ECHA
EUROPEAN CHEMICALS AGENCY

# Evaluation under REACH Progress Report 2015

## Safer chemicals – focusing on what matters most

**Disclaimer:**

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

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**Evaluation under REACH: progress report 2015**

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**European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

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,

Welcome to the eighth annual report on the progress made on our evaluation activities in 2015. The report also reflects our experiences in the form of recommendations that registrants can use to help improve the quality of their existing and future registrations.

2015 saw the successful implementation of our current compliance check strategy. Over half of the dossiers checked by ECHA were on substances expected to have the greatest impact on improved protection for people and the environment.

In examining these, priority is now given to substances which have suspected data gaps in the higher tier human health or environment endpoints, and a high potential for human or environmental exposure. The proportion of compliance checks where ECHA concluded that further information was needed, increased in 2015. This increase should not be interpreted as an indication of the overall quality of the registration database, but instead reflects the improved efficiency of the selection process in targeting the right substances with the right tools.

REACH strives for a balance between increasing our understanding of the hazards of chemicals whilst simultaneously avoiding unnecessary animal testing. To further ensure that testing on animals is only done as a last resort, we have started requesting additional information from registrants who submit new testing proposals for vertebrate animal tests. This follows the European Ombudsman's recent decision about ECHA's role in evaluating testing proposals.

A large proportion of addressees comply with ECHA’s decisions on compliance checks and testing proposals, and the quality of data in dossiers is progressively improving. I encourage industry associations to convince and support their members in filling the knowledge gaps rather than seeking to delay addressing the identified gaps that stop us from concluding whether a substance is a concern or not. Overall, further improvement is still needed and the recommendations within this report provide registrants with useful advice to achieve this.

It is encouraging to see that many registrants are proactively updating their dossiers as a direct consequence of the recommendations provided within these annual reports or through other complementary measures that we have set up in promoting voluntary action. I want to urge both future registrants for the 2018 deadline and existing registrants to follow this practice by utilising the available advice and tools to help further improve dossier quality.

My sincere thanks go to all staff involved in the Member States and at ECHA – and to co-operative registrants for their work on improving registration dossiers. Remember that we rely on you to achieve the 2020 goals defined at the World Sustainable Development Summit in 2002.

# Executive summary

The report describes the results of ECHA's evaluation activities in 2015 and provides recommendations to registrants to foster improvement in the quality of registrations. Registrants are encouraged to consider them and to be proactive in updating and improving their dossiers. Continuous improvement of the hazard, use and exposure information in the registration dossiers will lead to a better assessment of risks and safer use of chemicals.

### Implementation of the current compliance check strategy

ECHA implemented its current compliance check strategy with the aim of increasing registrant's compliance with key information requirements that are essential to conclude whether substances are of concern or not. The current strategy was endorsed by ECHA's Management Board in September 2014 and one of its key elements is to prioritise the "substances that matter" in the selection of dossiers to undergo a compliance check.

### Improved selection of substances of concern

With the help of Member States, ECHA is using an integrated selection and priority setting approach (so called common screening across all processes), which enables substances that raise potential concern to be identified as well as the most suitable route to address the concern, either compliance check, substance evaluation, risk management option analysis, or any of the regulatory risk management measures. As a consequence, compliance checks are targeted towards those substances where improved quality of information has the most potential to increase the protection of human health and the environment.

### Use of complementary measures

The use of complementary measures plays an important role in improving the overall dossier quality under the current compliance check strategy. Besides providing general advice and communication to registrants, ECHA uses targeted campaigns to registrants with potential deficiencies in their dossiers. Based on the common screening, ECHA regularly publishes a list of substances that will be potentially subject to compliance check. ECHA also launched a targeted letter campaign on 178 shortlisted substances where letters were sent to registrants informing them of the outcome of common screening and inviting them to improve the dossier quality in advance of any compliance checks. Overall, results show that complementary measures can stimulate registrants to be more proactive, and update their dossiers on the key information requirements.

### Effective use of compliance checks

In line with the current compliance check strategy, ECHA wished to reserve most of its evaluation capacity for compliance checks on registrations from lead and individual dossiers of chemicals produced in volumes over 100 tonnes per year that may require substance evaluation or risk management measures. Of the concluded cases in 2015, 107 (58 %) were performed on the dossiers of high priority substances. This involved the evaluation of 853 higher tier human health and environment endpoints.

### Outcomes of compliance checks

A total of 183 compliance check evaluations were concluded by ECHA. Of these, 33 (18 %) were concluded with no further action and 150 cases (82 %) 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 the decision-making phase, 59 were closed after the draft decision. For 144 dossiers, ECHA took decisions under compliance check with non-compliances most commonly identified in substance identification and composition, CSR-based issues, pre-natal developmental toxicity, and effects on terrestrial organisms.

### Testing proposals

In total, ECHA concluded 184 examinations and took 194 decisions. ECHA has evaluated 81 % of the testing proposals originating from the 2013 registration deadline and will conclude on the remaining 19 % by the legal deadline of 1 June 2016. As of November 2015, ECHA also publishes registrant's considerations on alternatives to their proposed vertebrate testing as part of the third party consultation. This follows the European Ombudsman's recent decision about ECHA's role in the examination of vertebrate animal testing proposals under dossier evaluation.

### Publication of the Read-across Assessment Framework

ECHA published the Read-across Assessment Framework (RAAF) for toxicological properties in May 2015. This first version of the framework presents the methodology applied by ECHA to assess read-across approaches. The aim of the RAAF is to provide a transparent and structured approach to the scientific evaluation of read-across justifications made by registrants in their dossiers. The publication of this framework should help registrants to assess the quality of their own read-across cases by presenting the scientific aspects that ECHA considers to be crucial in read-across approaches.

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

ECHA conducted 300 compliance check and testing proposal follow-up evaluations with 88 % (505) of the endpoints originally identified as non-compliant with the REACH information requirements being subsequently deemed compliant as a consequence of the new information contained in the dossier updates.

### Progress in substance evaluation

Of the 50 substances evaluated during 2014, the evaluating Member States concluded that 39 of these required further information to clarify the suspected concern(s). Consequently, ECHA sent draft decisions for commenting to the registrants of these substances in 2015. ECHA adopted 29 substance evaluation decisions, requesting further information from registrants to verify the suspected concern(s). Furthermore, ECHA published 16 substance evaluation conclusion documents, concluding on whether the risks are sufficiently controlled with existing measures, or proposing EU-wide risk management measures.

### Progress with the extended one-generation reproductive toxicity study (EOGRTS) decisions

Extended one-generation reproductive toxicity studies (EOGRTS) were incorporated in the REACH information requirements in March 2015. ECHA has started to address the EOGRTS information requirement in dossier evaluation and a batch of 34 draft decisions were sent to registrants in 2015. It is expected that the majority of the 216 cases referred to the Commission for decision making in 2011–2015 will be sent back to the affected registrants for reconsideration and eventual re-submission as testing proposals to ECHA during 2016.

### Improved transparency of ECHA's evaluation process

In 2015, ECHA developed new dissemination web pages that will provide a more integrated view of the regulatory information for each substance and improve access to key registration data. The improved visibility of the published non-confidential versions of adopted evaluation decisions in the substance's Brief Profiles will increase the transparency and provide greater insight into ECHA's evaluation processes. During 2015, ECHA published 250 non-confidential versions of adopted evaluation decisions.

## 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 potential shortcomings in their current dossiers and update them accordingly.

### TESTING ON ANIMALS MUST ONLY BE UNDERTAKEN AS A LAST RESORT

- Actively explore all possibilities to use already existing information and alternative methods in meeting information requirements. Keep records to show your considerations.
- Remember that the REACH annexes are applied sequentially. Therefore, Annex VII requirements for *in vitro* irritation testing should be fulfilled before considering the Annex VIII *in vivo* test methods.
- The obligation to share data applies to any registrant under the REACH Regulation irrespective of the phase-in or non-phase-in status of their substance. Consequently, potential registrants of the same substance must collaborate to share the requested information and agree on the data to be submitted jointly.
- Testing proposal consultations provide an opportunity for submission of any valid information that may address the hazard endpoint(s) in question and may make animal testing unnecessary.

### FAMILIARITY WITH THE READ-ACROSS ASSESSMENT FRAMEWORK (RAAF) IS ESSENTIAL FOR BUILDING A SUCCESSFUL READ-ACROSS CASE

- Adequately document the scientific reasoning for any read-across.
- Registrants can use the RAAF to identify the aspects of read-across justifications that ECHA considers to be crucial and can assess the robustness of read-across adaptations against these aspects.
- Structural similarity is needed for grouping and read-across approaches under REACH; however, it is not sufficient on its own to establish a basis for prediction of toxicological properties between substances.
- The hypothesis must address why structural differences between the substances do not affect the prediction of the property under consideration.
- Data on toxicokinetic properties of substances constitutes invaluable supporting information to justify a read-across hypothesis based on metabolic convergence.
- Supporting evidence must be included in the dossier, in the format of robust study summaries when possible.

## MAINTAIN EFFICIENT COMMUNICATION AND PLANNING THROUGHOUT THE SUBSTANCE EVALUATION PROCESS

- Maintain good communication with the evaluating Member State competent authority during the substance evaluation process.
- Coordinate your comments with co-registrants during the relevant steps of the decision-making process and provide a single set of consolidated comments.
- Inform the evaluating Member State competent authority and ECHA of the relevant update whereby all requested information is submitted.

## ACCURATE SUBSTANCE IDENTIFICATION IS VITAL

- The substance identity information in each registration dossier must be specific for a substance that is registered by a given Legal Entity.
- Substance identification is an obligation for each registrant and therefore it cannot be left to the lead of the substance information exchange forum (SIEF).
- The key elements of the substance identity information that must be included in the registration dossier consists of substance name and related identifiers, molecular and structural formulae (if applicable), composition, and the analytical data.
- Make use of support and services for improvement of the data quality, including substance identity information provided by ECHA. For example, ECHA developed the dossier quality assistant, which is a tool available for registrants to check their IUCLID substance datasets and dossiers for common shortcomings and inconsistencies before submitting their registration dossiers to ECHA.

# 1. The evaluation process

ECHA's evaluation work is divided into dossier evaluation and substance evaluation. Dossier evaluation consists of two types: compliance check (CCh) and testing proposal examination (TPE). The outline of an evaluation is shown in Figure 1. Further details of the evaluation processes are provided in previous evaluation reports[1] and the ECHA web section on evaluation[2].

