ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH Progress Report 2014

Knowing more, getting safer

To make Europe healthier, safer and more prosperous, we want to know more about the chemicals we use. This is how we gather, check and share the knowledge, and how we can do even better

Disclaimer

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.

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

Evaluation under REACH: Progress Report 2014

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The Management System of ECHA has been approved to ISO 9001:2008 standard. The scope of the approval is applicable to managing and performing technical, scientific and administrative aspects of the implementation of the REACH and CLP regulations and developing supporting IT applications.

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FOREWORD FROM THE EXECUTIVE DIRECTOR

Dear reader,

This is the seventh annual report on our activities in evaluating dossiers and coordinating substance evaluation, ending with a list of recommendations for registrants. It shows how the collective efforts of registrants, ECHA and Member States are improving the quality of Europe's chemical knowledge and safety information.

Maximising the availability of high-quality data is one of ECHA's strategic objectives. 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 2014, we developed a new compliance check strategy to maximise the impact on the safe use of chemicals. The aim is to identify those substances that matter the most for the protection of people and the environment. These are substances produced in high volumes with data gaps in human health or environment endpoints and with high potential for exposure of workers or the general public.

To increase transparency, ECHA will start to periodically publish a list of likely cases for compliance checks. At the same time, we will tighten deadlines with dossier updates to reduce processing times and increase efficiency.

ECHA was successfully awarded the ISO 9001 certificate in relation to our REACH and CLP tasks. This demonstrates that in evaluating registration dossiers ECHA applies internationally recognised good business practices.

The findings of this report and the first measurements of dossier quality improvement that will be reported in the next general report show improvement in dossier quality. Registrants have taken evaluation decisions seriously and improved their dossiers accordingly. The increased number of cases where requested information was provided after involvement of the Member State authorities also shows that the cooperation between ECHA and the enforcement agencies is working and delivers results. As in previous years, the information quality and consistency of registration data still need to improve, especially related to exposure assessment, risk characterisation and substance identity. That is why recommendations on how industry can improve dossier quality forms an integral part of this annual report.

With this in mind, I want to remind registrants that the registration process does not stop with a registration number. Please be proactive and update your dossiers. I also want to encourage all the registrants preparing for the 2018 deadline to start their preparations early and make use of this report and existing support. ECHA's REACH 2018 web section is a good starting point for newcomers.

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

Geert Dancet
Executive Director
European Chemicals Agency

EXECUTIVE SUMMARY

The report describes the results of ECHA's evaluation activities in 2014, highlights the most commonly observed deficiencies in registration dossiers and provides recommendations to registrants. These recommendations serve as an annual reminder on how to improve the quality of registrations. All registrants are encouraged to consider them and to be proactive in updating and improving their dossiers. Continuous improvement of the hazard, use and exposure information in the registration dossiers will lead to better assessment of risks and safer use of chemicals.

Testing proposals in focus

In 2014, ECHA's focus of evaluation shifted from compliance checks to testing proposal examination, to examine the 770 proposals submitted by the 2013 registration deadline by the 1 June 2016, proposals submitted in 2014 for new substances and unfinished examination of proposals carried over from 2013. In total, ECHA concluded 239 examinations and took 129 decisions. In 112 of the decisions taken, ECHA accepted the tests proposed by the registrants, while in 16 cases the Agency modified at least one of the tests proposed. In one case, ECHA rejected the test proposed altogether.

Compliance checks

The high volume of dossiers opened during 2013 resulted in a large quantity of compliance check work being carried over into 2014. Additionally, ECHA started to check some of the new registration dossiers submitted for the second registration deadline of 31 May 2013 for compliance. A total of 283 compliance check evaluations were concluded as new cases by ECHA. Of these, 111 (39%) were concluded with no further action and 172 cases (61%) led to a draft decision. Since the selection criteria are intended to find cases with high potential for compliance issues and only a small portion are selected randomly, these figures cannot be taken to indicate the overall quality of the whole registration database. Regarding compliance check cases at a decision-making phase, 132 were closed after the draft decision. For 273 dossiers, ECHA took decisions under compliance check.

Most frequent shortcomings

REACH places the responsibility for establishing the safe use of chemicals on the companies manufacturing and importing chemicals in the EU. They must show in their registration dossiers that their chemicals are

being used safely. The safe use of chemical substances can only be ascertained by reliable test results or by alternative information justified scientifically, along with rigorous risk assessment that reflects the real situation.

If ECHA finds data gaps or invalid waiver justifications when checking a dossier for compliance, it sends a decision to the registrant, requesting for the missing information. Most of these information requests in 2014 related to exposure assessment and risk characterisation, substance identity, pre-natal developmental toxicity studies, sub-chronic toxicity studies, and physicochemical properties.

Improved compliance after decisions

Compliance with ECHA's decisions on compliance checks and testing proposals has increased. ECHA conducted 282 follow-up evaluations in 2014, examining whether the registrants had provided the information requested in ECHA's decisions. A comparison of the 2014 outcome types with those reported for 2013 shows a higher proportion of cases in 2014 where the evaluation could be completed as the registrant had complied with the decision.

Progress in substance evaluation

Of the 47 substances evaluated during 2013, the evaluating Member States concluded that 38 of these required further information in order to clarify the suspected concern(s). Consequently, in 2014, ECHA sent draft decisions for commenting to the registrants of these substances. The completion and publication of numerous decisions under substance evaluation has increased ECHA's experience of this process and provided a better understanding of the subsequent steps, also for registrants.

Progress with Extended One Generation Reproductive Toxicity Study (EOGRTS) decision

The Commission made progress on how to incorporate the EOGRTS in the REACH information requirements. ECHA trusts that the over 200 dossier evaluation cases currently pending with the Commission concerning this issue will finally be resolved.

Scientific developments

A number of regulatory science developments of direct relevance to the evaluation process were progressed significantly or were finalised during 2014. REACH promotes the use of alternatives to testing on animals and several of the scientific developments during 2014 concerned approaches that promote the replacement, reduction and refinement of animal experiments in the safety assessment of chemicals.

Development of a new compliance check strategy

ECHA developed a new compliance check strategy to achieve high quality information for the safe manufacture and use of chemicals. The most important change will be to focus on checking the quality of information of those substances and information requirements which are expected to have the biggest impact on the improved protection of people and the environment.

According to the new approach, ECHA will maximise the impact of compliance check on the safe use of chemicals, by improving the selection of substances of concern and by refining the coordination of different REACH and CLP measures to address these concerns effectively.

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 can identify any potential shortcomings in their current dossiers and update them accordingly.

The correct identity and composition of the substance is crucial

A (joint) registration must cover exactly one substance; the information given in each registration dossier must correspond to that specific substance.

Each element of the substance identity information must be included within the registration dossier. Manufactured/imported substances should be identified in a specific and exact manner.

EC and CAS identifiers must precisely describe the presence of all the main constituents included in the composition of the substance.

Report hazard information clearly

Robust study summaries should be clear and robust, including tabular data, according to the criteria published in ECHA's Practical Guide 3 and the relevant test guidelines.

The rational for a testing proposal should be considered carefully. The test material should be clearly identified and representative for all member registrations in a joint submission.

The testing proposal must be identified exclusively within IUCLID in the corresponding endpoint study record by selecting 'Experimental study planned' in the field 'Study result type'.

Adapt according to REACH rules

The adaptation needs to be adequate for the chemical safety assessment, with a level of confidence that is comparable to the test it aims to replace.

For QSAR, the structural characteristics of the registered substance should be covered by the training set of the QSAR model.

All QSARs, irrespective of the predicted property, need to be properly documented. This includes the compilation of QSAR Model Reporting Format (QMRF) and QSAR Prediction Reporting Format (QPRF) for the prediction.

For read-across/grouping, justify why the similarity in structure leads to a similarity of the considered property.

Read-across to information which has not yet been generated for the read-across substance is not a valid adaptation. Instead, a testing proposal for a test to be performed with that read-across substance, should be submitted, indicating that the test results will be used for read-across purposes and justifying why the read-across is plausible.

The CSR should reflect realistic uses and conditions of use

Automatised use of Tier 1 tools for mass production of exposure scenarios can lead to unhelpful or misleading risk management advice in the exposure scenarios.

More realistic information on uses and conditions of uses can be gained by employing use maps that have been developed by downstream user sector associations in dialogue with registrants.

As a first step in the assessment, map out all the uses including information on the corresponding conditions of use. The use description needs to be clear and consistent with the uses of the substance in the supply chain.

For the environmental exposure assessment, always ensure that an adequate explanation on the conditions of use leading to the assumed release rate is provided.

Use ECHA's guidance and tools

When preparing and maintaining a registration, consult the guidance material on ECHA's 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 a registration to gain valuable advice for checking both the completeness and the quality of the dossier.

Consult ECHA's web section on how to improve your dossier[1], which provides information and tools to support registrants in improving their dossiers.

Further recommendations can be identified within the 'Observation' boxes provided throughout this report.

[1] http://echa.europa.eu/en/support/how-to-improve-your-dossier

1. The evaluation process

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.

Observation

Registrants who familiarise themselves with the evaluation processes tend to be better informed of the subsequent steps involved upon receipt of a draft decision for the first time.

Figure 1: The process of evaluation

Details of the evaluation processes are provided both in previous evaluation reports[2] and the ECHA website[3], which also includes non-confidential versions of evaluation Decisions[4].

[2] http://echa.europa.eu/regulations/reach/evaluation
[3] http://echa.europa.eu/documents/10162/13607/pro_0017_03_dossier_evaluation_en.pdf
[4] http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions

2. ECHA'S progress in 2014

Two key changes were made to the evaluation work performed during 2014. Firstly, the focus of evaluation shifted from compliance check (CCh) to testing proposal examination (TPE). This was necessary to address the late 2010 submissions and to begin work on the 2013 testing proposals in time for the June 2016 statutory deadline. Secondly, ECHA used its extensive experience of compliance checks, to refine the overall approach, priorities and objectives for dossier evaluation in order to improve the quality of information provided by companies.

ECHA continued with the decision-making process on those draft decisions issued in 2012 and 2013. However, for the third year in a row, ECHA was unable to issue any dossier evaluation decisions concerning the information requirement for a two-generation reproduction study (Annex IX/X, 8.7.3) as detailed in section 2.6.7 of this report. This was because, in the decision-making process, ECHA's Member State Committee could not reach a unanimous agreement on what test should be imposed to address this information requirement (two-generation reproductive toxicity study versus EOGRTS[5]). As a result, altogether 33 draft decisions on compliance checks and 183 draft decisions on testing proposals have had to be referred to the Commission for decision making.

In 2014, the Commission made progress in preparing a regulation amending Annexes VIII, IX and X of the REACH Regulation to incorporate the EOGRTS (adopted as a new test guideline in July 2011) in the REACH information requirements. ECHA therefore expects that the long-standing stalemate on this information requirement will be finally resolved in 2015. ECHA trusts that the Commission will then be able to reach a decision with respect to the over 200 cases pending as a result of this issue. This should also allow ECHA to start issuing decisions itself on this endpoint. As a result of these pending cases and the high number of draft decisions issued in 2014, an important part of ECHA's resources will continue to be allocated to the decision-making process on the draft decisions.

In 2014, ECHA developed an overall strategy for CCh selection and its strategic direction for the period of 2014-2018 to achieve high quality information for the safe manufacture and use of chemicals. ECHA's revised approach to CCh's was initiated in a workshop in March-April 2014 with stakeholders, Member States representatives and the Commission, which resulted in a range of recommendations reported in the workshop proceedings[6]. The new CCh strategy[7] was endorsed by ECHA's Management Board in September 2014 and implemented from 2015 onwards. According to the new approach, ECHA will maximise the impact of CCh on the safe use of chemicals, by improving the selection of substances of concern for CCh, by focusing the evaluation on key information requirements for human health and the environment, and by refining the coordination of different REACH and CLP measures to address these concerns effectively.

As part of the increased transparency under the new CCh strategy, in January 2015 ECHA published a list of substances which will be potentially subject to compliance check. The list is developed in accordance with ECHA's new CCh strategy and is based upon the results of the common screening approach that has been developed by ECHA together with the Member States. The list of substances potentially subject to CCh will be updated periodically each year. Registrants are advised to check this list regularly, and may wish to review their related registration dossiers and update them with any new and/or relevant information including, where applicable, an update of the CSR.

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[5] Extended One-Generation Reproduction Toxicity Study
[6] http://echa.europa.eu/documents/10162/13628/cch_workshop_en.pdf
[7] http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

Implementation of the new CCh strategy also provided an opportunity to review ECHA's current practice concerning consideration of dossier update submissions during the dossier evaluation processes (TPE and CCh). It was concluded that the current practice seriously affected the efficiency of dossier evaluation. Therefore, from January 2015, ECHA will implement the following important changes:

- For TPE, any dossier update received within 30 days after the end of the registrant's (30 days) commenting period will be taken into account by ECHA. Updates coming after this period will not be considered.

- For CCh, dossier updates submitted after issuing the draft decision for registrant's comments will no longer be taken into account.

These changes aim to increase the efficiency of dossier evaluation and to provide increased predictability and certainty to registrants and MSCAs.

2.1 COMPLIANCE CHECKS

The compliance check determines whether the information submitted within a registration dossier is compliant with the requirements of REACH. During 2014, ECHA adopted 273 CCh decisions requesting additional information from registrants where essential data on substances was missing. This valuable work assisted registrants in improving the quality of their dossiers and contributed towards maximising the availability of high quality data to enable the safe manufacture and use of chemicals.

