision-making process much easier for all involved.

If, upon receipt of a draft decision, a registrant decides to cease manufacture or import and informs the Agency about it, no further information can be requested from that registrant (i.e. the current decision making is terminated) and the registration will no longer be valid. However, if the manufacture or import ceased only after the decision has been issued, the registrant still needs to comply with the decision.

If, during the decision-making process, there is a change of legal entity (for example, the business is sold to another company), the registration stays valid with the same registration number, so the new entity will receive the decision. All prior correspondence with the previous legal entity is considered to be available to the new legal entity. Therefore, the former lead must prepare a comprehensive hand-over file to the new lead.

If you receive a decision, remember that ECHA has taken it with unanimous agreement from all Member States. To avoid enforcement action as well as unnecessary, time-consuming and costly communication, remember these too:

- In the period from the decision date to the deadline in the decision, a legally-binding decision is in force unless an appeal is lodged. ECHA's possible actions in such cases are limited. In some cases, registrants ask ECHA to postpone the deadline for various reasons. ECHA does not have the authority to alter the deadline specified in the decision since that deadline has been agreed unanimously by the Member States. Furthermore, REACH does not provide for the postponement of the deadline of an evaluation decision. In the registration dossier, document your justifications for not meeting the deadline so that when a statement of non-compliance is issued, the Member State can access this information and decide when/whether to follow-up with enforcement actions.
- Again, keep the communication channels open and working within your SIEF and joint submission. Some decisions also have implications for other members, for example, those regarding SID and substance sameness. So, be prepared to inform and involve members of your joint submission or SIEF if you receive a (draft) decision.
- If you wish to seek clarification on your obligations pursuant to the decision, you should approach the ECHA Helpdesk to ask concrete and specific questions. Bear in mind that once the decision has been taken, neither ECHA nor the Member States can change the decision's content, and therefore only questions that help you understand how to fulfil the requests in the decision can be answered.
- Registrants may, under their own responsibility and risk, decide to fulfil the information requirements in an alternative way than requested in the decision, by providing justified adaptations of the standard information requirements. For instance, they might provide a prediction of a relevant property of the registered substance by using information from a structurally similar substance (read-across). Nonetheless, the use of such adaptations to the standard information requirements must fulfil the rules outlined in Annexes VI to X and/or the general rules in Annex XI. Any adaptation needs to be accompanied by sound scientific reasoning and documented fully and clearly, following the relevant guidance. If these conditions are not fully met, the adaptation would not be accepted by ECHA and a statement of non-compliance following a dossier evaluation decision would be issued.

3.5.1 If it is a decision under dossier evaluation...

You will receive a decision under dossier evaluation if your dossier does not comply with the information requirements as specified in REACH.

In some cases, registrants would like to ask ECHA whether the way they want to fulfil the information requirements is acceptable (for example, by using general or specific adaptations). However, ECHA does not provide advice or comments on any alternative strategies or approaches that the registrant intends to use to fulfil the request in the decision. As mentioned in section 2.3, ECHA only starts to assess whether a registrant complied with the requests in the decision when the deadline has passed, and based on the dossier provided in the latest update.

Once a statement of non-compliance following a dossier evaluation decision has been sent, any question regarding the follow-up action should be addressed to the national authorities responsible. ECHA will re-examine the dossier once the registrant has addressed the requested information in an updated dossier. A communication system has been set up to allow ECHA and the Member States to exchange information on such cases.

3.5.2 If it is a decision under substance evaluation...

One substance evaluation decision is typically issued for each substance. This means that if there are many registrants for a substance, a single decision will address all registrants of that substance. The intention is that there should only be one decision per substance listing all the requests that are necessary for the risk assessment. This may mean that if there are, for example, use-specific requests, not all registrants are liable for submitting the

information, but only those for whom the request is relevant. In some rare cases, due to confidentiality reasons, there may also be a separate decision addressed to a single registrant in addition to the decision addressed to the other registrants.

The addressees of the decision will typically be the registrants that have valid registrations when ECHA first sent the draft decision for their comments. If during the decision-making process new registrations are submitted, the decision will not address these registrants. Along with the decision, you will receive a list of the registrations whose registrants are responsible for fulfilling the requests.

Remember:

- Although the evaluating Member State drafted the decision and handled the comments made by the registrants, it is ECHA that took the decision after consultation with all the Member States and (in case of a proposal for amendment) after reaching an agreement in the MSC. So in the end, the substance evaluation decision is an ECHA decision with similar rules for appeal as dossier evaluation decisions.
- Unless an appeal is lodged, a legally-binding decision is in force and the decision defines the deadline by when the requested information needs to be submitted to ECHA in the form of a dossier update. It might be enough that only the lead registrant updates the dossier and the attached chemical safety report. But depending on the nature of the requests in the decision and the existence of individual chemical safety reports, the member dossiers may also have to be updated.
- Communicating smoothly in the SIEF is essential for substance evaluation decisions, which almost always have implications for all members. In some cases, it is important to have good communication with downstream users in the supply chain as well. When new tests, especially vertebrate tests, are requested, the registrants should inform ECHA who is performing the test on behalf of the others (Article 53 of REACH). If ECHA is not informed of such agreement within 90 days from the decision, the Agency will designate one of the registrants (or downstream users) to perform the tests.
- In some cases, the evaluating Member State may offer the possibility of further informal interaction after the decision has been taken. Only after the deadline has passed is the evaluating Member State obliged to start assessing whether the updated dossiers complied with the information requests in the decision.

List of acronyms and abbreviations

C&L	classification and labelling
CCh	compliance check
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	carcinogenic, mutagenic or toxic for reproduction
CoRAP	Community rolling action plan
CSR	chemical safety report
DNEL	derived no-effect level
ECHA	European Chemicals Agency
ERC	environmental release category
EU	European Union
IUCLID	International Uniform Chemical Information Database
MSC	Member State Committee
MSCA	Member State competent authority
PBT	persistent, bioaccumulative and toxic
QMRF	QSAR Model Reporting Format
QObL	quality observation letter
QPRF	QSAR Prediction Reporting Format
QSAR	quantitative structure–activity relationship
REACH	Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals
SID	substance identity
SIEF	substance information exchange forum
SONC	statement of non-compliance following a dossier evaluation decision
t/a	tonnes per annum (year)
TPE	testing proposal examination
vPvB	very persistent and very bioaccumulative

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