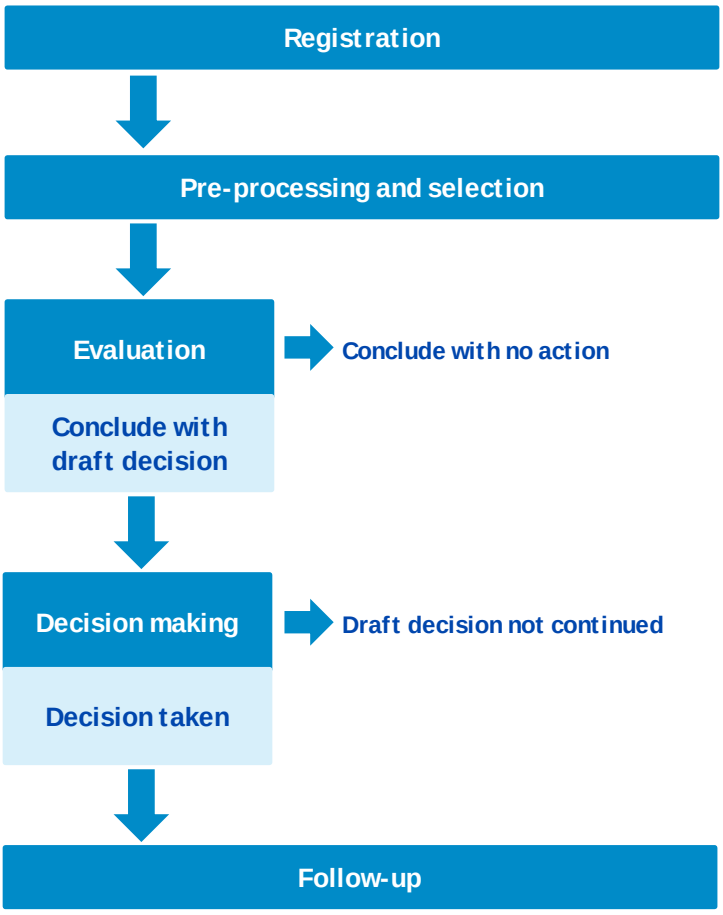



**Figure 1: The process of an evaluation**

In September 2014, the ECHA Management Board endorsed the current compliance check strategy[3] that aims to increase compliance and quality of the dossiers. The compliance check strategy included the following objectives:

- Providing confidence amongst stakeholders and the public that registrants meet the REACH information requirements, follow this up by improved communication on safe use in the supply chain, and REACH is thereby making a difference;
- Efficiently selecting substances that raise potential concern, generating the standard information for assessing safety through CCh or other means so that any remaining concerns can subsequently, where necessary, be addressed through the most suitable regulatory instrument;

[1] http://echa.europa.eu/regulations/reach/evaluation/#evaluation-reports
[2] http://echa.europa.eu/regulations/reach/evaluation
[3] http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

- Improving the transparency of relevant outcomes of the different steps of the CCh process, for the benefit of Member States, stakeholders and individual registrants.

One of the key elements of the strategy is to prioritise the '**substances that matter'** in the selection of dossiers that undergo a CCh. Other elements are:

**Integrated selection and priority setting**[4] (common screening) which enables substances that raise potential concern to be identified as well as the most suitable route to address the concern, either CCh, substance evaluation (SEv), risk management option analysis, or any of the regulatory risk management measures.

More information on how the common screening work interlinks with evaluation and risk management processes can be found on ECHA's web pages[5], which includes an interactive flowchart illustrating how each activity and regulatory process relates to each other, and shows the various lists of substances that result from the work of the authorities.

All substances contained in the database are screened, i.e. substances registered in full, substances registered as intermediates and NONS substances. Screening algorithms are applied together with estimation techniques (e.g. QSARs, read-across) and cross-checks with external data sources, to identify the substances that are most likely to be of highest concern (Figure 2).

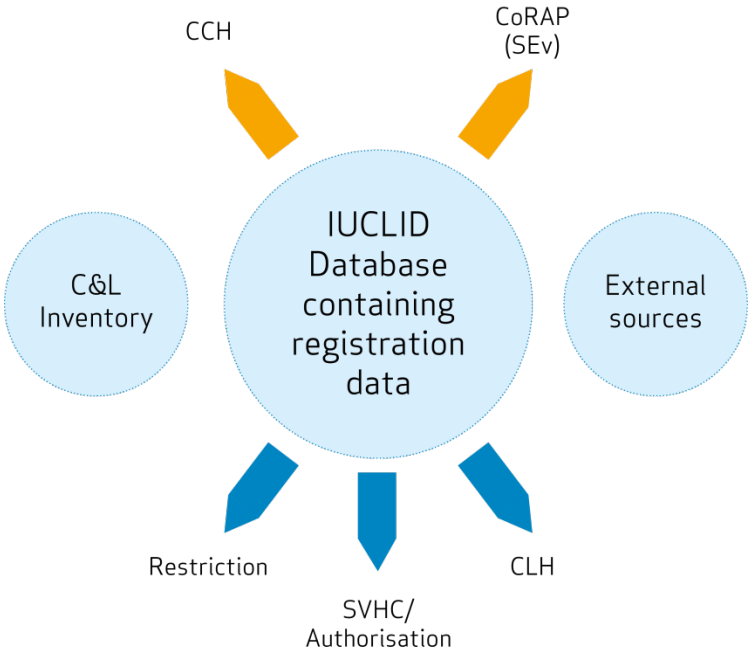



**Figure 2: Common screening of substances of concern**

A manual expert review confirms whether each CCh candidate fulfils the strategy prioritisation criteria and whether ECHA can effectively address the potential deficiencies under CCh. The information provided for the higher tier human health and environment endpoints and directly interrelated endpoints is reviewed and any considered to have a potential non-compliance are selected for a detailed evaluation.

[4] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening
[5] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

A detailed evaluation is not performed if no potential non-compliance is found for an endpoint. Other endpoints will be reviewed and obvious non-compliances highlighted for a detailed evaluation, provided that these may significantly affect substance safety (e.g. classification). Figure 3 demonstrates the CCh selection process.

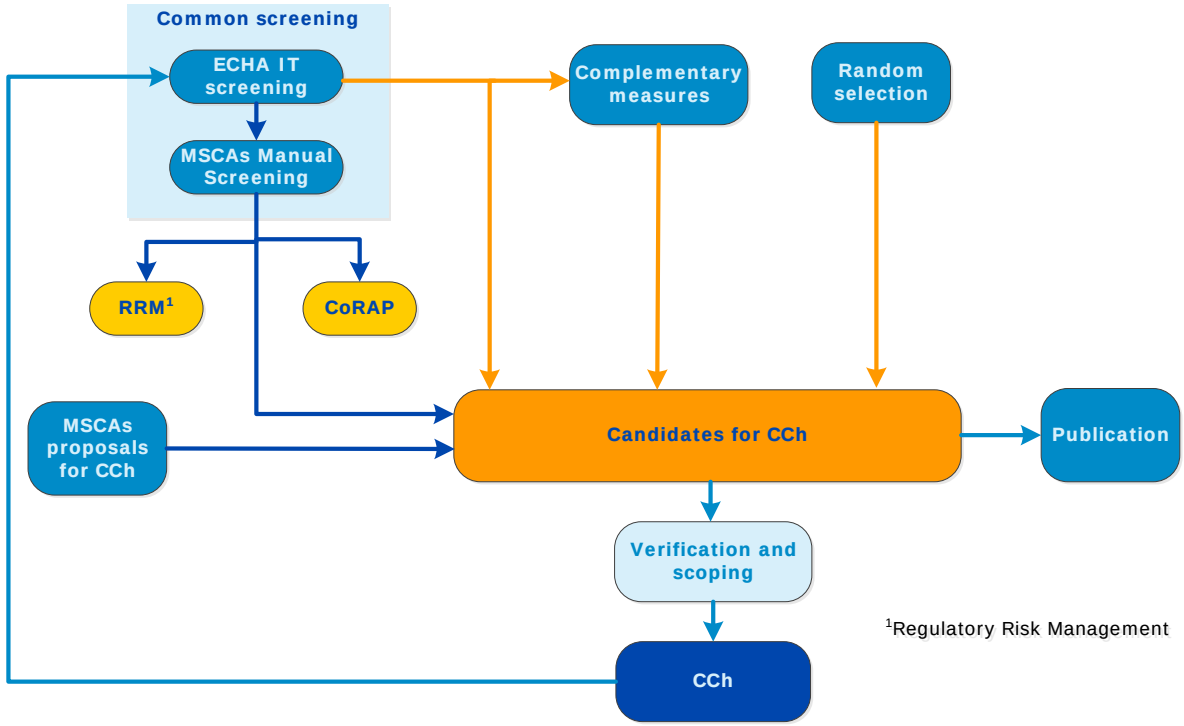



**Figure 3: Selection of dossiers for CCh**

**Effective use of compliance check**

- Priority is given to full registrations from lead and individual dossiers of chemicals produced in volumes over 100 tpa – focusing on substances with potential concern that may require substance evaluation or risk management measures.
- The main focus is on the higher tier (Annex IX and X) human health and environment endpoints.
- Substance identity is assessed, to the extent relevant.
- If the concern is confirmed based on the data submitted in line with the decision, conclude as part of the RMOA process if and which risk management processes need to be initiated.

The above approach was further elaborated in the May 2015 CCh Workshop[6] and has thereafter been applied by ECHA.

ECHA performs a detailed scientific and legal evaluation of all relevant suspected non-compliances identified during the scoping process. The scientific grounds, the legal basis for the request of further information, and its effect on substance safety are all elaborated in the draft decision.

**Use of complementary measures**

In addition to the formal evaluation processes, a number of other measures can support CCh and improve overall dossier quality (see section 2.1.5).

[6] http://echa.europa.eu/documents/10162/13628/cch_workshop_2015_en.pdf

# 2. Evaluation progress in 2015

The following is a summary of the evaluation progress according to the main outputs defined in the Agency's 2015 Work Programme[7]:

**Implementation of the current compliance check (CCh) strategy**[8] to maximise the impact of CCh on the safe use of chemicals, by improving the selection of substances of concern and by focusing the evaluation on key information requirements for human health and the environment.

**Systematic screening for substances of potential concern** in the REACH registration dossiers and other databases, identifying approximately 200 substances for further scrutiny.