Despite focusing on testing proposal examination, the high volume of dossiers opened during 2013 resulted in a large quantity of CCh work being carried over into 2014. Additionally, over 9 000 new registration dossiers were submitted for the second registration deadline of 31 May 2013, which ECHA also started to check for compliance. The CChs opened and/or processed during 2014 were derived from three separate sources:

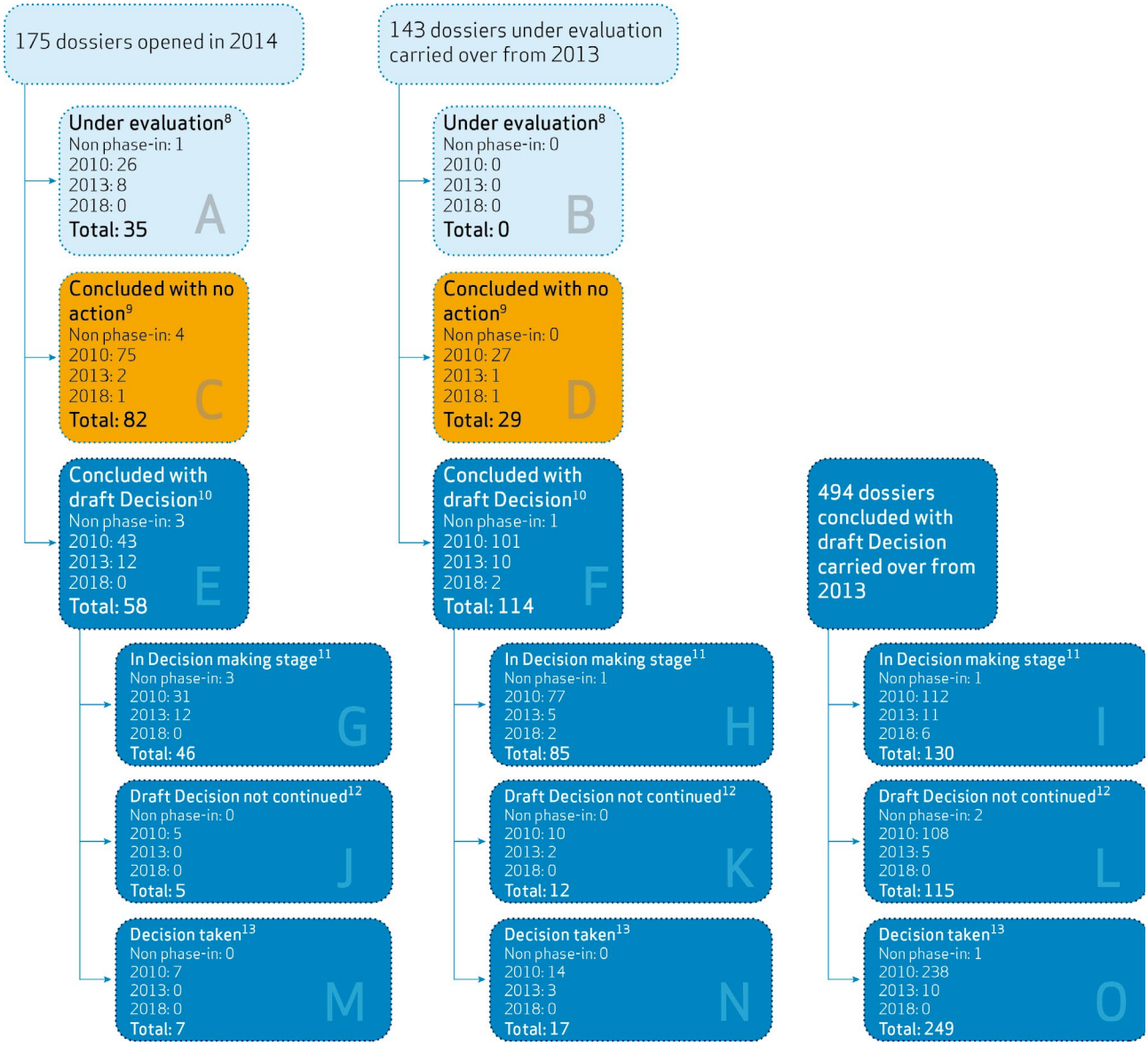
- 143 CChs opened in 2013 but with no conclusion, carried over for completion in 2014.

- 494 CCh draft decisions sent to the registrants in 2013, carried over for completion in 2014.

- 175 CChs opened in 2014.

Figure 2 highlights the numbers and outcome of CCh dossiers during 2014.

Figure 2: Number and outcome of CCh dossiers processed during 2014



[8] Scientific and legal evaluation stage.
[9] No formal action towards the registrant is deemed necessary.
[10] Formal action to request further information from the registrant is deemed necessary.
[11] Stages of processing the draft decision, including notification of the draft decision to the registrant(s), notification to the MSCAs, referral to the MSC (where applicable), and referral to the Commission (where applicable).
[12] Scientifically relevant data or important administrative changes lead to termination of the ongoing decision making procedure.
[13] ECHA evaluation decision taken either following a unanimous agreement of the MSC, or where no proposals for amendment of the draft decision were submitted by the MSCAs.

Of the 283[14] dossiers evaluated under CCh during 2014, ECHA concluded that 61% (172[15]) did not comply with all the checked REACH information requirements, and draft decisions were sent to the registrants. The remaining 111[16] cases were concluded with no further action; see Table 1.

Table 1: Compliance checks concluded in 2014, by tonnage band.

TONNAGE BAND	NUMBER OF CCHS		TOTAL
	WITH DRAFT DECISIONS	WITHOUT DRAFT DECISIONS	
→ 1000 t/a	136	94	230
100 to 1000 t/a	29	13	42
10 to 100 t/a	3	2	5
1 to 10 t/a	4	2	6
Total	172	111	283

All of the draft decisions were sent to the registrants within the 12-month legal deadline.

2.1.1 Decisions taken under compliance check

During 2014, ECHA adopted 273[17] decisions under CCh and closed 132[18] cases after draft decision.

For the decisions taken under CCh, 190 (70%) of these decisions were taken without proposals for amendments (PfAs) from the MSCA's. The remaining 83 decisions were taken after the MSC reached a unanimous agreement on draft decisions, either in a written procedure or by discussion in one of its meetings.

Observation

Pursuant to Article 51(5) of the REACH Regulation registrants are invited to comment on any proposals for amendment (PfA). Registrants' comments that do not address the PfA (but other issues of the draft decision) are not taken into account during the decision-making process.

A total of 33 CCh draft decisions referred to MSCAs for commenting, contained requirements for a two-generation reproduction toxicity study. The MSC handled these proposals separately from other information requests due to recent scientific developments that require further policy considerations before the testing can be decided (further information is provided within section 2.6.6 of this report).

[14] C+D+E+F within Figure 2
[15] E+F within Figure 2
[16] C+D within Figure 2
[17] M+N+O within Figure 2
[18] J+K+L within Figure 2

After the MSC established the absence of a unanimous agreement on an appropriate study for this endpoint, those CCh draft decisions that also contained other information requests were each split into two parts. ECHA referred the part of the draft decisions addressing reproductive toxicity to the European Commission for decision making. The other part of the draft decisions addressing other information requirements was adopted as final decisions by ECHA following the MSC unanimous agreement on that part of the draft decision.

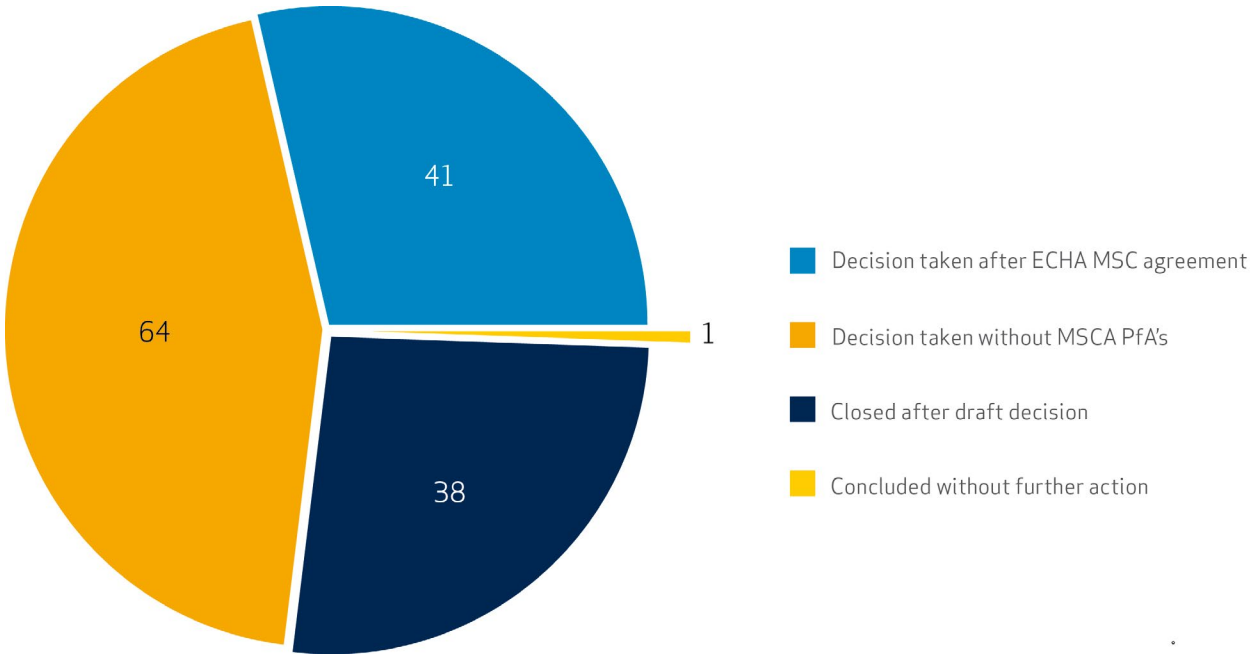
The dossiers selected for checking can be divided into two main types, overall compliance checks and targeted compliance checks.

Overall compliance checks

For overall compliance checks, ECHA either selects these dossiers randomly or using concern-driven criteria. Ideally, an overall CCh of a dossier occurs in one single assessment and decision making. In practice, every overall CCh 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. 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.

Of the 516 dossier CCh evaluations finalised with decision, closed after draft decision or concluded with no action during 2014 by ECHA, 144 were overall CChs. Figure 3 shows the outcome of these checks (draft decisions still in the decision-making process are not included).

Figure 3: Outcome of the 144 'overall' compliance checks performed in 2014



In 26% of the cases, registrants promptly updated their dossiers, which significantly improved the quality of their registration dossiers and rendered them compliant with the requested information.

Targeted compliance checks

In 2014, ECHA completed the enhanced computer-assisted selection of registration dossiers for targeted compliance checks to address severe non-compliances in all dossiers. For targeted checks, the majority of the registration database is screened and then dossiers with a higher potential to be deficient in priority endpoints called 'areas of concern' are selected for compliance check.

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

- Substance identity issues (often necessary before initiating a testing proposal examination).
- Areas of concern: endpoints considered highly relevant to risk management and chemical safety.
- Substances listed in the Community rolling action plan (CoRAP).

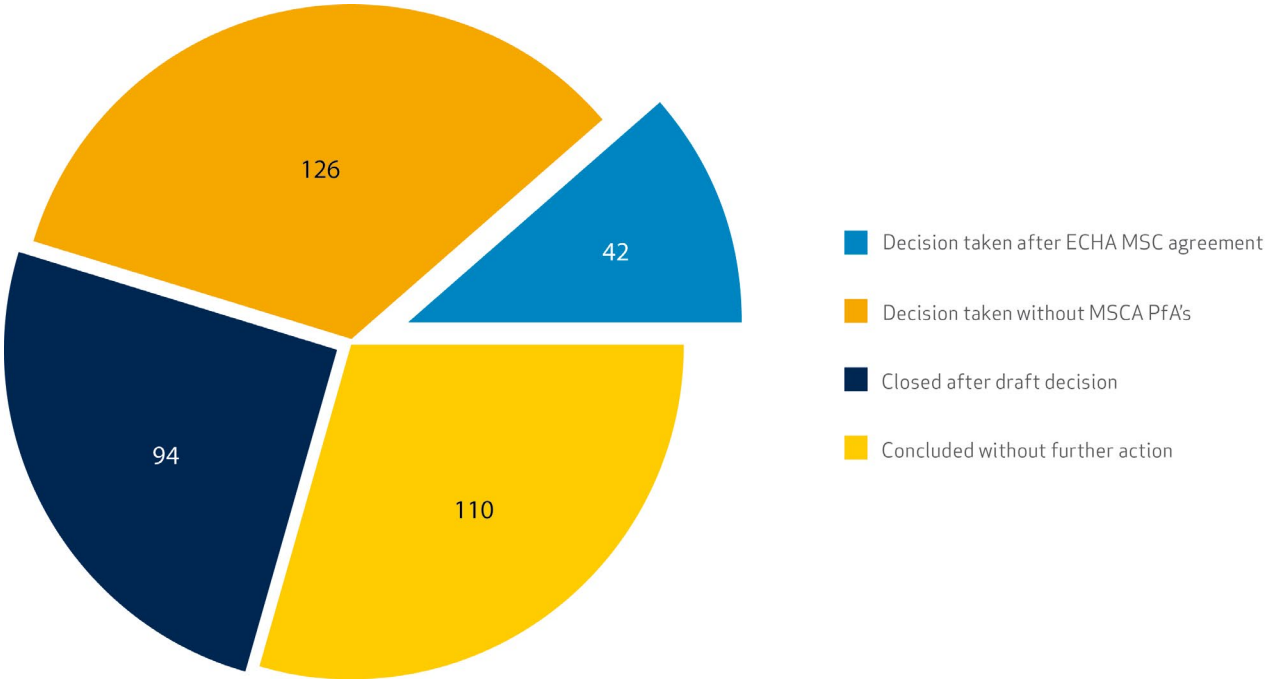
The CCh of substances listed in the CoRAP has usually been regarded as targeted since the scope is defined in order to support and potentially complement the subsequent substance evaluation. It normally implies a general screening but with a special focus on all endpoints that will not be investigated as a concern to be clarified under the ensuing substance evaluation. Moreover, when there is limited time before the start of the substance evaluation by Member States, the CCh can be limited to the substance identity check.

If ECHA is unable 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.

When many non-compliances are found in a single dossier, ECHA may decide to increase a targeted check to an overall check because the dossier deserves a wider assessment.

Of the 516 dossier CCh evaluations finalised with a decision, closed after a draft decision or concluded with no action during 2014 by ECHA, 372 were targeted compliance checks. Figure 4 shows the outcome of these checks (draft decisions still in the decision-making process are not included).

Figure 4: Outcome of the 372 'targeted' compliance checks performed in 2014



In 25% (94) of the cases, registrants updated their dossiers before ECHA proceeded to decision making. This significantly improved the quality of their registration dossiers and in some cases, led to termination of the case before a final decision needed to be issued.