**183 compliance checks concluded**, resulting in 150 new draft decisions. Of the 183 CChs concluded in 2015, 107 (58 %) were performed on the dossiers of high priority substances, which involved the evaluation of 853 higher tier human health and environment endpoints.

**184 testing proposal examinations concluded.** By the end of 2015, ECHA has evaluated 81 % of the testing proposals originating from the 2013 registration deadline and will conclude on the remaining 19 % by 1 June 2016.

**338 dossier evaluation decisions adopted.** ECHA adopted decisions originating from CCh and testing proposal draft decisions prepared in 2012-2015, requesting additional information from registrants where essential data on substances was missing.

**300 dossier evaluation follow-up evaluations conducted** to examine whether the information provided by registrants, in response to decisions adopted by ECHA, complies with the REACH requirements.

**Adoption of the third Community rolling action plan (CORAP) update.** The third CoRAP update was adopted on 17 March 2015, consisting of 134 substances, of which 48 substances were scheduled for evaluation in 2015.

**50 substance evaluations completed in 2015.** The evaluating Member State competent authorities (eMSCAs) considered that 39 substances required further information to clarify suspected concerns. For the remaining 11 substances, the eMSCAs considered the available information was sufficient to conclude on the concerns.

**29 substance evaluation decisions adopted.** ECHA adopted decisions originating from substance evaluation, requesting further information from registrants, to verify the suspected concerns.

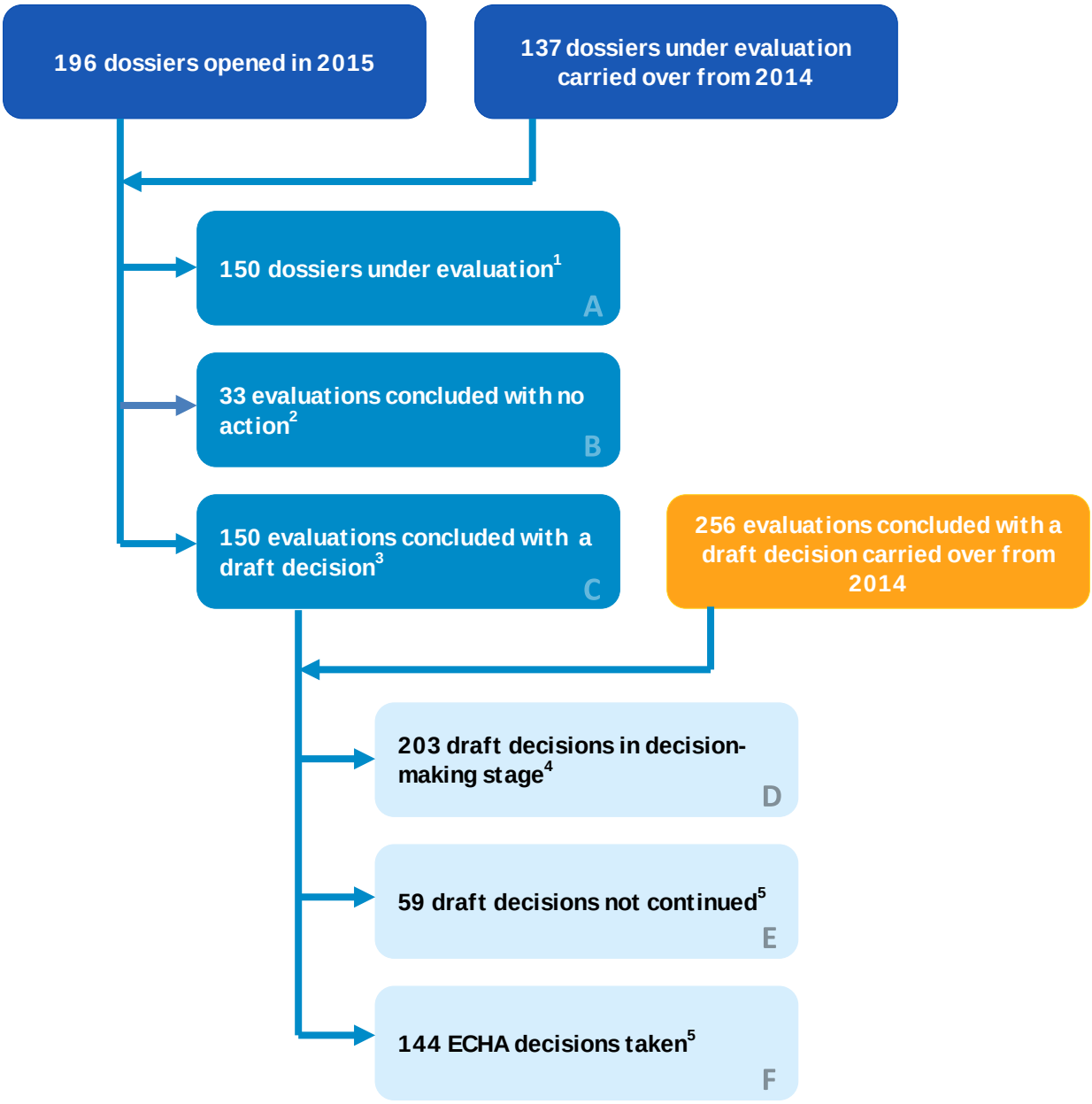
**16 substance evaluation conclusions published.** Concluding on whether the risks are sufficiently controlled with existing measures, or proposing EU-wide risk management measures.

**Advice and assistance on evaluation**. The ECHA Helpdesk received approximately 90 enquiries regarding evaluation, mostly requesting information on evaluation decisions. Some concerned the use of data from non-GLP tests, test methods, waiving possibilities, effects of cease of manufacture on testing proposals, and tonnage changes.

[7] http://echa.europa.eu/documents/10162/13608/final_mb_31_2014_wp_2015_en.pdf
[8] http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

## 2.1 Compliance checks

The CCh determines whether the information submitted within a registration dossier is compliant with the requirements of REACH. Figure 4 highlights the number and outcome of CCh's during 2015.




[1] Scientific and legal evaluation stage.
[2] No formal action towards the registrant is deemed necessary.
[3] Formal action to request further information from the registrant is deemed necessary.
[4] Stages of processing the draft decision, including notification of the draft decision to the registrants, notification to the MSCAs, referral to the MSC (when MSCAs submitted proposals for amendment), and referral to the Commission (when unanimous agreement was not reached in the MSC).
[5] Scientifically relevant data or important administrative changes lead to termination of the ongoing decision-making procedure.
[6] 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.

**Figure 4: Number and outcome of CCh's processed during 2015**

### 2.1.1 Pre-processing and selection

In line with the current compliance check strategy, ECHA's CCh focus is on standard registrations from 2010 and 2013 in the two highest tonnage bands. There has been good progress with the integrated selection and priority setting from the compliance check strategy during 2015. Candidates for risk management identified during CCh are now directly flagged for manual screening for the Member State competent authorities.

One of the aims of the current compliance check strategy is to coordinate different REACH and CLP measures to address the substances of concern effectively. Figure 5 shows the breakdown of sources for the concern-based CCh selections in 2015.

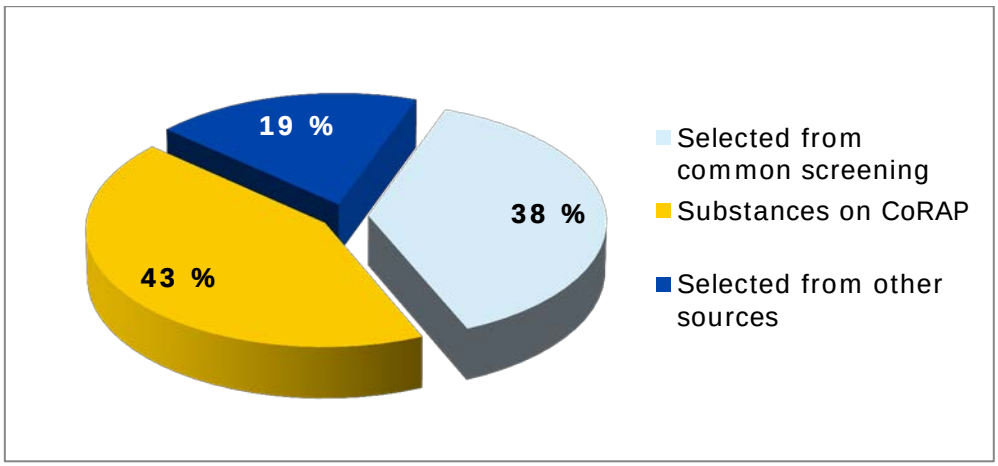



**Figure 5: Breakdown of sources for the concern-based CCh selections in 2015**

The common screening approach ensures all processes are integrated and parallel procession is avoided, with the aim of targeting the right substances using the right tools. Consequently, CChs are targeted at those substances where improved quality of information has the most potential to increase protection of human health and the environment.

During 2015, the scoping of CCh was matched with the potential concerns identified, ensuring that CCh was 'fit for purpose' rather than applying a 'one size fits all' approach. More details about this can be found in the 2015 CCh Workshop proceedings[9]. CCh focuses on eight key endpoints of Annexes IX and X, which are outlined in the CCh strategy:

- Mutagenicity/genotoxicity
- Repeated-dose toxicity
- Pre-natal developmental toxicity
- Reproduction toxicity
- Carcinogenicity
- Long-term aquatic toxicity
- Biodegradation
- Bioaccumulation

These are key higher tier human health and environment endpoints for identifying substances of concern and will allow a conclusion to be made on whether the criteria for substances of very high concern are likely to be fulfilled.

[9] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

### 2.1.2 Evaluation

Clarity of the substance identity (SID) information is a prerequisite for ensuring the dossier complies with the information requirements. If the provided SID information allows ECHA to interpret the scope of the registration, the CCh proceeds to the next phase of addressing REACH information requirements on hazard data in the technical dossier.

**Observation**
Unclear SID information in the dossier may hinder ECHA's evaluation of the hazard and risk information of the substance.

A total of 183[10] dossiers were evaluated under CCh during 2015. In 82 % (150[11]) of these, ECHA concluded that the non-compliances found were severe enough to require further action and generation of new information. All draft decisions were sent to the registrants within the 12-month legal deadline.

In 18 % (33[12]) of the cases, ECHA concluded that the generation of new information was not needed or proportionate and therefore no further action was required. Table 1 summarises the CCh conclusions during 2015.

**Table 1: New CChs concluded in 2015, by tonnage band**

| Tonnage band | Targeted CCh | | Overall CCh | |
|---|---|---|---|---|
| | Concluded with DD | Concluded without action | Concluded with DD | Concluded without action |
| ≥ 1 000 tpa | 54 | 6 | 13 | 7 |
| 100 to 1 000 tpa | 74 | 14 | 6 | 2 |
| 10 to 100 tpa | 3 | 1 | 0 | 1 |
| 1 to 10 tpa | 0 | 2 | 0 | 0 |
| **Total** | 131 | 23 | 19 | 10 |

In a number of these cases, ECHA assessed the read-across/category approach submitted as an adaptation of the standard testing regime. Currently, ECHA is unable to extract the exact number of cases with read-across from the database. However, it can be assumed that approximately 75 % of the dossiers contain read-across or other adaptations, as indicated in ECHA's report on the use of alternatives to testing on animals[13]. ECHA is committed to transparency and working on a solution to have those numbers available in future reports.

[10] B+C within Figure 4
[11] C within Figure 4
[12] B within Figure 4
[13] http://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2014_en.pdf

**Focusing on the substances that matter most**

The use of CCh is now more effective in addressing substances of concern. In 2015, 107 of the CChs concluded by ECHA addressed high priority substances i.e. high-tonnage registration dossiers with important data gaps and with a high potential for worker, consumer or environmental exposure.

Out of the 107 priority CChs concluded in 2015, the evaluation outcome was a draft CCh decision in 82 % of the cases and no action in 18 % of the cases.

The impact of the current strategy on the safe use of chemicals in 2015 can be seen in the high number of higher tier human health and environment endpoints of concern addressed as the outcome of CChs for prioritised substances of potential concern shown in Table 2 below. In total, 853 higher tier human health and environment endpoints were evaluated in the 2015 priority CChs.

For the priority substances addressed in CChs during 2015, the most common suspected concerns were as follows:

82 % suspected of reproduction toxicity and/or mutagenicity concerns
63 % suspected of bioaccumulation, persistence and environmental toxicity concerns
45 % suspected of other human health related concerns
9 % suspected of endocrine disruption or sensitisation concerns

It is worth noting that a substance may have more than one of the abovementioned concerns.

These hazard-based concerns cause potential risk in combination with high potential for exposure. Of the priority substances addressed under CCh during 2015:

- 65 % are widely used by workers or the general public
- 22 % are used in articles.

The majority of the remaining substances had high potential for environmental exposure.

**Table 2: Higher tier human health and environment endpoints of concern addressed as the outcome of CChs for prioritised substances of potential concern concluded in 2015**

| Endpoint | CCh outcome | |
|---|---|---|
| | Concluded with draft decision | Concluded without action |
| Repeated-dose toxicity | 38 | 69 |
| Mutagenicity/genotoxicity | 42 | 65 |
| Pre-natal developmental toxicity | 62 | 45 |
| Reproduction toxicity | 47* | 57 |
| Carcinogenicity | 1 | 106 |
| Long-term aquatic toxicity | 28 | 79 |
| Biodegradation | 33 | 74 |
| Bioaccumulation | 19 | 88 |
| **Total** | 270 | 583 |

* 22 of these were requests for Annex IX screening studies.

For all dossiers containing endpoints deemed non-compliant with the REACH information requirements, a draft decision was sent to registrants requesting additional information where essential data was missing.

### 2.1.3 Decision making

To shorten the processing time of draft decisions within the decision-making stage, ECHA changed its practice concerning consideration of dossier update submissions during the CCh evaluation process. Consequently, from January 2015 onwards, any dossier updates submitted after issuing the draft decision for registrant's comments are normally no longer taken into account.

As part of the decision-making process, registrants in receipt of a CCh draft decision are offered the opportunity to informally discuss the scientific rationale behind the draft decision with ECHA during their 30-day commenting period.

When MSCAs submit proposals for amendment (PfAs), the Member State Committee (MSC) seeks unanimous agreement through a written procedure or in plenary meetings (for the latter, registrants can attend the open sessions). Registrants are always invited to comment on the PfAs within 30 days and the MSC takes those into account.

If the MSC does not reach a unanimous agreement on the draft decision, the case is referred to the Commission.

During 2015, ECHA adopted 144[14] decisions under CCh and closed 59[15] cases after a draft decision. One draft decision was referred to the Commission in 2015. Table 3 summarises the decisions adopted during 2015.

**Table 3: Compliance check (CCh) decisions adopted in 2015**

| Type | CCh decisions adopted | |
|---|---|---|
| | Without proposals for amendment (PfAs) | Unanimous agreement in the MSC |
| Targeted CCh | 72 | 24 |
| Overall CCh | 24 | 24 |
| **Total** | 96 | 48 |

Consistency between decisions has increased through improvements in ECHA's knowledge management and a more efficient application of previously agreed policies.

There is a noticeable increase in the number of CCh decisions agreed through written procedure. Furthermore, registrants have become more active in seeking agreement by increased commenting on PfAs and participation in the MSC plenary meetings.

**Observation**
Only comments that address PfAs are considered during the decision-making process. Registrant comments on PfAs should not be submitted as PDF attachments but through the available webform that is structured according to the endpoints addressed.

[14] F within Figure 4
[15] E within Figure 4

### 2.1.4 Information requested

Figure 6 provides a summary of the types of information requested in ECHA's CCh decisions adopted in 2015. A decision may contain more than one request.

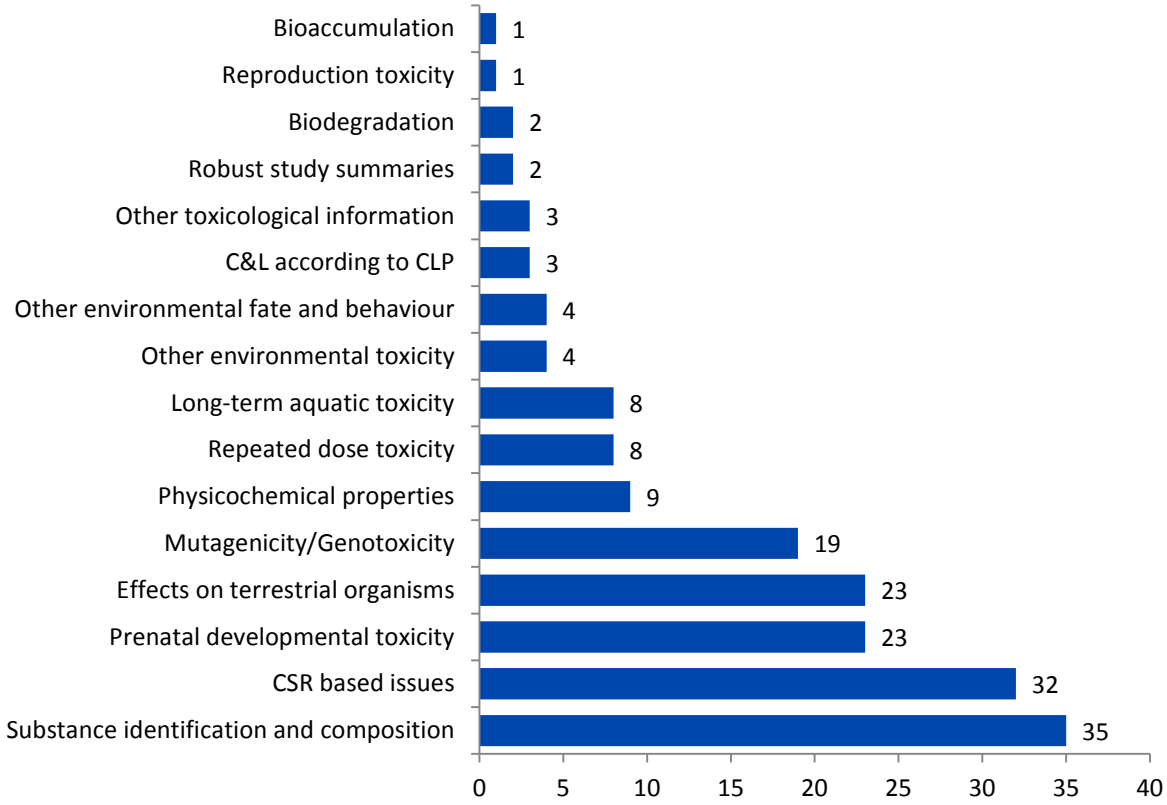



**Figure 6: Information requested as a percentage of the 144 CCh decisions taken in 2015**

It is worth noting that the majority of the information requests summarised in Figure 6 above, arose from CCh evaluations concluded before the current compliance check strategy was implemented. Consequently, most of the draft decisions generated from CCh evaluations performed in 2015 under the current compliance check strategy are still within the decision-making stages.

### 2.1.5 Complementary measures

Complementary measures play an important role in the current compliance check strategy to improve overall dossier quality. In addition to providing general advice and communication to registrants, ECHA uses targeted campaigns to registrants with potential deficiencies in their dossiers. When necessary, dossiers which are not improved as a result of such campaigns will be followed up in CCh or through other regulatory measures.

In 2015, ECHA used the following measures complementary to CCh to improve dossier quality:

- Publication of a periodically updated indicative list[16] of substances that may be selected for CCh.
- A targeted letter campaign on 178 shortlisted substances where 1 340 letters were sent to registrants to inform them of the start of common screening and inviting them to improve the dossier quality.
- Sector-specific work discussing areas that have proved challenging for particular sectors (i.e. petroleum substances, essential oils).
- Improved transparency and reporting of dossier evaluation.
- Cooperation with the Forum for Enforcement.

In the 2015 CCh Workshop, ECHA encouraged all actors to use complementary measures to improve dossier quality. The German study[17] on data availability in REACH registrations above 1 000 tonnes, where large numbers of high volume dossiers were manually screened, was referred to as a good example of Member States national complementary actions that can contribute to improving registration dossier quality.

Experience has shown that the letter campaigns have had a good response rate, often exceeding 80 %. They are efficient for clarification purposes where high numbers of dossiers are involved, and are effective for issues that can be communicated in short letters. However, follow-up with possible regulatory action is needed for some cases.

The letter campaigns enable ECHA to focus resources on the substances that matter in situations where a dossier is not updated or the update does not address the identified deficiencies.

**Observation**

Complementary measures such as letter campaigns have also had an indirect effect on the quality of dossiers not addressed in the campaigns, which increases as a consequence of registrants scrutinising all their registrations for the presence of the identified deficiencies.