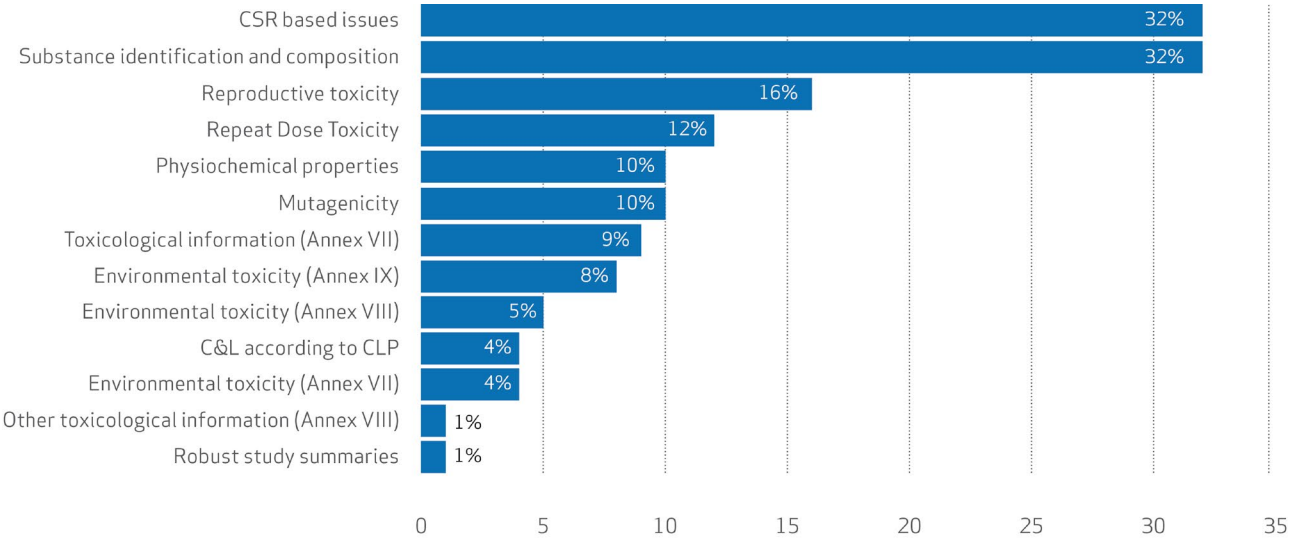
Observation

ECHA acknowledges that more comprehensive reporting is needed to demonstrate what was checked during CCh of dossiers for substances registered at tonnage bands of ≥1 000 and 100-1 000 t/a. Unfortunately, such thorough reporting was not technically possible during 2014 , however, ECHA is working to develop methods to achieve this in 2015.

Information requested from the registrants

Figure 5 provides a summary of the types of information requested as a percentage of the overall number of CCh decisions taken in 2014.

Figure 5: Types of information requested as a percentage of the 273 CCh decisions taken in 2014.



The information requested from the registrants in ECHA's CCh decisions is summarised in Table 2. It is important to note that a decision may contain more than one request.

Table 2: Information requested by compliance check decisions.

Type of information requested	Number of decisions
Exposure assessment and risk characterisation	88
Identification and verification of the composition of the substance	86
Pre-natal developmental toxicity (Annex IX)	37
Sub-chronic toxicity study, 90-day (Annex IX)	34
Physicochemical properties	27
Toxicological information (Annex VII)	24
Ecotoxicological information (Annex IX)	21
In vitro gene mutation study in mammalian cells (Annex VIII)	20
Ecotoxicological information (Annex VIII)	15
C&L according to CLP	12
Ecotoxicological information (Annex VII)	11
In vitro cytogenicity study in mammalian cells (Annex VIII)	6
Two-generation reproduction toxicity study[19] (Annex IX and X)	6
Robust study summaries	2
Screening for reproductive/developmental toxicity (Annex VIII)	1
Other toxicological information (Annex VIII)	1

[19] Requesting study results that already exist.

2.2 TESTING PROPOSALS

ECHA continued to draft and take decisions on testing proposals to make sure that these addressed the actual information needed and avoided unnecessary testing, particularly when testing involved the use of vertebrate animals.

Among the dossiers submitted by the 2013 registration deadline, ECHA has so far identified testing proposals within 770 endpoints included in 376 unique dossiers. Of these, 563 proposed testing 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 TPEs opened and/or processed during 2014 were derived from three separate sources:

- 27 TPEs opened in 2013 but with no conclusion, carried over for completion in 2014.
- 208 TPE draft decisions sent to the registrants in 2013, carried over for decision making in 2014.
- 396 TPEs newly opened in 2014.

Observation

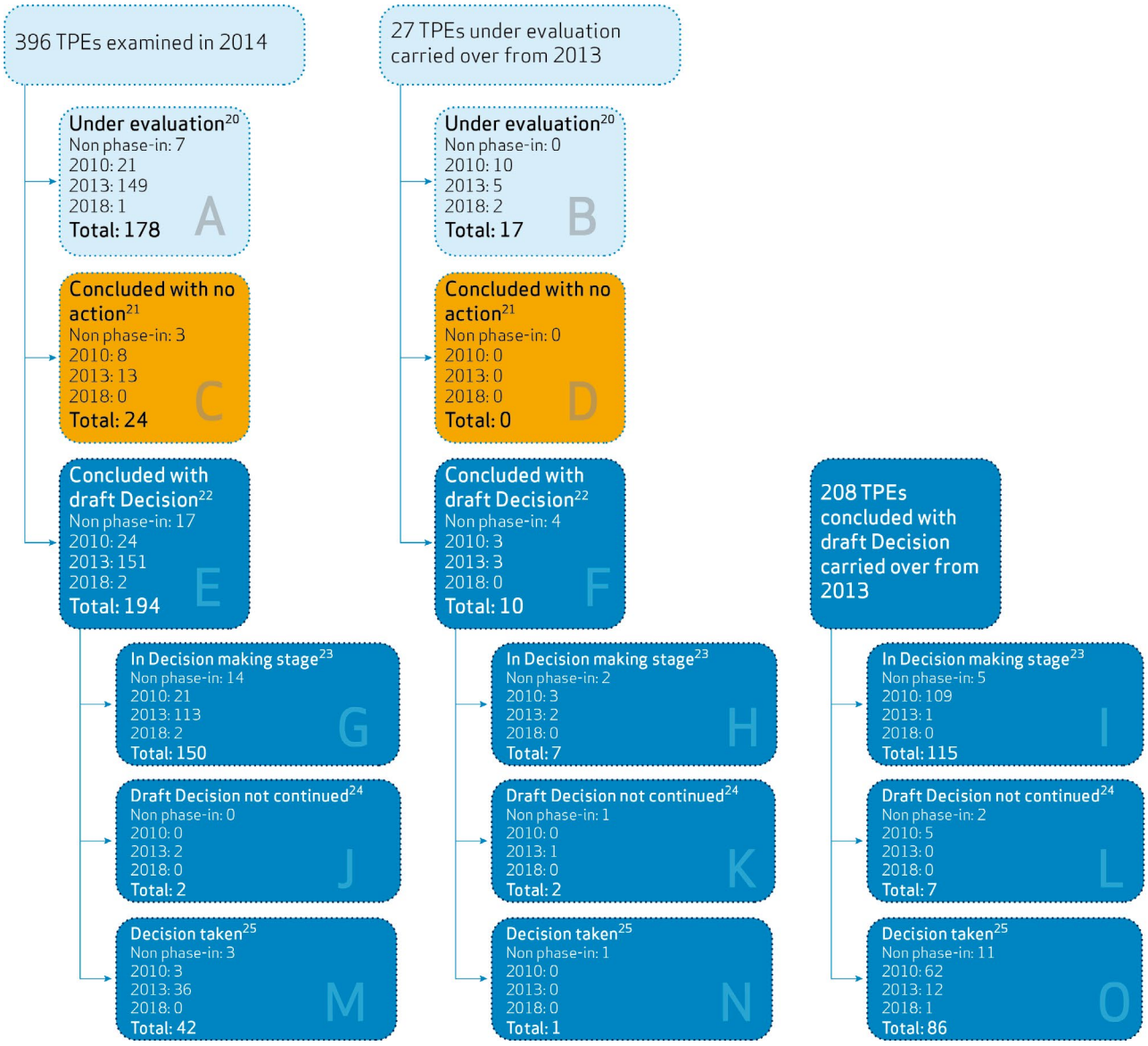
Some testing proposals submitted in the registration dossier remain undetected because of improperly compiled dossiers, e.g:

- *Changing the text of a previous testing proposal in the endpoint study record (ESR) in IUCLID.*
- *Indicating the testing proposal only in the Chemical Safety Report.*
- *Failing to indicate as a testing proposal the intention to test an analogue substance(s) for the purposes of read-across.*

A testing proposal must be identified exclusively within IUCLID in the corresponding endpoint study record by selecting 'Experimental study planned' in the field 'Study result type'. A new ESR needs to be created for each new test proposed.

Figure 6 highlights the number and outcome of testing proposal examinations processed during 2014.

Figure 6: Number and outcome of Testing Proposal Examinations processed during 2014

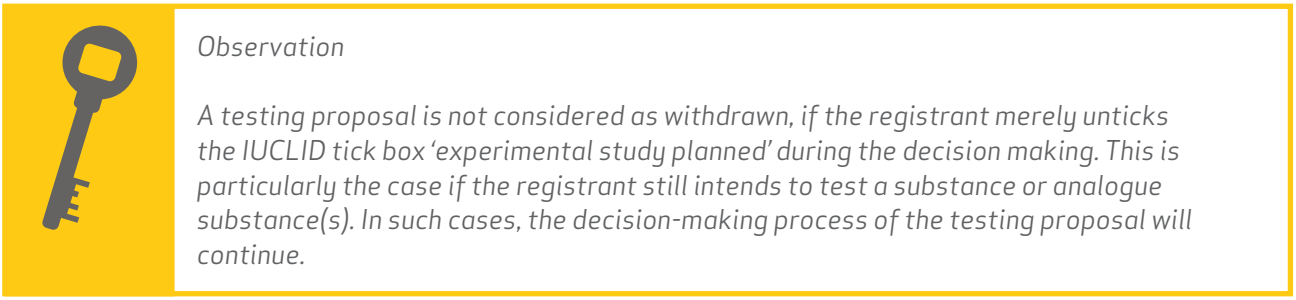


[20] Scientific and legal evaluation stage
[21] Testing proposal is deemed inadmissable by ECHA or is withdrawn by the registrant
[22] A draft decision on the proposed testing is deemed necessary
[23] Stages of processing the draft decision, including notification of the draft decision to the registrant(s), notification to the MSCAs, referral to the MSC (where applicable), and referral to the Commission (where applicable)
[24] Scientifically relevant data or important administrative changes led to termination of the ongoing decision-making procedure
[25] ECHA evaluation decision taken either following a unanimous agreement of the MSC, or where no proposals for amendment of the draft decision were submitted by the MSCAs

By the end of 2014, ECHA concluded 239[25] testing proposal examinations by:

- Sending 204[26] draft decisions.
- Terminating 35[27] cases.

An examination may be terminated because the registrant withdrew the proposal after ECHA started to examine it, or because the proposal is not admissible.



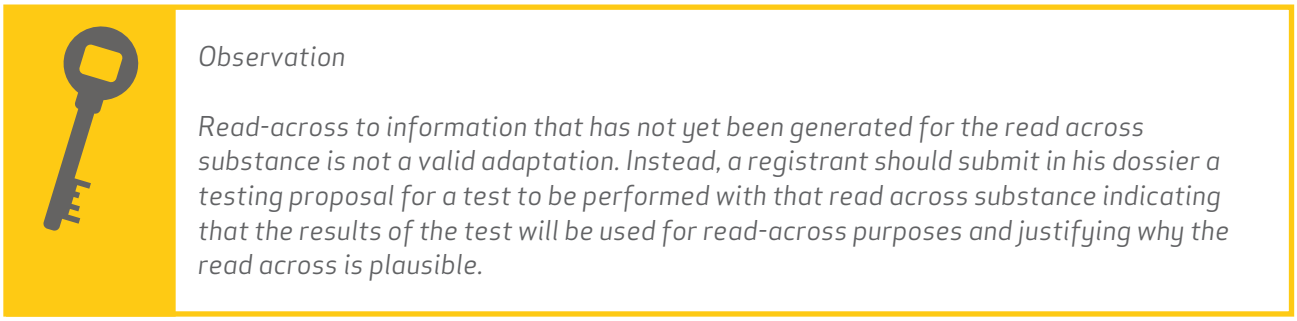
Observation

A testing proposal is not considered as withdrawn, if the registrant merely unticks the IUCLID tick box 'experimental study planned' during the decision making. This is particularly the case if the registrant still intends to test a substance or analogue substance(s). In such cases, the decision-making process of the testing proposal will continue.

The evaluation of a further 195[28] dossiers continues beyond 2014; for these, a draft decision has not yet been issued.

2.2.1 Decisions taken under testing proposal examination

In 2014, ECHA took 129[29] decisions under testing proposal examination. In 112 (87%) decisions taken, ECHA accepted the tests proposed by the registrants, while in 16 cases the Agency modified at least one of the tests proposed. In one case, ECHA rejected the test proposed altogether.



Observation

Read-across to information that has not yet been generated for the read across substance is not a valid adaptation. Instead, a registrant should submit in his dossier a testing proposal for a test to be performed with that read across substance indicating that the results of the test will be used for read-across purposes and justifying why the read across is plausible.

[25] C+D+E+F+J+K+L within Figure 6
[26] E+F within Figure 6
[27] C+D+J+k+L within Figure 6
[28] A+B within Figure 6
[29] M+N+O within Figure 6

Of these 129 decisions, 68 were taken without referral to the MSC because the MSCAs did not propose amendments. For the remaining 61 cases, the draft decisions received at least one proposal for amendment from the MSCAs. In all 61 cases, the MSC unanimously agreed on the decisions and ECHA accordingly took them.

Information requested from the registrants

In total, in 2014, ECHA adopted 129 testing proposal examination Decisions and Figure 6 provides a summary of the types of information requested as a percentage of the overall number of those Decisions taken in 2014.