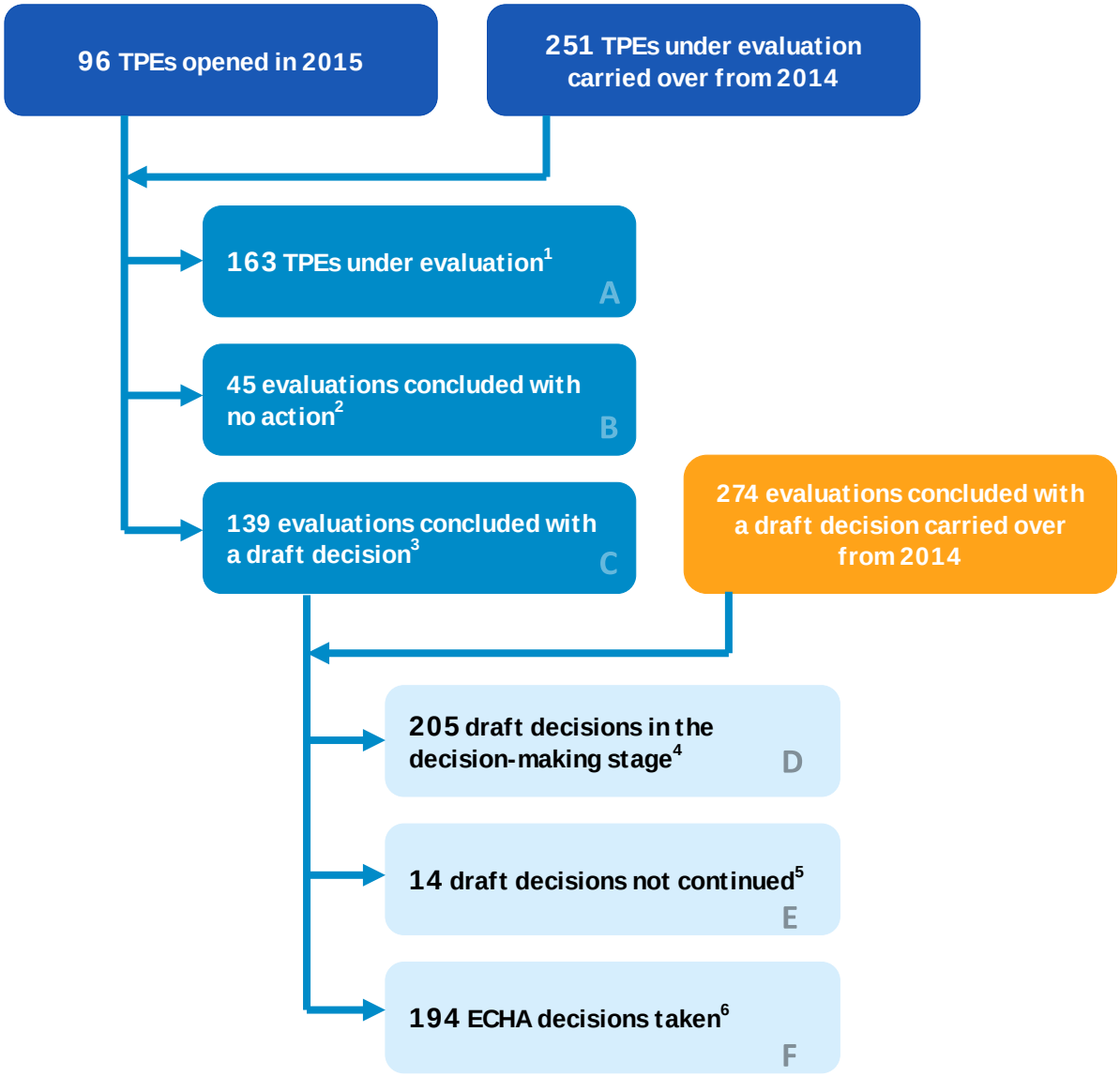
The campaigns signal to registrants that despite the prioritisation of substances, essentially all registrations are in the ‘spotlight’ at all times. However, ECHA aims to ensure that the campaigns are not overwhelming, overlapping or conflicting.

Overall, results show that complementary actions can stimulate registrants to be more proactive, and help to focus the CCh activity.

[16] http://echa.europa.eu/documents/10162/13628/substances_compliance_checks_2015_en.pdf
[17] http://www.umweltbundesamt.de/en/publikationen/reach-compliance-data-availability-of-reach

## 2.2 Testing proposals

ECHA examines each testing proposal to make sure that they address the actual information needed and avoid unnecessary testing, particularly when testing involves the use of vertebrate animals. Figure 7 highlights the number and outcome of testing proposal examinations (TPEs) processed during 2015.




[1] Scientific and legal evaluation stage.
[2] Testing proposal is deemed inadmissible by ECHA or is withdrawn by the registrant.
[3] A draft decision on the proposed testing is deemed necessary.
[4] Stages of processing the draft decision including notification of the draft decision to the registrants, notification to the MSCAs, referral to the MSC (when MSCAs submitted proposals for amendment), and referral to the Commission (when unanimous agreement was not reached in the MSC).
[5] Scientifically relevant data or important administrative changes led to termination of the decision-making procedure.
[6] ECHA evaluation decision taken either following unanimous agreement of the MSC, or where no proposals for amendment of the draft decision were submitted by the MSCAs.

**Figure 7: Number and outcome of TPEs processed during 2015**

### 2.2.1 Evaluation

Testing on vertebrate animals is the last resort for obtaining missing information on a substance, to meet the information requirements of REACH. ECHA examines each proposal to make sure that reliable and adequate data will be produced, and to prevent unnecessary animal testing.

ECHA publishes[18] every testing proposal that involves vertebrate animals and invites third parties to submit scientifically-valid information or studies addressing the substance and hazard endpoints in question that could be taken into account by ECHA in preparing its decision on the testing proposal. As of November 2015, ECHA also publishes registrant's considerations on alternatives to their proposed vertebrate testing as part of the third party consultation.

Of the 175 third party consultations launched during 2015, ECHA received 24 third party contributions (14 %).

Consideration of a read-across approach was suggested in 10 comments. In most 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.

Summaries of third party contributions and ECHA's responses are published on ECHA's web sections as part of ECHA's decisions on testing proposals[19].

ECHA evaluated a total of 184[20] testing proposals during 2015. For 76 % (139[21]) of these, ECHA sent draft decisions to the registrants, whilst in 24 % (45[22]) of the cases, no further action was necessary because the registrant withdrew the proposal after ECHA started to examine it, or because the proposal was not admissible.

The evaluation of a further 163[23] dossiers continues beyond 2015. For these, a draft decision has not yet been issued. From these, 71 originate from the 2013 registration deadline and ECHA has an obligation to conclude on them by 1 June 2016. This means that by the end of 2015, ECHA had concluded 81 % of the testing proposals from the 2013 registration deadline.

[18] http://echa.europa.eu/information-on-chemicals/testing-proposals
[19] http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions
[20] B+C within Figure 7
[21] C within Figure 7
[22] B within Figure 7
[23] A within Figure 7

### 2.2.2 Decision making

To shorten the processing time of draft decisions within the decision-making stage, ECHA changed its practice concerning the consideration of dossier update submissions during the testing proposal examination process. Consequently, from January 2015 onwards, any dossier update received within 30 days after the end of the registrant's (30-day) commenting period will be taken into account by ECHA. Updates coming after this period will normally not be considered.

In one appeal case (Case A-001-2014), the Board of Appeal found that, in certain circumstances, ECHA may have to take into account substantial new information contained in other registration dossiers for the same substance even after the Member States Committee has reached a unanimous agreement on a dossier evaluation decision[24].

As part of the decision-making process, registrants in receipt of a testing proposal draft decision are offered the opportunity to informally discuss the scientific rationale behind the draft decision with ECHA, during their 30-day commenting period.

When MSCAs submit PfAs, the MSC seeks a unanimous agreement through a written procedure or in plenary meetings. For the latter, registrants can attend the open sessions. If the MSC does not reach a unanimous agreement, the case is referred to the Commission.

In 2015, ECHA adopted 194[25] decisions under testing proposal examination and closed 14[26] cases after draft decision. No testing proposals were referred to the Commission in 2015. Table 4 summarises the types of testing requested and the TPE decisions adopted during 2015. It is important to note that a decision may contain more than one request.

**Table 4: Summary of TPE decisions adopted in 2015, by endpoint**

| Endpoint | TPE Decision | | | Total |
|---|---|---|---|---|
| | Accepted | Modified | Rejected | |
| Pre-natal developmental toxicity | 122 | 1 | 1 | 124 |
| Sub-chronic 90 day toxicity | 81 | 7 | 4 | 92 |
| Long-term aquatic toxicity | 41 | 0 | 1 | 42 |
| Physicochemical properties | 28 | 0 | 0 | 28 |
| Mutagenicity/genotoxicity | 19 | 1 | 1 | 21 |
| Effects on terrestrial organisms | 14 | 2 | 1 | 17 |
| Bioaccumulation in aquatic species | 4 | 1 | 0 | 5 |
| Long-term toxicity to sediment organisms | 3 | 0 | 0 | 3 |
| Two-generation reproductive toxicity | 0 | 0 | 1 | 1 |
| Biodegradation | 1 | 0 | 0 | 1 |
| **Total** | 313 | 12 | 9 | 334 |

Consistency between decisions has increased through improvements in ECHA's knowledge management and a more efficient application of previously agreed policies.

As identified for CCh, there is a noticeable increase in the number of decisions agreed through written procedure and registrants are more active in agreement seeking by increased commenting on PfAs and participation in the MSC plenary meetings.

[24] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions
[25] F within Figure 7
[26] E within Figure 7

### 2.2.3 Information requested

Figure 8 provides a summary of the types of information requested in ECHA's testing proposal examination decisions adopted in 2015, as a percentage of the overall number of the 194 TPE decisions taken.

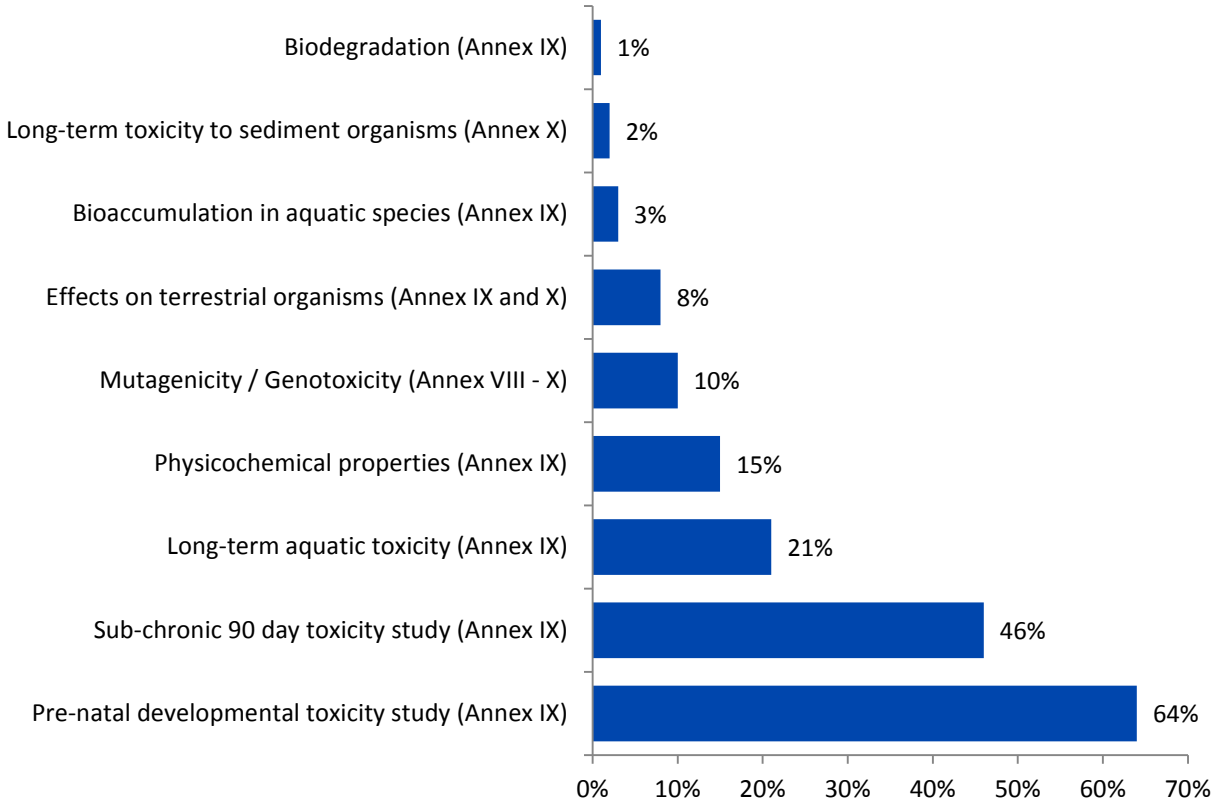



**Figure 8: Types of information requested as a percentage of the 194 TPE decisions taken in 2015**

## 2.3 Follow-up evaluation of dossier evaluation decisions

Under Article 42 of REACH, ECHA examines the information provided by the registrants in their dossier updates and considers whether the information complies with the REACH requirements. This follow-up evaluation takes place after the deadline specified in the decision has passed. Further information on the follow-up process can be found in the follow-up factsheet[27].

ECHA is involved in ongoing discussions with the Commission, Member State competent authorities (MSCAs) and national enforcement authorities (NEAs) following the Board of Appeal decision[28] in 2015 to annul a statement of non-compliance following a dossier evaluation decision (Case number: A-019-2013).

ECHA Secretariat and the Forum, through its Working Group 'Interlinks' continued to cooperate on fine tuning and further specifying the process for the enforcement of dossier evaluation decisions.

ECHA provided enforcement authorities with its opinion in cases where the dossier evaluation decision was not complied with through statements of non-compliance following a dossier evaluation decision (SONCs).

Challenges that NEAs face in this process and ideas for its streamlining were discussed at the Interlinks Workshop in January 2015, and with the Forum Working Group 'Interlinks'. The discussions clarified a number of questions that NEAs had, such as the possibility to seek expertise from ECHA or the MSCAs. NEAs also recommended that ECHA informs registrants about the details of the NEA-ECHA cooperation, so that registrants know how to act after receiving a SONC. This information was added in the appendix to the SONC notification letter. The Forum Working Group 'Interlinks' and ECHA Secretariat have also revised the chapter of the 'Interlinks Guide' that addresses the follow up of the dossier evaluation SONCs.

ECHA notes that, in some cases, registrants indicate cease of manufacture or import in REACH-IT after the evaluation decision has been adopted. In REACH-IT, such a cease of manufacture is indicated to fall under Article 50(2) of the REACH Regulation. This means that the registrant's registration is put to zero and no further information will be requested on that substance unless the registrant notifies a restart of the manufacture or import.

However, ECHA's current interpretation is that any existing decisions still apply, and the registrant is obliged to fulfil the requests in the decision. If the registrant indicates a cease of manufacture or import after a draft decision has been sent, but before the final decision is adopted, Article 50(3) applies, and the registration will no longer be valid. In all such cases, ECHA confirms with the registrants that they understand the consequences before invalidating the registration.

**Observation**

Registrants are invited to familiarise themselves with the process related to SONCs described in the SONC notification letter. Once a SONC is issued, any dossier updates related to the evaluation decision should be performed in liaison with the registrant's national enforcement authorities.

In 2015, ECHA conducted 300 follow-up evaluations, which are summarised in Table 5.

[27] http://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf

[28] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

**Table 5: Number and outcome of the 300 follow-up evaluations conducted in 2015**

| Decision Type | Outcome | | |
|---|---|---|---|
| | Article 42(2) without SONC[29] | Article 42(2) after SONC[30] | SONC[31] |
| TPE decisions | 88 (29 %) | 23 (8 %) | 17 (6 %) |
| CCh decisions | 136 (46 %) | 11 (4 %) | 25 (8 %) |
| **Total** | 224 (75 %) | 34 (11 %) | 42 (14 %) |

Value in ( ) denotes the percentage of the total follow-up evaluations conducted in 2015.

Table 6 provides a summary of the outcome of the follow-up evaluations, performed in 2015, for each endpoint. It is important to note that a follow-up evaluation outcome may contain both compliant and non-compliant endpoints.

**Table 6: Number and outcome of follow-up evaluations conducted in 2015, by endpoint**

| Endpoint | Outcome | | |
|---|---|---|---|
| | Fully compliant | Compliant with deviations* | Non-compliant |
| Substance Identity | 62 | 36 | 24 |
| Physical/chemical properties | 49 | 37 | 10 |
| Biodegradation | 10 | 4 | 1 |
| Bioaccumulation | 1 | 2 | 0 |
| Other environmental fate/behaviour | 9 | 5 | 1 |
| Long-term aquatic toxicity | 29 | 17 | 1 |
| Other ecotoxicological | 51 | 10 | 1 |
| Mutagenicity/genotoxicity | 23 | 14 | 6 |
| Carcinogenicity | 0 | 0 | 0 |
| Repeated dose toxicity | 32 | 9 | 7 |
| Pre-natal developmental toxicity | 36 | 22 | 13 |
| Reproduction toxicity | 0 | 1 | 0 |
| Other Human Health hazard | 0 | 0 | 0 |
| CSR | 36 | 10 | 6 |
| **Total** | 338 | 167 | 70 |

*The registrant provided the information requested in the decision, but ECHA observes that adaptations have been used, or there are deviations from guideline standards or from reporting standards. However, the information is still judged to fulfil the information requirement, which is the basis for the decision.

The outcome of the 2015 follow-up evaluations shows that 88 % (505) of the endpoints originally identified (by CCh or submission of a testing proposal) as non-compliant with the REACH information requirements, are now deemed compliant as a consequence of the dossier evaluation process. For the remaining 12 % (70) of endpoints deemed non-compliant, ECHA sent a SONC to the Member State authorities for consideration of enforcement actions.

[29] All requests in the decision were complied with, without a SONC being issued.
[30] A SONC and subsequent Member State actions led to a dossier update now compliant with the requests in the decision.
[31] A SONC, 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. The Article 42(2) notification has been put on hold. As such, the statement is triggering a transient status in the dossier evaluation process.

## 2.4 Substance evaluation

Substance evaluation aims to verify whether a substance constitutes a risk to human health or the environment from an EU-wide perspective. It contributes to the identification of chemicals of concern requiring further risk management.

The substance evaluation process assesses all registration dossiers from all registrants specific to the same substance although other available sources of information may also be considered.

The evaluating Member State competent authority (eMSCA) has 12 months from the publication of the Community rolling action plan (CoRAP) to conclude whether further information needs to be requested from the registrants to clarify the concerns. The information requested may go beyond the standard information requirements of REACH and may relate to the intrinsic properties of the substance or its exposure.