Figure 7: Types of information requested as a percentage of the overall number of TPE Decisions taken in 2014.

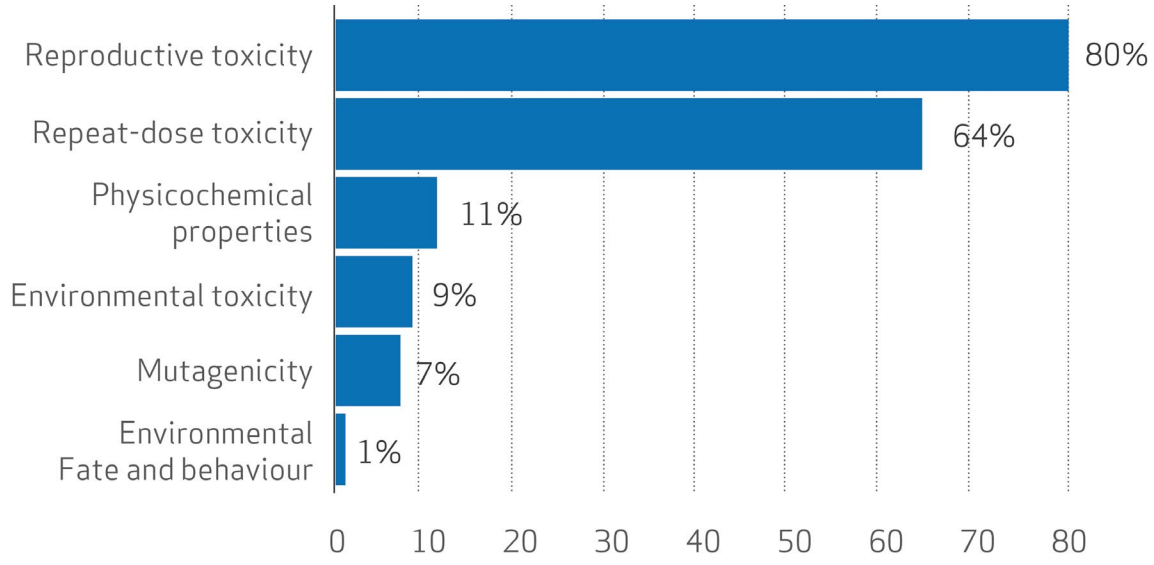


Table 3 provides a summary of the type of testing requested. It is important to note that a decision may contain more than one request.

Table 3: Information requested in testing proposal decisions (sorted by annex).

Type of testing requested	Number of decisions
Pre-natal developmental toxicity study (Annex IX)	102
Sub-chronic toxicity study, 90-day (Annex IX)	83
Physicochemical properties (Annex IX)	14
Effect on terrestrial organisms (Annex IX)	5
Long-term aquatic toxicity testing on invertebrates (Annex IX)	4
Mutagenicity (Annex IX)	3
Mutagenicity (Annex VII and VIII)	2
Pre-natal developmental toxicity study (Annex X)	1
Long-term toxicity to sediment organisms (Annex X)	1
Effect on terrestrial organisms (Annex X)	1
Biotic degradation (Annex IX)	1
Mutagenicity (Annex X)	1*

* Rejected pursuant to Article 40(3)(d)

In addition, a total of 112 testing proposal examination draft decisions contained requirements for a two-generation reproduction toxicity study. The MSC handled these proposals in the same manner as those described for the CCh draft decisions specified within section 2.1.1 of this report. As a result, 112 draft decisions were referred to the Commission for decision taking.

2.2.2 Third party consultation

Since June 2008, ECHA has received approximately 1 500 proposals for performing tests on vertebrate animals, which are subject to public consultation[30], in order to avoid unnecessary duplication of animal testing.

According to Article 40(2), ECHA shall publish the TPs submitted and require any third party information.

ECHA received 782 third party contributions (52%) related to the public consultations launched. 191 submitters requested for their identity to not be disclosed (24%) and therefore further details cannot be

[30] For previous consultations: http://echa.europa.eu/web/guest/information-on-chemicals/testing-proposals/previous/outcome. For current consultations: http://echa.europa.eu/web/guest/information-on-chemicals/testing-proposals/current.

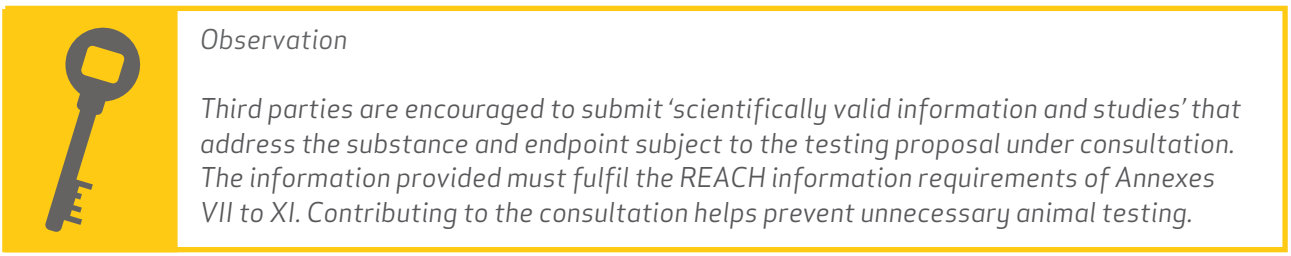
provided. The remaining 591 third party contributions (76%) were submitted by:

- 17 individual companies, accounting for 47 comments (7.9%)
- Eight industry or trade associations, accounting for 59 comments (10.1%)
- One foundation accounting for one comment (0.2%)
- Two international NGOs, accounting for 477 comments (80.7%)
- One national authority, accounting for two comments (0.3%).

Finally, four individuals, accounting for five contributions (0.8%) submitted information during the consultation process. The identity of those individuals is being protected under our data privacy rule and cannot be disclosed.

Third parties frequently sent scientific information for ECHA's consultations of testing proposals in 2014. In several contributions, third parties provided scientific reasoning with references to the specific adaptation possibilities provided in the REACH Regulation.

Consideration of a read-across approach was suggested in approximately 200 comments. In the majority of cases, the third party information received was not sufficient for ECHA to conclude that further testing was unjustified. However, registrants are always informed of the information received and may further develop adaptations based upon the third party contributions.



Observation

Third parties are encouraged to submit 'scientifically valid information and studies' that address the substance and endpoint subject to the testing proposal under consultation. The information provided must fulfil the REACH information requirements of Annexes VII to XI. Contributing to the consultation helps prevent unnecessary animal testing.

Public versions of third party contributions and ECHA's responses are published on ECHA's web sections as part of ECHA's decisions on testing proposals[31].

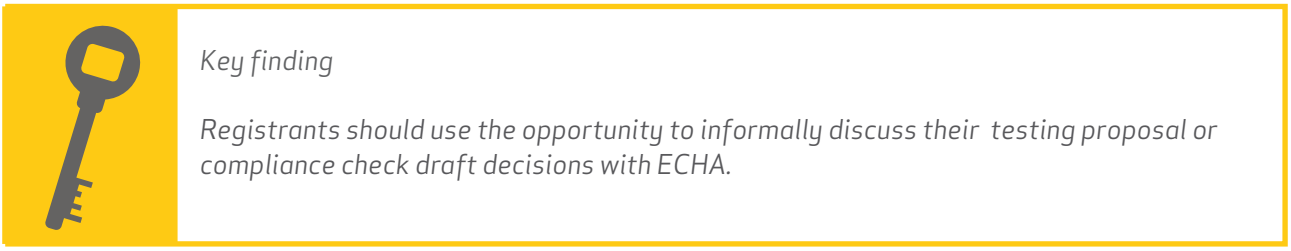
[31] http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions

2.3 INFORMAL COMMUNICATIONS AND DOSSIER UPDATES

As part of the decision-making process, registrants in receipt of a certain draft decision under dossier evaluation (CCh or TPE) are offered the opportunity to clarify its rationale with ECHA. The following is an analysis of the informal communications held and the comments submitted by registrants during their 30-day commenting period on the draft decision, and their subsequent consequences on the draft decisions.

To date, only approximately 20% of the dossier evaluation draft decisions (CCh or TPE) where registrants were offered the opportunity to clarify their rationale with ECHA resulted in informal discussions being held. However, around 73% of these draft decisions subsequently received formal comments from the registrants.

In addition, around 34% of these draft decisions were amended as a result of registrant comments and another 19% were subsequently terminated (after a dossier update).



Key finding

Registrants should use the opportunity to informally discuss their testing proposal or compliance check draft decisions with ECHA.

2.4 FOLLOW-UP EVALUATION AND ENFORCEMENT OF DOSSIER EVALUATION DECISIONS

Under Article 42 of REACH, ECHA examines whether the registrant has provided the information requested in the decision in their latest dossier update. This follow-up evaluation happens after the deadline specified in the decision has passed.

In 2014, ECHA conducted 282 follow-up evaluations. The possible outcomes of the follow-up evaluation are:

1. An Article 42(2) notification is sent to the Member States and the European Commission to inform them that the information requirement has been met.

2. A Statement of non-compliance following a dossier evaluation decision (SONC) is sent to the relevant Member State authorities informing them that (part of) the requested information was not received by the deadline set. The registrant receives a copy of the SONC. Enforcement measures are considered by the Member States. Article 42(2) notification is put on hold until all information requested in the decision has been received.

3. Requests in the decision have been complied with, but the information provided makes some further requests necessary. A new CCh is opened according to Article 42(1).

Note that an Article 42(2) notification will be sent, ultimately, after a SONC has already been issued, if the

registrant eventually submits the requested information. Further information on the follow-up process can be found in the follow-up factsheet[32]. The number of outcome types is summarised in Table 4.

Table 4: Number of outcome types for follow-up evaluations conducted in 2014. A comparison of the 2014 outcome types with those reported for 2013[37] shows a slight increase in the number of cases in 2014 where

	Article 42(2) notification without SONC[33]	Article 42(2) notification after a SONC[34]	New CCh based on Article 42(1)[35]	SONC[36]
TPE Decisions	88 (31%)	11 (4%)	0	27 (10%)
CCh Decisions	117 (41%)	19 (7%)	3 (1%)	17 (6%)
Total	205 (72%)	30 (11%)	3 (1%)	44 (16%)

Value in ( ) denotes the percentage of the total follow-up evaluations conducted in 2014.

registrants complied with the requests in the decision, without a SONC having to be issued. However, the number of cases that require involvement from the Member State authorities increased. The number of cases for which the requested information was provided after involvement of the Member State authorities increased to 30 in 2014 indicating that the cooperation between ECHA and the enforcement agencies is working and delivers results.

It is noteworthy that a significant number of follow-up evaluations in 2014 concerned requests from targeted CCHs, which can partially explain the higher rate of compliance with decisions compared to 2013.

In addition, ECHA conducted follow-up evaluations on 11 quality observation letters (QObLs). In 10 cases, the QObLs resulted in an improvement of the dossier quality either by fully (three cases) or partly (seven cases) meeting the information needs addressed. In one case, the information needs were not addressed at all. In another case, the registrants had ceased manufacture. The Member States have been informed on the results.

Observation

Often, the quality of the provided robust study summaries prevent an independent assessment by ECHA and therefore SONCs are issued. Registrants should provide clear robust study summaries, including tabular data, according to the criteria published in ECHA's Practical Guide 3 and the relevant test guidelines.

The implications of new information on hazard endpoints need to be addressed for the chemical safety assessment, including revising the DNEL and PNEC derivation as necessary.

[32] http://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf
[33] All requests in the Decision have been complied with, without a SONC having to be issued.
[34] A SONC and subsequent Member State actions led to a dossier update now compliant with the requests in the Decision.
[35] Requests in the Decision have been complied with, but new requests for data are needed. Article 42(2) notification has been put on hold.
[36] 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.
[37] Comparison based upon percentage of Article 42(2) notifications without a SONC being issued: 64% in 2013 compared to 72% in 2014.

2.5 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 the identification of chemicals of concern requiring further risk management.

ECHA's priorities for substance evaluation in 2014 were:

- Finalise and publish the CoRAP 2014-2016 update on ECHA's website.
- Prepare the CoRAP 2015-2017 update for March 2015.
- Continue processing the 36 substances evaluated in 2012.
- Receipt and processing of outcome documents from the 47 substances evaluated in 2013.
- Provide support for the 51 substances undergoing evaluation in 2014.

2.5.1 Finalising the annual CoRAP 2014–2016 update

The proposal for the CoRAP 2014–2016 update covered 120 substances, with 50 substances to be evaluated in 2014. The list contained 52 newly selected substances and 68 substances carried over from the existing CoRAP. The CoRAP 2014–2016 update was adopted in March 2014.

2.5.2 Preparing the annual CoRAP 2015-2017 update

For the first time, the CoRAP update has been based on the outcomes of an integrated screening of the registration database serving different REACH and CLP processes. Therefore, the same screening process has supported the identification of candidate substances for CoRAP and substances for regulatory risk management, in order to be more effective in addressing substances of concern. This integrated screening has also streamlined the development and application of IT screening tools and methods (see chapter 2.6.5).

The proposal for the CoRAP 2015–2017 update covered 143 substances, with 53 substances to be evaluated in 2015. The list contained 75 newly selected substances and 68 substances carried over from the existing CoRAP.

ECHA forwarded the draft to the MSC in mid-October 2014 to collect opinions and posted a public version on its web section on 30 October. 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, carcinogenicity, mutagenicity and reproductive toxicity, in combination with wide dispersive use, consumer exposure and high aggregated tonnage. ECHA anticipates the adoption of the CoRAP 2015–2017 update in March 2015.

2.5.3 Substances evaluated in 2013

ECHA had previously agreed with Member States and accredited MSC stakeholders that interaction between the eMSCA and the registrants is highly recommended, particularly during the evaluation phase. The interactions performed during the evaluation of the 2013 substances were regarded as useful and

this interaction policy[38] was published in January 2014. Furthermore, registrants have applied ECHA's recommendation to gain advanced agreement with the evaluating Member States on the acceptability of proposed dossier updates during either the evaluation stage or the commenting period.

Of the 47 substances evaluated during 2013, the evaluating Member States concluded that 38 of these required further information to clarify the suspected concern(s). As with previous years, 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 2014, almost all Member States used this possibility. ECHA provided its feedback within one month before the 12-month evaluation period deadline.

Consequently, ECHA sent draft decisions for commenting to the 371 registrants of these substances. After this, the eMSCA submitted the case for consultation, where both ECHA and other MSCAs could propose amendments to the draft decision. To date, 100% of all consulted draft decisions under substance evaluation have received proposals for amendments.

For the remaining nine substances evaluated during 2013, the eMSCAs considered the available information as sufficient to conclude on the concerns and submitted their conclusion documents to ECHA. All nine conclusion documents have been published on ECHA's web section.

2.5.4 Substances evaluated in 2014

During 2014, the eMSCAs continued their evaluations of the substances and ECHA provided continual support during this process. Each substance under evaluation was appointed a substance manager within ECHA, who acted as a coordinator and contact point for the eMSCAs. One substance has already been subject to draft decision, while the consistency screening and finalisation of all the other draft decisions will be in early 2015.

2.5.5 Substance evaluation decisions

During 2014, based on the finalisation of some evaluations started in 2012, ECHA has had the opportunity to gain experience on the entire decision-making process including the conclusion stage. The progress of the evaluations started in 2012-2014 is summarised in Table 5.

[38] Interaction between the evaluating Member State and the registrants under Substance Evaluation – Recommendations, ECHA-14-R-01-EN. Located at: http://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf.

Table 5: Progress of the substance evaluations started in 2012, 2013 and 2014.

CURRENT SUBSTANCE STATUS	2012	2013	2014	TOTAL
Total number of substances in the CoRAP	36	47	51	134
Under evaluation	0	0	50	50
Concluded without draft decision	4	9	0	13
In decision-making	4	36	1	41
Draft decisions not unanimously agreed at the MSC	1	0	0	1
To be concluded after draft decision	3	0	0	3
Awaiting requested information	15	2	0	17
Follow up evaluation	3	0	0	3
Under appeal	6*	0	0	6

* 2 of the 6 appeals brought against substance evaluation decisions were not published on the Board of Appeal's web pages by the end of 2014 and therefore do not appear within table 7 under section 2.6.8.

One important factor for an efficient substance evaluation is the capacity of registrants of the same substance to coordinate their actions. Registrants are encouraged to appoint a single representative or 'registrants contact point' for discussions with evaluating Member State Competent Authority (eMSCA). Also during the official commenting period ECHA recommends registrants to submit only one set of comments coordinated among all the registrants subject to a draft decision.

ECHA appreciates the efforts already made by registrants to coordinate their views. In all cases where a draft decision was notified to the registrants of the substance, the registrants communicated with one voice in their comments.

Observation

Registrants should continue the good practice of coordinating their views, for the submission of comments under substance evaluation.

ECHA also acknowledges the tight deadline (30 days) that registrants must observe for submitting their comments on SEv decisions that typically concern many registrants at the same time. However, as this is a statutory deadline, it was considered together with the Member States that the deadline could not be extended. Thus, in this respect, the decision making on information requests for the 2012 and 2013 CoRAP substances has progressed well.

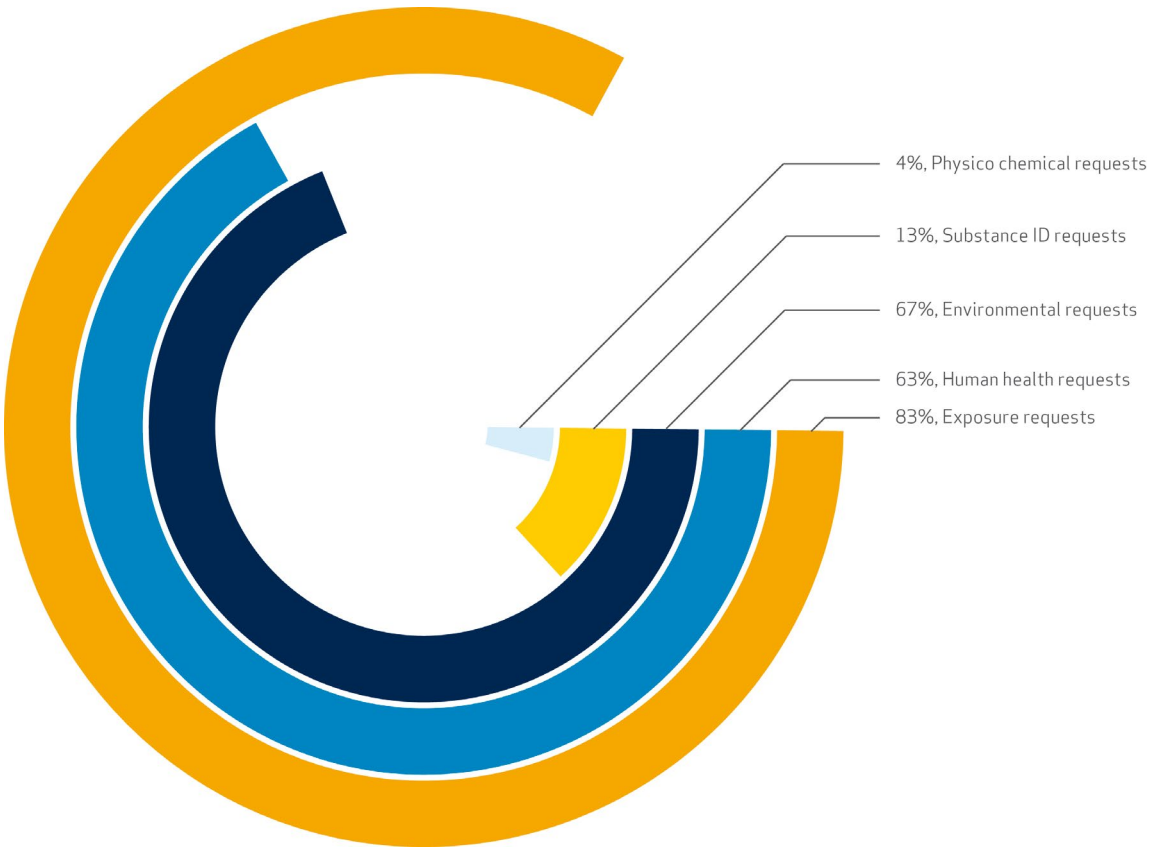
ECHA has taken decisions on 26 of the substances evaluated and non-confidential versions of these decisions have been published on ECHA's web section.

Observation

Registrants should clearly indicate, within 90 days of receipt of a substance evaluation decision, who is volunteering to perform the tests on behalf of others. The webform link in the notification letter can be used for this.

Figure 8 summarises the typical requests made within these decisions.

Figure 8: Percentage of the 26 substance evaluation decisions containing each type of request. In this general outline, requests made in relation to endocrine disruptor properties fall under human health or environmental requests.



In addition, the Member State Committee failed to reach a unanimous agreement on a draft decision for one substance evaluated during 2012. Subsequently, the draft decision was referred to the European Commission for its decision making, where it is currently under consideration.

After ECHA issued the draft decisions for the 2012 substances, some registrants changed their registration status from full to intermediate or ceased to manufacture/import in accordance with Article 50(3). ECHA will monitor such cases in the future to check that after closing the case, registrants do not restart production without newly registering the substances or introducing new uses. In such cases, the Member States may use their right to consider still further (regulatory) risk management measures, and the substance could potentially be reintroduced into the CoRAP to start a new substance evaluation process. In addition, the possibilities of using enforcement to verify that the registration reflects the real situation will be explored in the future.

During 2014, a total of four appeals against ECHA substance evaluation decisions were announced by the Board of Appeal. More information on these is provided within section 2.6.8.

2.5.6 Follow-up of substance evaluation

Upon receipt of the information requested by the decision, in the form of a dossier update, the MSCA responsible has 12 months to complete the assessment of the substance.

Once this assessment is complete, the MSCA uses the information available to decide whether:

- Further information is required to clarify the concern(s). In this case a new draft decision must be sent to the concerned registrant(s) and the decision-making process begins once again.

Or,

- 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 classification and labelling of the substance.
    - To identify it as a substance of very high concern for the Candidate List.
    - To restrict its use.

In 2014, three substances were at the stage where new information has been submitted following an initial request for further information. The responsible MSCAs are currently evaluating the newly submitted information in order to conclude on its suitability and application.

The foreseen process for the follow up evaluation was discussed in the 2014 Substance Evaluation Workshop. During the initial evaluation phase, it is clear when the evaluation starts as it is the date of the CoRAP publication. In the subsequent follow-up stage, the evaluation should begin when the information requested is submitted.

However, the registrants may have reasons to submit information in subsequent multiple dossier updates. Therefore, a practical and workable approach was agreed with the Member States whereby the provided 12-month period (Article 46(3)) for the Member State's follow-up evaluation will begin only when all data requests in a decision have been submitted by the registrant(s).

Apart from making the dossier update(s) with the information requested, ECHA started requesting the registrant(s) in the notification letter to the decision to inform the eMSCA and ECHA of the relevant update when all data are submitted. As a benefit the registrants will have clarity on the subsequent timeline for the follow-up evaluation.

2.6 FURTHER ACTIVITIES

2.6.1 Substance Identification

Dossier screening

During 2014, ECHA launched an IT-based screening on the substance identity information of all registrations received[39] to help industry proactively improve the quality of their dossiers. This automated computational screening serves as an efficient way for identifying registration dossiers with potential substance identity concerns. This activity is also in line with one of the primary strategic aims of the Agency – improvement of the information quality.

Based on the screening results, registrants might receive an informal letter from ECHA, providing advice on how to address their specific substance identification shortcomings. Registrants are strongly encouraged to address deficiencies indicated in these letters. Failure to address any detected shortcomings may lead to legally binding follow-up actions from ECHA (e.g. compliance check).

During 2014, a total of 1 350 letters were sent to 449 registrants concerning 309 substances. The registrants were given three months to improve the quality of their dossiers. A high response rate exceeding 80% of the affected dossiers has been recorded[40].

Communication to the joint submission members

When ECHA performs an evaluation of a registration dossier during the compliance check process, a draft decision is normally communicated to the registrant if the identity of the registered substance is not sufficiently/correctly reported. In this manner, the registration of another member registrant is not directly affected by the decision issued to the registrant concerned. However, the non-compliances addressed in the decision may ultimately impact the substance sameness in the joint submission, which concerns all its members.

Therefore, ECHA has started to directly inform the joint submission members, in cases when a decision targeting substance identity issues has been sent to a registrant. This information is given through a common standard letter (through REACH-IT), in order to advise a member of the joint registration to contact the lead registrant and other members of the SIEF to assess whether the draft decision may have any impact on their own registration. The information in the letter does not contain any confidential data. During 2014, over 600 letters were sent to the member registrants.

2.6.2 Intermediates

ECHA continued to verify the intermediate status of registrations for on-site and transported isolated intermediates. ECHA used Article 36 letters to ask registrants to provide additional information on the use of the substance as an intermediate, where necessary. For transported isolated intermediates, ECHA also requested registrants to provide documentary evidence that, when an intermediate is supplied to a downstream user, the registrant knows that the substance is used by the downstream user as an

[39] http://www.echa.europa.eu/support/how-to-improve-your-dossier/it-screening-campaigns-on-dossiers
[40] see also the October 2014 ECHA Newsletter available at http://newsletter.echa.europa.eu/

intermediate under strictly controlled conditions (SCCs), or has received confirmation from the downstream user to that effect. In practice, many registrants included copies of these downstream user confirmations in their dossier.

In 2014, ECHA published a Practical Guide[41] with advice for registrants on how to check that a substance is used as an intermediate according to Article 3(15) and how to document in the registration dossier. The Guide includes practical examples of the information needed to document that an intermediate is used under SCCs, as defined in Article 18(4)(a) to (f). The Guide also supports downstream users who need to provide information to their suppliers on their uses of an intermediate. This Guide complements the ECHA Guidance on intermediates[42].

Observation

Continuous releases of an intermediate from a process under strictly controlled conditions (SCC) are not expected. If such releases occur either by the registrants or their customers, the substance cannot benefit from reduced requirements for registration of intermediates under SCC (Articles 17 and 18 of REACH) but has to be registered in full (Article 10 of REACH).

ECHA expects that when describing an intermediate use, in addition to the standard use descriptors, the following information is provided in the registration dossier, as a minimum:

- A description of the relevant chemical reactions taking place when the intermediate is used to manufacture the other substance(s).
- A description of the technical role for which the intermediate is used in the manufacturing process of the other substance(s).
- A description of the chemical identity of the other substance(s) manufactured from the intermediate (e.g. name, CAS and EC number and any further information that is necessary to enable the substance(s) to be identified).
- An indication for each other substance manufactured from the intermediate whether it is subject to registration requirements under the REACH Regulation and, if not, the reason why not.

The clarity on the intermediate use in the registration dossier is crucial to allow authorities to take well informed decisions in the context of the regulatory risk management. For example, ECHA has to regularly recommend substances to be included in Annex XIV of REACH (the Authorisation List). These substances

[41] ECHA Practical Guide 16 "How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID", can be found at: http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf.
[42] http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

are prioritised from the substances of very high concern (SVHC) included in the Candidate List. They are prioritised based on criteria set out in Article 58(3) of the REACH Regulation using an agreed prioritisation approach[43]. In this prioritisation, the volume within the scope of authorisation plays an important role. In accordance with Article 2(8)(b) of the REACH Regulation intermediates are exempt from the requirement to apply for authorisation. Therefore, the tonnage used as intermediate is not considered for the purpose of prioritising substances from the Candidate List to the Authorisation List.

ECHA bases its recommendations on information provided in the registration dossiers. Therefore, it is important that the registration dossier includes i) sufficient information which allows a conclusion to be made that the use fulfils the definition of an intermediate use set out in Article 3(15) and ii) provides the tonnage intended for intermediate use. If a registration dossier does not clearly demonstrate which uses are as intermediate and what the associated quantities are, the whole tonnage will be taken into account. As a result, a substance may receive higher priority than justified by its actual use.