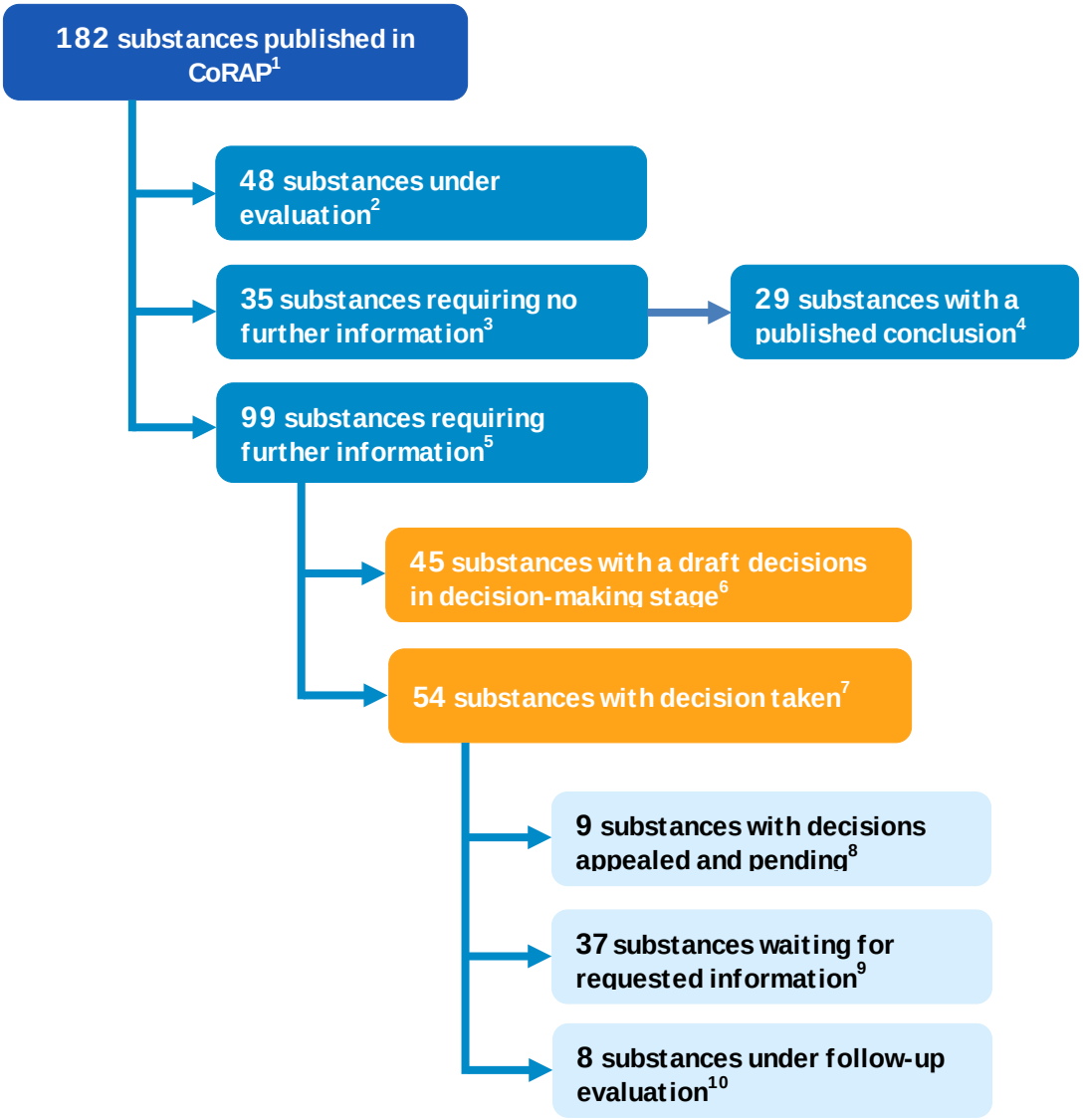
The view that further information is needed, is shared with all the other Member States and ECHA to achieve a general agreement. ECHA takes the decision to request further information, whenever necessary.

ECHA is committed to increasing the efficiency and effectiveness of the substance evaluation process. In 2015, a review of the substance evaluation process was undertaken. More detailed results of the outcome of the review are explained in a separate report [32].

Recommendations for increasing efficiency and effectiveness were discussed in a workshop in November 2015. The conclusions from this workshop are reported in separate proceedings[33].

The current status of substance evaluations started in 2012-2015, is summarised in Figure 9.

[32] http://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf
[33] http://echa.europa.eu/documents/10162/13628/sev_workshop_2015_en.pdf




[1] The CoRAP specifies the substances to be evaluated.
[2] Evaluation performed by the eMSCA.
[3] The eMSCA can conclude on the suspected risk based on the available information.
[4] Conclusion documents are published on ECHA's web pages.
[5] A draft decision requesting further information to clarify the concerns is deemed necessary.
[6] Stages of processing the draft decision, including notification of the draft decision to the registrants, notification to the MSCAs, referral to the MSC, and referral to the Commission (when a unanimous agreement was not reached in the MSC).
[7] ECHA evaluation decision taken following unanimous agreement of the MSC, or when no proposals for amendment of the draft decision were submitted by the MSCAs.
[8] Decision appealed before the Board of Appeal of ECHA. It should be noted that for the nine substances reported, there are 10 decisions appealed and pending.
[9] Registrants to submit the requested information, within the timelines specified in the decision.
[10] eMSCA will examine all new information in the updated registration.

**Figure 9: Current status of substance evaluations started in 2012-2015**

### 2.4.1 Pre-processing and selection

Article 44(1) of REACH provides general criteria for substances to be selected for substance evaluation. In cooperation with the Member States, ECHA has refined the criteria[34] and these are applied in the initial step of the identification of substances with potential concerns.

An integrated selection and priority setting[35] (common screening) approach, as described in section 1 of this report, is used to consider whether the substances are already subject to regulatory measures and the effectiveness of the substance evaluation to clarify the concerns.

Following the established risk-based criteria, ECHA and the Member States identify substances that could be included in the CoRAP. Member States express their interest to evaluate a certain substance so that ECHA can create a draft CoRAP with the substance names and the tentative assessment years. The final CoRAP is adopted after consultation among the Member States and the opinion of ECHA's Member State Committee (MSC).

The CoRAP 2015–2017 update was adopted on 17 March 2015 and contained 134 substances. The list contained 66 newly-selected substances and 68 substances carried over from the existing CoRAP.

ECHA forwarded the draft 2016-2018 CoRAP to the MSC on 15 October 2015 to collect opinions, and published the draft on 28 October 2015. The draft list contained 138 substances, with 47 substances planned to be evaluated in 2016. The list contained 53 newly-selected substances and 85 substances carried over from the existing CoRAP.

Depending on the opinion of the MSC, the number and order of substances may change before the list is adopted. ECHA anticipates the adoption of the CoRAP 2016–2018 update in March 2016.

### 2.4.2 Evaluation

ECHA provides continual support during the evaluation process. For each substance under evaluation, a substance manager is appointed within ECHA who acts as a coordinator and contact point for the eMSCAs.

The eMSCAs started their evaluations of the 48 substances allocated for evaluation in 2015 and finalisation of all draft decisions generated as a result of this evaluation work, will be performed in early 2016.

Furthermore, of the 50 substances allocated for evaluation during 2014, the eMSCAs considered that 39 (78 %) of these required further information to clarify the suspected concerns. For the remaining 11 substances evaluated during 2014, the eMSCAs considered the available information as sufficient to conclude on the concerns and submitted their conclusion documents to ECHA.

[34] http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf
[35] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

### 2.4.3 Decision making

ECHA sent draft decisions for commenting to the 390 registrants of the 39 substances evaluated during 2014, where the eMSCAs considered further information was needed to clarify the suspected concerns. To date, 100 % of all consulted draft decisions under substance evaluation have received PfAs. Table 7 summarises the total substance evaluation decision-making steps performed in 2015.

**Table 7: Decision-making steps performed for substance evaluation during 2015**

| Decision-making step | Evaluation year | | | Total |
|---|---|---|---|---|
| | 2012 | 2013 | 2014 | |
| Draft decisions sent to registrants | 0 | 0 | 39 | 39 |
| Draft decisions notified to MSCAs and ECHA | 0 | 21 | 7 | 28 |
| Final decisions adopted by ECHA | 1 | 27 | 1 | 29 |
| Draft decisions referred to the Commission | 0 | 0 | 0 | 0 |

When MSCAs submit proposals for amendment (PfA), the MSC seeks a unanimous agreement through a written procedure or in plenary meetings. For the latter, the registrants can attend the open sessions. If the MSC does not reach a unanimous agreement, the case is referred to the Commission.

Consistency between decisions has increased through improvements in ECHA's knowledge management and a more efficient application of previously agreed policies. As identified for dossier evaluation cases, there is a noticeable increase in the number of substance evaluation decisions agreed through written procedure and registrants are more active in seeking agreement by increased commenting on PfAs and participation in MSC plenary meetings.

During 2015, the Board of Appeal developed the requirements for the proportionality of information requested in substance evaluation decisions. It considered that ECHA must be able to demonstrate:

(i) that there is a potential risk,
(ii) that this risk needs to be clarified, and
(iii) that the requested information has a realistic possibility of leading to improved risk management measures.

Based on those requirements, it annulled one appealed decision (Case A-005-2014), and upheld two (Cases A-004-2014 and A-006-2014)[36].

In addition, the Board of Appeal found that dossier evaluation should normally come before substance evaluation, and that a data gap in a dossier is not by itself sufficient grounds for establishing a concern to be addressed in a substance evaluation decision (Case A-005-2014).

Furthermore, it confirmed that substance evaluation does not need to be limited to the concerns identified at the time a substance was placed on the CoRAP.

### 2.4.4 Information requested

During 2015, ECHA took decisions on 29 of the substances evaluated and non-

[36] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

confidential versions of these decisions have been published on ECHA's web page.

**Observation**
ECHA continues the practice of sending the adopted decision only to those registrants that had an active registration for the substance at the time the draft decision was sent for commenting. In 2015, the Board of Appeal confirmed this practice: companies that register a substance during the course of the evaluation procedure (after the draft decision) do not need to be addressees of a decision (Case A-004-2014[37]).

Figure 10 summarises the typical requests made within the decisions taken during 2015. In this general outline, requests made in relation to endocrine disruptor properties fall under human health or environmental requests.

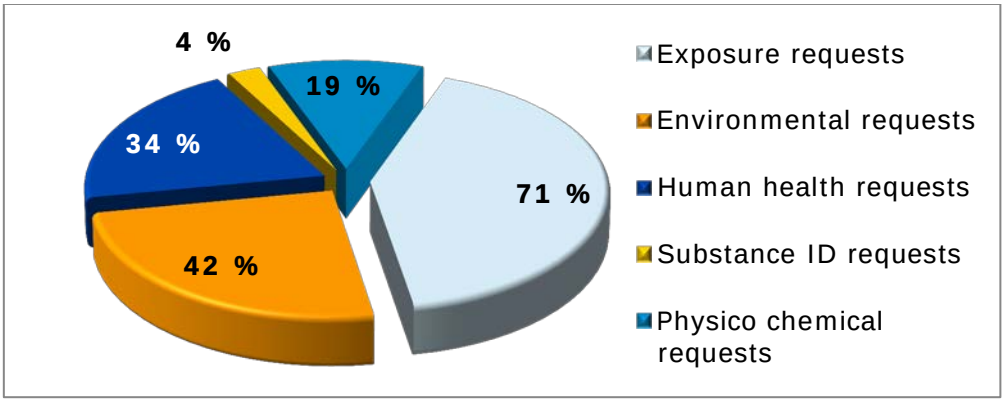



**Figure 10: Percentage of the 29 substance evaluation decisions adopted by ECHA in 2015 containing each type of request**

[37] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

### 2.4.5 Follow-up evaluation of substance evaluation decisions

During 2015, ECHA implemented a new webform[38], which enables registrants to notify ECHA once all the information requested in the decision is delivered by dossier update. The eMSCA examines whether the registrant has provided the information requested in the decision in their latest dossier update.