In 2014, ECHA sent 280 letters to companies that had submitted a dossier under Article 10 for an SVHC substance, in which uses as an intermediate were registered. Registrants were asked to verify and, if necessary, update their dossiers to make sure that the required information on intermediate use was provided. Furthermore, ECHA recommended registrants to indicate, in their dossier, the corresponding tonnage for the intermediate use.

2.6.3 Nanomaterials

During 2014, nanomaterials were evaluated in the frame of both dossier evaluation and substance evaluation. For dossier evaluation, ECHA has performed a number of compliance checks on dossiers covering, or suspected to be covering nanomaterials. These compliance checks have targeted the information requirements on substance identity and granulometry. Three final decisions had been sent in 2013 on dossiers covering nanomaterials, and the registrants have complied with these decisions. This demonstrates that REACH applies to nanomaterials and can enable the generation of new data on these substances.

The three decisions targeting the information requirement on granulometry show clear examples of the ability of ECHA and the registrants to reach a positive outcome, despite the presence of serious challenges. In those cases, ECHA had requested registrant's to submit information demonstrating whether the substances fall under the EC recommendation for the definition of a nanomaterial.

[43] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

Despite the challenges such as absence of internationally agreed protocols (e.g. OECD guidelines), the registrants were able to comply with the decision. The outcome of these decisions will be published on ECHA's website as best practice examples. The cases also demonstrated the opportunity to utilise the ECHA nanomaterials working group (NMWG). The ECHA-NMWG was consulted on the technical and scientific aspects of nanomaterial characterisation in these cases, which enabled knowledge transfer between the MSCAs, Commission and ECHA representatives. This was helpful in the adoption of the decisions during the formal compliance check decision-making process.

2.6.4 Classification and labelling

Classification and labelling (C&L) plays a role in both dossier and substance evaluation. In CCh decisions, registrants are required to respect the harmonised classification and/or 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.

About 25% of the notified substances have different self-classifications for one or more hazard classes. Differences in self-classifications could be problematic for formulators, when re-classifying their mixtures in view of the June 2015 deadline when all mixtures as well as substances have to be classified according to the CLP Regulation. Moreover, different classifications for the same substance may be confusing in the communication of the hazards. ECHA provides industry with a discussion platform (C&L Platform) which allows notifiers to get into contact with one another to discuss the classification on an anonymous basis. In 2014 however, the C&L Platform was used much less frequently than was expected.

Observation

Registrants should check if the classification of their substance(s) is in agreement with the mandatory harmonised classification and with the classifications of other registrants and notifiers. Where differences exist, take the initiative to agree on the classification and update the notification. The C&L Platform may be a helpful tool for doing this.

An analysis of the C&L Inventory[44] published in ECHA's 2014 CMR report[45], shows that most registrants classify in line with the harmonised classification for carcinogenity, mutagenicity and reprotoxicity (CMR). Only a few registrants do not follow the mandatory classification for CMR.

[44] http://echa.europa.eu/information-on-chemicals/cl-inventory-database
[45] http://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf

Observation

Previous enquiries to ECHA's Helpdesk indicate that some registrants are unaware that all hazard classes and differentiations not covered by the harmonised classification, require both an evaluation of hazards and a self-classification.

Notifiers also generally respect the harmonised classification for CMR. The percentage of notifiers diverging from Annex VI of CLP is 3.4% for carcinogenicity, 3.0% for mutagenicity and 3.7% for reprotoxicity. Although substances that are to be classified as CMR 1A, 1B and 2 are normally harmonised, there are several hundred substances where at least one registrant self-classifies for CMR properties where the substance is not classified or classifies stricter than the harmonised classification (231 substances for carcinogenity, 163 for mutagenicity and 516 for reproductive toxicity).

2.6.5 Development of computational methods and tools

ECHA developed further tools to automatically analyse available information for registered substances to maximise the effectiveness of ECHA's regulatory actions by making an intelligent selection of registration dossiers and substances for CCh, substance evaluation, risk management and enforcement. The main features are grouped as follows:

- Tools and methods to extract information from single registration dossiers and from all dossiers in the joint submission. These tools were successfully used for clarifying the intermediate status and strictly controlled conditions of intermediate dossiers and for addressing substance identity issues in screening campaigns. ECHA summarised these developments on its web section[46].

- Tools and methods to analyse the data in the registration dossiers for scientific purposes or regulatory reporting needs under REACH (e.g. Article 117(3) report).

- Integration of algorithms for identifying potential CCh issues and for selecting substances for substance evaluation, harmonised classification and SVHC identification on the same computational platform. This integrated selection and priority setting mechanism (integrated screening) is performed in collaboration with substance specific groups comprised of Member State competent authorities and stakeholders.

- Improved analysis of the information in attachments and free-text fields of the technical dossier.

- Use of hazard and exposure information found outside the registration dossiers. Such information not only allows prioritising CCh or substance evaluation for data gaps when external information suggests that risk is likely, but also enhances the identification of possible shortcomings in reported test results in the registration dossiers.

[46] www.echa.europa.eu/support/how-to-improve-your-dossier.

Observation

It is important to use all available information on the substance. Computational methods and tools have been developed to retrieve information from external hazard and exposure databases, such as the QSAR Toolbox.

Experience from automated analysis of registration data has been used to provide input into the further development of IUCLID, by identifying sections where clarity can be improved. In addition, ECHA continually updates the IUCLID Dossier Quality Assistant tool (included as a separate tab in the validation assistant plug-in), which allows registrants to check their data for common inconsistencies and quality issues before submitting their dossier to ECHA. The consistency checks carried out by this tool are guided by the learnings from dossier evaluation work and the automated screening campaigns. The latest version was released in March 2014.

2.6.6 Publication of decisions

As of December 2012, ECHA started publishing[47] the non-confidential versions of the decisions originating from CCh and TPE (the two dossier evaluation processes) it has sent to registrants.

The reasons for publishing the non-confidential versions of the dossier evaluation decisions taken were two-fold:

- To increase the transparency of ECHA's process of assessing registrants' dossiers.
- To offer registrants and third parties an opportunity to follow and increase their insight into ECHA's scientific evaluation processes of CCh and TPE.

It is important to remember that these decisions are directed at specific registrants with potentially confidential manufacturing processes and/or information. Before publication of any decision, ECHA systematically consults the addressee on the non-confidential version it intends to publish. Since April 2014, the REACH-IT terms of agreements have changed, allowing ECHA to simplify its internal process of consultation on decisions. The published documents represent decisions where any personal data are removed, and display blanked out sections which were deemed to harm the registrants' commercial interests if disclosed. The decisions are only available in their original language.

ECHA therefore strongly recommends that registrants carefully read the content of their decisions, which may reflect strategies or information on substances potentially of complex nature, in order to make sure that no confidential content may be published by ECHA.

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

Observation

If registrants wish to raise further objections to the publication of a decision, they are advised to provide ECHA with robust justifications in order to demonstrate why disclosure of such contested information would harm their commercial interests, referring to the provisions laid out in the Access to Documents Regulation (EC) No 1049/2001.

The first consultations took place in November 2012, and since then 787 out of a total of 1 052 decisions taken, have been published. Table 6 provides a summary of the number of decisions published on ECHA's website since 2012.

Table 6: Summary of the number of ECHA decisions published on the ECHA website.

YEAR	CUMULATIVE NUMBER OF DECISIONS		PERCENTAGE OF PUBLISHED DECISIONS
	ISSUED	PUBLISHED	
2009 - 2012	381	73	19%
2013	650	362	56%
2014	1052	787	75%

Overall, the figures show a marked improvement in the status of decisions publication with ECHA succeeding in publishing 75% of all decisions issued in 2014.

The two key changes, allowing for this noticeable improvement have been the unique sending of the confidential and public versions of the decision to the registrant (optimising the consultation process) and

also the new terms and conditions of the REACH-IT use (optimising of the read receipts, ensuring ECHA that registrants opened the message containing their documents). Both have resulted in a process that has required less administrative effort from issuing to publishing those decisions, leading to a measurable efficiency gain. However it is important to remember that the creation of the non-confidential version remains a manual intervention.

As an outlook to 2015, further improvements will cover the implementation of further internal IT tools and subsequent automation of the publication (dissemination) process.

2.6.7 Scientific developments

The following is a summary of the regulatory science developments of direct relevance to the evaluation process, which have progressed significantly or were finalised during 2014.

JRC Report on non-standard methods

The state-of-the-art review of test methods and computational approaches promotes the replacement, reduction and refinement of animal experiments in the safety assessment of chemicals. ECHA ordered this report from the Joint Research Centre (JRC).

The report[48] reviews the current scientific status of alternatives to animal experiments, such as *in vitro* test methods (for example, using cells or tissues) and computational models for several human health and ecotoxicological endpoints. It describes their availability and applicability based on knowledge of the underlying mechanisms of toxicological actions. The endpoints covered for the assessment of potential human health effects range from skin and eye irritation to mutagenicity and carcinogenicity. In relation to ecotoxicology, the report focuses on methods for acute and chronic fish toxicity.

Besides referring to REACH, CLP and the Biocidal Products Regulation, the report also informs about alternative methods in other sectors, such as cosmetics and plant protection products.

ECHA's Test Methods web section

In March 2014, ECHA launched a web section to inform registrants about new OECD and EU Test Guidelines. Due to scientific and regulatory developments, test guidelines are updated and new ones introduced. With this web section, ECHA supports registrants by indicating how these may be used to meet the information requirements under REACH. For example, the role of new in vitro test guidelines within testing strategies is described, when appropriate. This information is often provided before ECHA's guidance is formally updated.

Each section of the web section covers for example:

- Which of the REACH information requirements may be met with the test(s).
- How to use the methods.
- The specific scope of the test guidelines (e.g. any limitations on chemical categories covered, and any limitation on classification and labelling).

[48] Alternative methods for regulatory toxicity: http://echa.europa.eu/documents/10162/13634/echa_jrc_sla_report_en.pdf

At present, the web section covers several in vitro methods that can be used to study skin and eye irritation/corrosion. New test guidelines on degradation and bioaccumulation as well as prioritised guidelines on aquatic, terrestrial and sediment testing are included. The next update of the site will cover e.g. genotoxicity test guidelines.

Skin sensitisation Integrated Approach to Testing and Assessment in partnership with JRC

In 2014 EURL ECVAM has validated three alternative test methods (*in chemico* and *in vitro*) to assess the skin sensitisation endpoint based on key events described in an OECD Adverse outcome pathway for skin sensitisation[49]. Currently there are draft OECD test guidelines available for these validated test methods.

Under the OECD Hazard Assessment Task Force a Guidance Document on skin sensitisation Integrated Approach to Testing and Assessment (IATA) is under development and the project is led by the Joint Research Centre (JRC). The guidance document aims to provide a framework on how different approaches to skin sensitisation testing and assessment can be used to determine if a substance is a sensitiser or not.

ECHA is involved in the process and aims to incorporate the developments of the test method and guidance document development at the OECD level into REACH specific guidance to the extent possible.

ECHA aims to provide advice to the registrants on when and how to use these alternative approaches to fulfil the standard information requirement for skin sensitisation. This advice will be provided in the form of an updated guidance document that will be drafted in collaboration with JRC.

ECHA also aims to update the Testing methods and alternative web section as soon as possible once the OECD test guidelines have been adopted. Therefore, it is advised that registrants closely follow up on the recent developments from international organisations and from ECHA's web section.

OECD guidance document on integrated approaches on testing and assessment (IATA) for skin corrosion and irritation

OECD published a guidance document on integrated approaches on testing and assessment for skin corrosion and irritation in July 2013[50]. The guidance document provides advice on how different information sources e.g. physico-chemical properties, in vitro and in vivo data and human data can be integrated for a decision making on the corrosive and irritant hazard potential of a substance, including advice on further testing needs, if necessary. ECHA actively participated in the drafting group of this guidance document.

[49] OECD 2012: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)10/part1&doclanguage=en).
[50] OECD GD 203: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)19&doclanguage=en

The guidance document is composed of "modules", each of which contains one or several individual information sources of similar types. The strengths and limitations as well as the potential role and contribution of each module and their individual components in the IATA for skin irritation and corrosion are described with the purpose of minimising the use of animals to the extent possible, while ensuring human safety.

The OECD guidance document is considered in the ongoing ECHA Guidance update on skin corrosion/ irritation.

For serious eye damage/eye irritation there is currently no IATA available by the OECD. The OECD is considering the development of a similar guidance document for an IATA for serious eye damage/eye irritation (a joint proposal by the US and EC (EURL ECVAM) on serious eye damage/eye irritation IATA has been submitted and is currently under consideration by the Working Group of National Coordinators for the Test Guidelines Programme (WNT)).

Reproductive toxicity

The REACH standard information requirement relating to reproduction toxicity is expected to change soon. The current standard information requirement of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) at Annex IX/X, 8.7.3 is in the process of being replaced by an extended one-generation reproduction toxicity study (EU B.56, OECD TG 433).

The study design of the extended one-generation reproductive toxicity study is flexible and modular and ECHA is updating the ECHA guidance on reproductive toxicity to address the challenges of this amended information requirement.

The standard information requirement is drafted to be a one-generation study design of extended one-generation reproductive toxicity study without developmental neurotoxicity or developmental immunotoxicity cohorts. However, if the conditions described in Annex IX/X, 8.7.3 column 2 are met, then the registrant must propose an adapted study design accordingly. The adaptations described in column 2 of Annex IX/X, 8.7.3 concern the extension of Cohort 1B to produce the second filial generation and/or inclusion of developmental neurotoxicity and/or developmental immunotoxicity cohorts.

Guidance on adaptations and further aspects of the study design (e.g. length of the premating exposure duration and dose level selection) are provided in the update of ECHA guidance on reproductive toxicity (Guidance on IR & CSA, Section R.7.6; to be published in 2015). The registrant is responsible for proposing and justifying the adequate study design of extended one-generation reproductive toxicity study.

The amended information requirement is expected to enter into force in spring 2015 and will affect all testing proposals and compliance checks which do not yet have a decision for this endpoint. The existing two-generation reproductive toxicity studies will fulfil the new standard information requirements but any new testing proposals for this endpoint reproductive toxicity have to be assessed against the amended information requirement. This standard information requirement is expected to enhance the possibility to identify certain endocrine disrupting modes of action *in vivo* and their potential relationship to adverse effect on reproduction. In addition, information on developmental neurotoxicity and developmental immunotoxicity, which are new aspects, can be obtained during the same study when needed.

Read-Across Assessment Framework (RAAF)

ECHA, in collaboration with Member States, is working on the finalisation of the Read-Across Assessment Framework (RAAF) for human health endpoints, which is intended to improve the consistency and quality

of the assessment work under dossier evaluation, with potential application to substance evaluation in the future.

The framework intends to recognise common scenarios, when read-across is applied, and to identify crucial elements for that scenario. The development of the RAAF progressed significantly over the last two years and a workshop with Member States and observers was organised by ECHA at the beginning of October 2014.

A number of useful comments were collected and this version of the framework will become operational once the underlying documents are revised. To support registrants, it is intended to make relevant elements of that framework available in 2015. The scope of the RAAF is currently limited to human health effects and mono-constituent substances; however, the development of a version for environmental endpoints has started. Extension to multi-constituent substances and UVCBs is contemplated for the future.

Preliminary work on weight of evidence (WoE) approaches to predict acute oral toxicity

In vivo acute toxicity information is required for all substances manufactured or imported at above one tonne per year. ECHA has examined how the combination of the repeated dose (28-day) oral toxicity test with a recently validated in vitro cytotoxicity test (NRU), supported by QSAR considerations may be used within a weight of evidence approach to replace the vertebrate animal study in several cases. This weight of evidence adaptation is expected to apply well for the Annex VIII substances, which are of low toxicity.

In collaboration with the Joint Research Centre, the use of the information, generated from sub-acute studies and/or range finding studies, has been examined; also in regard of recording the clinical signs of toxicity during the first days of the study. This information was considered relevant to adapt the standard information requirement of the acute oral toxicity study.

ECHA will perform a IUCLID-based analysis to examine whether the acute toxicity classification can be based on the information obtained in the sub-acute studies. Subsequently, ECHA aims to update the relevant part of the ECHA Guidance.

Nanomaterials

In 2014, a number of significant developments for nanomaterials have taken place, such as preparing the review of the EC recommendation for the definition of a nanomaterial. In parallel, the discussions have continued on the review of the applicability of the REACH annexes, in particular the information requirements for nanomaterials.

Furthermore, ECHA organised a two-day Topical Scientific Workshop on regulatory challenges in risk assessment of nanomaterials which addressed key scientific questions related to the regulation and safety assessment of nanomaterials. The outcome of the workshop provides input to ECHA's further work on nanomaterials.

2.6.8 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. During 2014, eight appeals against ECHA evaluation decisions were announced by the Board of Appeal; see Table 7. Of these, four concerned substance evaluation decisions.

Table 7: Appeal cases related to evaluation lodged in 2014[51].

APPEAL CASE NUMBER	KEYWORDS	DATE OF APPEAL ANNOUNCEMENT
A-001-2014	Testing proposal Information in other dossiers	26 March 2014
A-004-2014	Substance evaluation Request for further information	25 June 2014
A-005-2014	Substance evaluation Proportionality	25 June 2014
A-006-2014	Substance evaluation Request for further information	2 July 2014
A-007-2014	Testing proposal Powers of the Agency	16 July 2014
A-009-2014	Substance evaluation Request for further information	14 October 2014
A-010-2014	Compliance check Intermediate	20 October 2014
A-011-2014	Compliance check Substance identity, Nanoforms	3 November 2014

By 2014, the Board of Appeal has issued eleven 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 section[52].

2.6.9 Recent EU Ombudsman conclusions

The European Ombudsman has in 2014 closed two complaints against ECHA relating to ECHA's practices in dossier evaluation (complaint O-1568/2012 and 1301/2013). These decisions can be found on the Ombudsman website. ECHA will take these conclusions into account when reviewing its related practices and approaches.

[51] In December 2014, two further substance evaluation appeals were filed and five further appeals related to a compliance check. Information on these appeals will be published on the Board of Appeal's website in due course.
[52] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/

3. Recommendations to registrants

In this section, ECHA provides the (potential) registrants with advice on how to improve the quality of their registration dossiers. These recommendations contain technical and scientific information which are of most use when preparing or planning to update the technical dossier and/or chemical safety report. These recommendations are based on the most frequent shortcomings observed when evaluating dossiers.

In many cases, the shortcomings observed have already been highlighted in previous Evaluation reports. These reports, available on the ECHA evaluation web section[53]; gave advice on how to avoid the shortcomings identified. 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.

3.1 THE IDENTITY AND EXACT COMPOSITION OF THE REGISTERED SUBSTANCE IS FUNDAMENTAL

The REACH Regulation requires importers/manufacturers to generate the necessary information to identify the hazards of substances and manage the resulting risks. For this purpose, determining the identity and composition of the assessed substance, as specified in section 2 of Annex VI, is essential.

Key recommendations to the registrants based on lessons from the substance identity assessment within compliance check in 2014:

- A (joint) registration must cover exactly one substance, the information given in each registration dossier shall correspond to that specific substance as defined by Article 3(1) and shall be sufficient for its identification.

- To this end, registrants shall ensure that each element within a registration dossier that is included to identify a manufactured/imported substance is specific and exact. For example, whenever a substance consists of different/specific isomeric forms, the identifiers (e.g. EC and CAS entries) or structural formula included in the different sections of a registration dossier shall reflect the identity of the specific isomeric form(s) present in the composition of that substance.

- Registrants shall consider in particular that for well-defined substances, EC and CAS identifiers shall describe precisely the presence of all the main constituents included in the composition of these substances, as specified in section 4.2 of the Guidance for identification and naming of substances under REACH (Version 1.3, February 2013). It should be noted that generic EC/CAS entries that do not specify the isomerism of a substance might exist. Such entries correspond to substances consisting of all possible isomeric forms as main constituents. Therefore, registrants are invited to carefully check the appropriateness of these entries for identifying the substance that is manufactured/imported.

- Registrants should note that the lack of clarity on the identity and composition of a substance may lead to a misjudgement of the properties of that substance and may therefore jeopardise the objectives set by REACH.

Registrants shall also ensure transparency about all the compositions covered throughout the joint

[53] http://echa.europa.eu/regulations/reach/evaluation

submission and which rely on the dataset jointly submitted. This is particularly important for substance evaluation as in some cases it is difficult to get a comprehensive view of the scope of the registered substance including all the different compositions covered in the registration dossier. In such situations, an understanding of the relationship between the property data included in the dossier and different compositions may be challenging. Therefore, transparency in terms of the scope (of registration) and composition of the registered substance is very important for ECHA and also for the evaluating MSCA, as it allows specification of the test requirements in their decisions.

3.2 REPORT HAZARD INFORMATION CLEARLY

Physico-chemical endpoints

When using textbook values, it is not sufficient to adapt the information requirement by using only one value, but a proper weight of evidence case should be built.

Where testing is possible, it is always preferred to test rather than using the Quantitative Structure-Property Relationship (QSPR). QSPR adaptations are not always appropriate and care should be taken when electing to use QSPR for a given endpoint, ECHA guidance R.7.A provides further information. Proper documentation according to Annex XI, 1.3. is always required when using QSPR.

Dissociation constant information is not required if the substance is hydrolytically unstable i.e. half-life less than 12 hours (Annex IX, section 7.16 Column II). To justify this adaptation, the technical dossier should also include a hydrolysis study. Acidic dissociation constant properties (pKa) of the substance should be analysed according to the integrated testing strategy (ITS) presented in ECHA Guidance[54]. For complex mixtures; UVCBs and multi-constituent substances, estimation of the representative constituent's pKa values, if appropriate, should be considered. The pKa values can be reported separately for different constituents.

For testing proposals, ECHA recommends a preliminary analysis to be performed (e.g. with QSAR methods) to verify the possible presence of dissociative groups in the molecule and based on this analysis to provide a testing proposal for an experimental test. A testing proposal is required as the dissociation constant is required at Annex IX level. A testing proposal will not rule out the possibility to use weight of evidence and read-across adaptations to fulfil the information requirement, if appropriate and justified.

Environmental endpoints

Biodegradation

If simulation testing is required for refining the risk assessment, the environmental compartment of highest exposure and risk should be tested first. Column 2 adaptation criteria for surface water simulation is not equal to the adaptation criteria for a sediment simulation test. Rapid degradation in one of the environmental compartments may not be a valid adaptation argument for other environmental compartments.

The applicability domain of the Test Guideline (TG) should be considered in relation to the properties of the test substance e.g. volatility, adsorptive properties and water solubility. Tests conducted with activated sludge as an inoculum or STP simulation test (e.g. OECD 303 or OECD 314) are not appropriate Test Guidelines to fulfil the standard information requirement for Annex IX 9.2.1.2, 9.2.1.3, 9.2.1.4 or 9.2.3 as a

[54] Chapter R.7a: Endpoint specific guidance, Version 3.0 – August 2014, p. 148, Figure R.7.1-7

sole source of information.

Results should be reported in detail as defined in TGs, the potential role of abiotic degradation should be considered, information on the validity of the test included and a clear conclusion on degradation provided.

Terrestrial toxicity[55]

According to Column 2 of Annex IX, registrants shall consider long-term toxicity testing according to Annex X instead of short-term testing in particular for substances that have a high potential to adsorb to soil or that are very persistent. ECHA considers this criteria met if the Log Kow >5 and/or DT50 >180 days or if the substance is not readily biodegradable.

The Column 2 adaptation may be possible when direct and indirect exposure of the soil compartment is unlikely, and the criteria of Annex XI section 3 can only be considered as fulfilled if:

- Adequate justification and documentation is provided.
- The justification is based on a thorough and rigorous exposure assessment.

The Equilibrium Partitioning Method (EPM) may first be applied as a "screening approach" when a $PNEC_{aquatic}$ is available. It may not be sufficient for risk assessment of substances that are very toxic to aquatic organisms and/or have a high potential for adsorption and/or are highly persistent.

Absence of toxicity in aquatic studies and no/not reliable $PNEC_{aquatic}$ derived may be used as part of Weight of Evidence to justify why testing is not required, but not to assign a substance to any of the Soil hazard categories.

If inhibition of sewage sludge microbial activity has been observed, a test on soil microbial community according to Annex IX section 9.4.3. should be considered either by testing or by providing a specific justification for adaptation. As the $PNEC_{aquatic}$ does not take into consideration any toxicity data on microorganisms, $PNEC_{soil\ screen}$ based on EPM may not provide sufficient protection for terrestrial microorganisms. Consequently, data relating to soil microbial toxicity is required when toxicity testing on soil organisms is seen relevant.

Sediment toxicity[56]

Sediment toxicity assessment is needed for substances that are potentially capable of depositing on or sorbing to sediments to a significant extent. A log Kow of ≥3 should be used as a trigger value for sediment effects assessment.

If no sediment toxicity data is available the equilibrium partitioning method (EPM) may be used as a screening approach to derive a predicted no effect concentration (PNEC) for sediment. However, this method can only be used when effects are observed in aquatic tests and the PNECaquatic is available. If a substance does not show effects in aquatic toxicity tests, the EPM cannot be used and at least one sediment study has to be performed at REACH Annex IX level.

[55] Chapter R.7c: Endpoint specific guidance, Version 2.0 – November 2014, R.7.11
[56] Chapter R.7b: Endpoint specific guidance, Version 2.0 – November 2014, R.7.8.7

Human Health endpoints

Sub-chronic and reproductive toxicity

Registrants should keep in mind that a screening study (Reproduction / Developmental Toxicity Screening Test, OECD 421 or Combined repeated dose toxicity / reproductive, OECD TG 422) does not fulfil the information requirement for a pre-natal developmental toxicity study or a two-generation reproductive toxicity study (note: the screening study covers the standard information requirement for reproductive toxicity at REACH Annex VIII level).

If Annex IX, Section 8.6.2. or 8.7 Column 2 adaptations for low toxicity are used, all criteria mentioned in the respective Column 2 must be met. A notion that a substance is inert, unreactive or immediately disintegrating is not sufficient as such, but needs to be substantiated by other information as specified in the relevant Column 2 adaptation. The Annex XI, Section 3 adaptation (substance-tailored exposure-driven testing) can be applied if strictly controlled conditions (SCCs) are comprehensively documented.

Mutagenicity

Any positive result in an *in vitro* experiment that has not been followed up by an *in vivo* study needs to be sufficiently justified in the dossier and supported by further information if necessary.

Version 3.0 of Chapter R.7a of ECHA's Guidance on Information Requirements and Chemical Safety Assessment, implementing the updated sub-sections R.7.7.1 to R.7.7.7 related to mutagenicity was published on 19 August 2014.

In particular, guidelines OECD TG 473 (*in vitro* Mammalian Chromosome Aberration Test), OECD TG 474 (in vivo Mammalian Erythrocyte Micronucleus Test), OECD TG 475 (*in vivo* Mammalian Bone Marrow Chromosome Aberration Test), OECD TG 487 (*in vitro* Mammalian Cell Micronucleus Test), OECD TG 488 (Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays) and OECD TG 489 (*in vivo* Mammalian Alkaline Comet Assay) have been updated and guidance on when and how to use these tests has been expanded upon. Additionally, the recommended testing strategy for mutagenicity has been updated.

Exposure based adaptations (EBAs)

These can be based upon either Column 2 of Annexes IX and X, or on Annex XI, section 3. For all adaptation possibilities, cumulative conditions apply and all of them have to be met. The registrant shall clearly indicate which adaptation is addressed for the respective endpoint (e.g. 'Annex XI, 3.2.(b)').

It is rarely possible to justify EBA for higher tier studies due to the Annex IX, section 3.2(a)(ii) requirement to derive a DNEL or a PNEC relevant and appropriate for risk assessment purposes. If EBAs are based on Annex XI, section 3, exposure scenarios have to be developed in the CSR.

Webinars on 'How to bring your registration dossier in compliance with REACH – Tips and Hints'

To help registrants to comply with the compliance check draft decisions and in general to update their dossiers to be in compliance with REACH, ECHA provided a series of webinars on "How to bring your registration dossier in compliance with REACH – Tips and Hints"[57].

[57] http://echa.europa.eu/support/training-material/webinars

As these webinars provide endpoint-specific recommendations on how to improve dossier compliance for the priority endpoints and address the scientific rationale behind the targeted-check draft decisions, they help the registrants to understand the non-compliance of their dossier by giving examples of good and bad working practices. In certain cases, the registrants have updated their dossier right away or if this has not been possible, they have updated due to the testing required, they agreed to ECHA's draft decision.

3.3 ADAPT ACCORDING TO REACH RULES

Grouping of substances and read-across approach

As reported in the second Article 117(3) report (published in June 2014), the most extensively used adaptation for the first and second registration deadlines (collectively) is read-across of a property from one substance to another, or within a category of structurally similar substances.

Any grouping or read-across approach proposed by the registrant must be adequately justified as an absolute prerequisite for their acceptance. Annex XI, section 1.5 requires that registrants making use of this adaptation must convincingly show that the prediction can be made for the considered endpoint, as a result of structural similarity of both the source and target substance. However, previous experience has shown that registrants still have difficulties in justifying these adaptations in the context of information requirements.

The registrant must justify why the similarity in structure leads to a similarity of the considered property (i.e. why structural differences between source and target do not affect the property under consideration). Annex XI stipulates that the prediction should cover the key parameters and the exposure duration of the test to be replaced and that it should be adequate for the purpose of classification and labelling and/or risk assessment. This means that the result should be equally fit for the same purpose as the result of a test with the target substance, if it had been performed.

The level of protection of human health and the environment should always be the same regardless of the approach to satisfy the information requirements. Construction of categories is still considered as a more robust way for reading across between the particular endpoints than the analogue approach. Extending existing categories with other substances is possible but should be verified if the category hypothesis is still valid, and any extension of the category domain has to be justified.

Expert judgment plays a central role in ECHA's assessment of grouping and read-across proposals in registration dossiers. The scientific reliability of a justification must be assessed, together with all the supporting data submitted. Experts must conclude on the quality of the justification and supporting data and whether they are sufficient to accept the proposal. Different types of justifications and supporting data, based on different endpoints are submitted for grouping and read-across. Thus, the assessment might differ

markedly in scope from the assessment of a standard study that is submitted to meet a REACH information requirement from studies that are used e.g. for screening and prioritisation.

Quantitative Structure-Activity relationships ((Q)SARs)

(Q)SARs make valuable adaptations mainly for physico-chemical endpoints, environmental toxicity and fate. The QSAR predictions for physico-chemical properties could be counted as a reference handbook data, provided that the prediction is for clearly defined endpoints under REACH, the conditions and the units are known and unambiguous, and if the predicted substance is within the applicability domain of the model. It is important to note that the structural characteristics of the registered substance with a data gap should be covered by the training set of the QSAR model. Additional parameters might be used to better identify the scope of the model and applicability to untested substances.

A potential interaction between parameters should always be considered (e.g. are the data for the octanol-water partition coefficient derived by a method suitable for hydrophobic substances). Other properties that usually need to be checked are volatility, adhesiveness, auto-oxidation, photosensitivity, and stability in water and air. An example could be given with an inaccurate Log P measurement of volatile substances, which escape the test system.

Another example could be given for an inaccurate water solubility measurement because the substance adsorbs on the surface of the laboratory equipment used for measurement. These considerations apply equally to the target substance (the one, for which prediction is made) as well as to the substances with measured values, which form the training set of the model. It might be foreseen that the registrant/consultant can best judge the properties of the registered substance but for the training set of the model (if not developed by the registrant) the information for the reliability of test data would be expected to be provided by the developer/vendor of the model.

All (Q)SARs, irrespective of the predicted property, need to be properly documented. This includes the compilation of the QSAR Model Reporting Format (QMRF) and QSAR Prediction Reporting Format (QPRF) for the prediction. The information could be inserted in the suitable IUCLID fields in the Endpoint Study Record (ESR), or attached in the appropriate place in the IUCLID dossier.

The QSARs are often not developed for a particular substance. A more general QSAR, which has been already documented, could be re-used for lower tonnage substances (if applicable). Another approach is to develop "local" QSAR models with freely available tools like the OECD QSAR Toolbox. By local model we understand a trend that is established for a congeneric chemical series or a set of similar substances within certain structural domains and physico-chemical boundaries. In any case, the QSAR should be preferably used as part of a weight of evidence approach, or as a supporting study, together with other supporting information.

QSAR predictions for human health and environmental endpoints which are based on predicted input values (e.g. Log Kow) may introduce additional uncertainty, and therefore measured physico-chemical data are preferable in such cases.

For complex human health endpoints (e.g. PNDT), it is in general not possible to provide a reliable (Q)SAR prediction that is fit for the purpose of classification and labelling and/or risk assessment. As the nature of different health endpoints varies, classification models (predicting yes/no answers) could be recommended for those endpoints where the test result is binary or can be expressed as such (e.g. skin corrosion, *in vitro* mutagenicity).

If the result is borderline or doubtful, more effort should be made to make use of it or a different line of evidence needs to be pursued. In documenting the model, a proper description of validity and applicability

is expected. Additionally, an estimate of error (model and substance specific) might be useful. However, it should be noted that such error parameters do not cover the reliability of the QSAR adaptation but proper explanations are always needed to cover the potential of the knowledge gap in the QSAR approach.

ECHA and the OECD continue developing the OECD QSAR Toolbox, which is free to download (http://www.qsartoolbox.org/). This is a tool that supports the grouping of substances and read-across, which also provides an opportunity for developing local models from data and assessing their domains of applicability.

The currently available version (3.3) was released at the beginning of December 2014. This version contains new specific features (like new QSAR models and decision trees), an expanded database of experimental data for a large number of endpoints (including updates from ECHA-CHEM from July 2014), as well as improved functionalities and documentation (e.g. standard format for describing profilers is introduced for selected profilers).

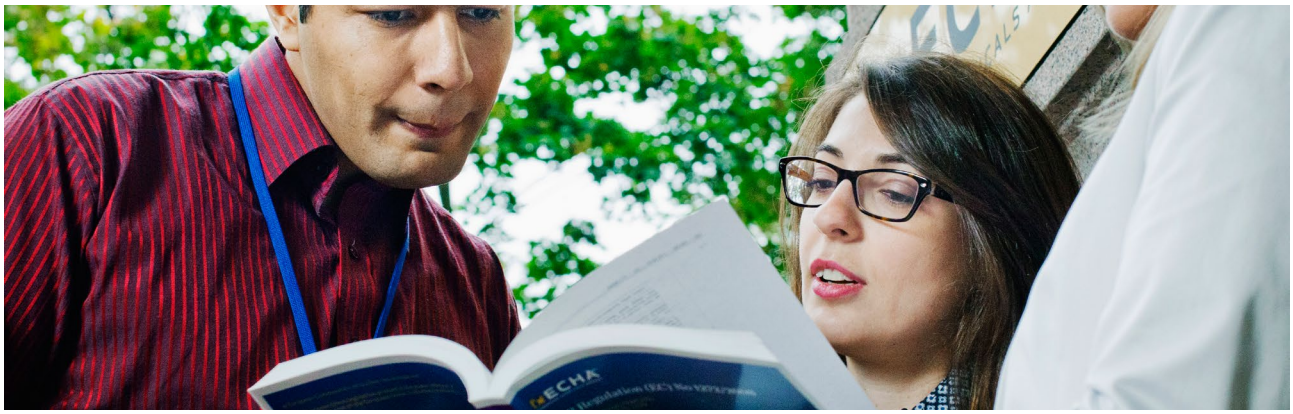
3.4 ENSURE REALISTIC INFORMATION ON USES AND CONDITIONS OF USE IN THE CHEMICAL SAFETY REPORT (CSR)

Registrants required to perform an exposure assessment in the context of the chemical safety assessment (CSA) have to address all the uses of the substance they place on the market in the EU and to report the outcome of their CSA in a chemical safety report. The CSA and CSR should reflect realistic uses and conditions of use based as much as possible on the current practices in industry. This is not only important for downstream users to receive meaningful information about safe use through the respective exposure scenarios (ESs), but also for authorities since many of their decisions are based on the use and conditions of use information submitted with the registration dossiers.

Observations

A frequent observation from compliance checks of CSRs is that the exposure scenarios do not sufficiently reflect the conditions of (safe) use for the user groups in the different markets of a substance. The automatised use of Tier 1 tools for mass production of exposure scenarios can lead to unhelpful or misleading risk management advice in the exposure scenarios.

Exposure scenarios must reflect European health and safety legislative requirements, and the hierarchy of control is a key theme within that, dictating that consideration of engineering controls is a primary pre-requisite when using chemical substances. Where there is reliance on the long-term use of Respiratory



Protective Equipment (RPE), users must have access to suitable equipment (i.e. specifically designed for long-term use) – such as air-fed hoods and more comfortable forms of respirator. A statement addressing the need for the equipment to be suitable for the purpose should be provided when exposure scenarios indicate long-term use of RPE (>4 hours).

CSRs also often include specification of operational conditions and risk management measures that affect the quantitative assessment of exposure. It is important that the selected exposure modifying factors are realistic and supported by evidence. For example, for many process categories it is not realistic to assume that local exhaust ventilation would be an effective measure to limit dermal exposure.

Very high levels of assumed performance must be associated with a strong justification and description that supports the selected values. An expected average level of performance under the proposed conditions of use for the specified risk management measure should be incorporated within a quantitative exposure assessment. Performance expectations for gloves or for engineering controls should be associated with management controls needed to achieve the anticipated performance.

In general, exposure models have exposure modification factors built into them. In these cases, registrants should not normally deviate from the defaults available within the model. For example:

- In the the TRA worker, reducing the concentration of the substance in the used product has a non-linear impact on the inhalative exposure estimation. Lineraising this relationship means that the assessor operates outside the documented tool.

- Local exhaust ventilation is not a suitable measure to reduce exposure under outdoor conditions

Within the environmental exposure assessment, an explanation on the conditions of use leading to the assumed release rate is often insufficient or even absent. For example, the CSR makes reference to a particular specific environmental release category (SpERC) as a justification for the release factors used in the assessment. However, there is no explicit indication that the assessed use falls into the applicability domain of the SpERC.

Advice

Use maps

An efficient way for registrants to get more realistic information on uses and conditions of uses is to employ use maps[58] that have been developed by downstream user sector associations in dialogue with registrants. The concept of use maps was launched for the 2010 registration deadline and is considered by ECHA as the preferred route to generate the required exposure scenarios for the purpose of the CSA. Use maps are developed at sector level to provide a brief description of the main uses relevant for the sectors in a way that facilitates the work of the registrant as:

- Their format is aligned with tools like IUCLID and Chesar.

- They provide information on conditions of use that are typical in the sector and that can be fed into the registrant's CSA.

[58] More information on use maps can be found in the CSR/ES Roadmap website: http://echa.europa.eu/csr-es-roadmap

However, uses that are not covered by such use maps still need to be addressed on a case-by-case basis.

Use description

Thorough and transparent use description plays a crucial role in the CSA process and forms the basis for a meaningful and complete exposure assessment.

As a first step in the assessment, a registrant must map out all the uses of their substances including information on the corresponding conditions of use. The use description needs to be clear and consistent with the uses of the substance in their supply chain. This will be supported by the use maps above.

Inputs to the exposure assessment

In addition to the use description, information on realistic conditions of use should be the basis for the exposure assessment. This will ensure that the resulting risk management measures are appropriate and can be put in place by downstream users.

Inputs to the exposure assessment should cover both human health and environmental exposure. Templates for creating the exposure assessment inputs have been developed and are already available to sectors: specific environmental release categories (SpERCs) for the environment and specific consumer exposure determinants (SCEDs) for consumers. Several completed sector use maps and sector-specific exposure assessment inputs (sPERCs, SCEDs) are already available[59].

A refined proposal for an improved use maps template will be published mid-2015 together with guidance. Downstream user sector and registrants associations are encouraged to follow these developments and contribute to them to ensure that appropriate exposure scenarios are generated.

How to get more information

The ongoing initiatives to improve the CSRs and ES are developed in the context of the CSR/ES Roadmap[60]. They are discussed in the Exchange Network on Exposure Scenarios ENES[61].

3.5 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. In addition to verifying business rules and CCh rules, it hosts the Dossier Quality Assistant module that warns the user of deficiencies and inconsistencies found within their dossier.

ECHA has continued to develop REACH guidance in 2014. The following updated guidance documents were published on the ECHA website during the year:

[59] A summary of the work done by associations in this regards is available at the following link: http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/
[60] Chemical safety report/Exposure scenario roadmap: http://echa.europa.eu/csr-es-roadmap.
[61] http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios.

- An update of the Guidance on the Preparation of an Annex XV dossier for the identification of substances of very high concern (SVHCs) (February 2014).
- An update of the Guidance on the Preparation of dossiers for harmonised classification and labelling (August 2014).
- An update of the Guidance on Information Requirements and Chemical Safety Assessment; Chapter R.7a: Endpoint specific guidance, Sections R.7.7.1 to R.7.7.7 related to mutagenicity (August 2014).
- Updates of the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11, Part C, Chapter R.7b, and Chapter R.7c, related to PBT/vPvB Assessment (November 2014).
- An update of the Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) (November 2014).

In addition, ECHA also made two Guidance documents obsolete and removed them from the ECHA website (January 2014): the Guidance on dossier and substance evaluation and the Guidance on Priority Setting. They have been replaced by current and updated information available on the ECHA Evaluation web section and registrants should refer to these for current information.

ECHA published translations of the Guidance for Downstream Users, version 2.0 (original version 2.0 published in English in December 2013 in 22 additional EU languages in April 2014). In addition, the Guidance in a Nutshell for Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD), was published in 23 languages in November 2014. These may be of particular interest to small and medium-sized enterprises.

ECHA invites you to take note of these new/updated resources and to 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.

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
DD	draft Decision
DNEL	derived no-effect level
ECHA	European Chemicals Agency
eMSCA	evaluating Member State competent authority
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
RPE	Respiratory Protective Equipment
SCED	Specific consumer exposure determinant
SID	substance identity
SIEF	substance information exchange forum
SONC	statement of non-compliance following a dossier evaluation decision
SpERC	specific environmental release category
t/a	tonnes per annum (year)
TPE	testing proposal examination
vPvB	very persistent and very bioaccumulative

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