**Observation**
Registrants should inform the eMSCA and ECHA of the relevant update whereby all requested information is submitted. This will provide further clarity on the subsequent timeline for the follow-up evaluation.

ECHA Secretariat and the Forum through its Working Group 'Interlinks' have defined the process for the NEA follow up of evaluation decisions. Under substance evaluation, this process is more complex than under dossier evaluation as it involves many registrants and potentially cooperation between different NEAs.

Upon receipt of a dossier update containing all information requested by the decision, the eMSCA has 12 months to complete the assessment of the substance. Once this assessment is complete, the eMSCA uses the available information to decide either to request further information to clarify the concerns, or conclude whether further regulatory actions on the substance are necessary.

In 2015, eight substances were at the stage where new information should have been submitted following an initial request for further information. The responsible eMSCAs are currently evaluating the newly submitted information to conclude on its suitability.

[38] https://comments.echa.europa.eu/comments_cms/Sedraftdecisioncomments.aspx

### 2.4.6 Conclusions

Following review of the available and new data (where relevant), if the eMSCA considers that the use of the substance poses a risk, it may then proceed with follow-up actions to substance evaluation. The following options may address the concern:

- A proposal for harmonised classification.
- A proposal to identify the substance as a substance of very high concern (SVHC).
- A proposal to restrict the substance.
- Actions outside the scope of REACH and CLP, such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

Of the 50 substances allocated for evaluation during 2014, the eMSCAs considered that 11 (22 %) of these had sufficient information available to conclude on the concerns.

During 2015, 18 conclusion documents originating from substance evaluations performed in 2012–2014 were submitted to ECHA by eMSCAs. Of these, 16 were subsequently processed and published in 2015 and the remaining two will be published in due course. Most of these conclusions were from evaluations that did not require any request of further information.

For the 16 conclusion documents published:

- Four were concluded with a proposal for risk management option analysis (RMOA) or regulatory risk management (RRM).
- 10 were concluded with removal of the concerns through clarification of hazard properties/exposure.
- Two were concluded with removal of the concerns through the registrants actions (e.g. change in supported uses, cease of manufacture, change in tonnages, applied risk management measures (RMMs), etc.).

## 2.5 Further activities

### 2.5.1 Substance identification

As a consequence of the complexity of the substance identification (SID) information in registration dossiers, the relevance of the substance identification profile (SIP) for both dossier evaluation and substance evaluation was acknowledged in several circumstances, including the ECHA Compliance Check Workshop in 2015[39].

The SIP would provide the necessary overview on the identity of the substance jointly registered, and the test data required for that substance. Therefore, ECHA's Management Board endorsed a strategic approach that included, as a main element, requesting the identification of the scope of joint registration from registrants.

**Observation**
ECHA is working closely with sectors of the chemical industry to develop guidance on how to identify substances for regulatory purposes. The sector-specific guidance, together with the official ECHA guidance, can help companies to identify their substances correctly and achieve compliance with REACH[40].

In June 2015, ECHA's Management Board endorsed the implementation of changes to the completeness check routine for incoming REACH registration dossiers. This will improve the automated check and involve manual completeness checks, in particular of the SID information. This step was recognised as a major way forward to improve the level/availability of SID information in registration dossiers. It may further affect the evaluation process, as it can minimise the risk of CCh targeted on SID[41].

Inconsistency within the substance identifiers is a non-compliance that would normally be included in a CCh decision. To help industry to proactively improve the quality of their dossiers, ECHA launched a service that allows registrants to change the chemical and numerical identifiers for a registered substance, under certain circumstances[42]. The change of identifier request may be initiated by the CCh of the dossier or by spontaneous request from companies.

ECHA is also working together with the European Commission to identify, for selected complex chemical substances, the difficulties faced by registrants to comply with the SID requirements under REACH[43].

[39] http://echa.europa.eu/documents/10162/13628/cch_workshop_en.pdf
[40] http://echa.europa.eu/web/guest/support/registration/how-to-characterise-and-identify-your-substance/sector-specific-support-for-substance-identification
[41] http://echa.europa.eu/documents/10162/13608/mb_38_preliminary_conclusions_en.pdf
[42] http://newsletter.echa.europa.eu/home/-/newsletter/entry/3_14_is-the-substance-identifier-in-your-registration-correct;jsessionid=6A468E6B0CA89E6960CE1AD8A06D7CAA.live2
[43] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8162

### 2.5.2 Alternative methods for animal testing

The primary means to ensure animal testing is only conducted as a last resort is data sharing.

According to REACH, registrants are obliged to consider generating information by means other than vertebrate animal tests, which should be only used for testing if there are no other scientifically reliable ways of assessing the potential effects on humans or the environment.

There are a number of alternative methods available: read-across; grouping approaches; specialised computer modelling; weight of evidence; and non-animal tests, for example, *in vitro* studies using cells rather than animals.

**Observation**
Considering that dossier updates may not normally be taken into account after receipt of a draft decision and since adaptations are often found to be problematic, registrants should proactively assess their adaptations and improve them. Updated ECHA guidance and new knowedge gained by registrants since submitting their initial dossier, provide a basis for the updates. Specifically for read-across approaches, the RAAF may provide registrants with useful information in relation to aspects that ECHA consider essential when using read-across.

***In vitro* methods**
ECHA updated Chapter R.7a of its Guidance on information requirements and chemical safety assessment related to skin corrosion/irritation and serious eye damage/eye irritation[44] in July 2015, with more clear advice on how to use *in vitro* methods. Guidance updates for skin sensitisation and acute toxicity are expected to become available before summer 2016.

**Observation**
Registrants should use the available *in vitro* test methods whenever possible irrespective of whether the information requirement for the *in vivo* test also applies. *In vivo* tests should only be performed if a conclusion cannot be reached based on the *in vitro* tests. In particular, for skin corrosion/irritation *in vivo* testing is now only needed in rare cases. Registrants should consider whether obligations to provide *in vitro* tests and to use alternative methods are met before opting to only perform new *in vivo* tests for skin corrosion/irritation and for serious eye damage/eye irritation.

New test methods for serious eye damage/eye irritation are:

- Short Time Exposure *In Vitro* Test Method (OECD 491).
- Reconstructed human Cornea-like Epithelium (RhCE) test method (OECD 492).

Several new *in vitro* test methods have been adopted by the OECD in 2015. New test methods for skin sensitisation are:

- *In Chemico* Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA) (OECD 442C).
- *In Vitro* Skin Sensitisation: ARE-Nrf2 Luciferase Test Method (OECD 442D).

[44] http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

ECHA's web page on the OECD and EU test guidelines[45] was updated with advice on how to use recently adopted non-animal testing methods for skin sensitisation. Furthermore, Chapter R7.a of ECHA's Guidance on information requirements and chemical safety assessment is currently being updated, especially in respect to the new developments in non-animal testing methods and how information generated by using such methods by using a *Weight-of-Evidence* (WoE) approach could be used for fulfilling the standard information requirement under the REACH Regulation where the first choice of assay is the murine Local Lymph Node Assay. The expected publication date is before summer 2016.

Furthermore, ECHA Guidance on acute toxicity is being updated. In the update, a WoE approach is recommended to cover acute oral toxicity. For this endpoint, a prediction based on the low toxicity seen in the sub-acute toxicity study, combined with other WoE elements (e.g. *in vitro* NRU cytotoxicity assay or QSAR) can be used.

**Integrated approaches on testing and assessment (IATA)**
The Guidance document on the reporting of structure approaches to data integration and individual information sources used within IATA for skin sensitisation is progressing and is expected to be adopted by the end of 2016 by the OECD.

Under OECD Test Guidelines Development, a Guidance document on IATA for Serious Eye Damage/Eye Irritation is under development and the project is led by the Joint Research Centre (JRC). The guidance document aims to advise how different approaches to serious eye damage/eye irritation testing can be used, especially for the identification of eye irritants (CLP Cat 2) for which there is currently no *in vitro* test method available. ECHA is involved in the process and aims to incorporate the developments into its REACH-specific guidance to the extent possible.

**Quantitative structure-activity relationships (QSARs)**
The adaptations of REACH Annex XI, section 1.3 (QSARs) have been used extensively during 2015 by registrants. These included read-across, WoE, and to some extent QSAR, besides *in vitro* methods for particular endpoints. Experience has shown that different advanced techniques such as new approach methodologies (NAM) are not used in many registration dossiers.

NAMs include a variety of new testing tools, such as "high-throughput screening" and "high-content methods" e.g. genomics, proteomics, metabolomics. Some more traditional approaches, including computational methods as well, can shed light on toxicokinetics and toxicodynamics of a substance but are not widely used as standalone tools for hazard assessment. This lack of use may be an indication that industry does not consider these NAMs to be sufficiently developed. ECHA will organise a workshop in 2016 to examine NAM development in relation to their use in a regulatory context[46].

QSAR predictions have been assessed for physico-chemical and environmental properties. These are often used as supporting evidence in WoE approaches and usually alongside other types of data, which may be derived from standard protocols, or not.

Overall, EpiSuite was used most frequently, closely followed by the OECD QSAR Toolbox where there are currently more than 4 000 references in the IUCLID database. However, it should be noted that in most cases the QSAR Toolbox is used to make read-across predictions and not QSAR predictions.

[45] http://echa.europa.eu/en/support/oecd-eu-test-guidelines
[46] http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-new-approach-methodologies-in-regulatory-science

**Observation**
The QSAR model reporting formats (QMRFs) and QSAR prediction reporting formats (QPRFs) should be provided. Furthermore, it is more useful to provide an attachment to an endpoint study record rather than providing a link, which may change with time. It is also good practice to provide the training set of the model used in the QMRF, whenever possible.

**Read-across**
ECHA published the Read-Across Assessment Framework (RAAF)[47] for toxicological properties in May 2015. The first version of this framework presents the methodology applied by ECHA to assess read-across approaches.

The aim of the RAAF is to provide a transparent and structured approach to the scientific evaluation of read-across justifications made by registrants in their dossiers. ECHA uses it to make sure that read-across cases for human health endpoints are assessed consistently during dossier evaluation. The publication of this framework should help registrants to assess the quality of their own read-across cases by presenting the scientific aspects that ECHA considers to be crucial in read-across approaches.

The first publication covers read-across of toxicological properties for mono-constituent substances. Efforts aimed at identifying key principles and challenges for the extension of the scope of the RAAF to multi-constituent substances are ongoing. Similarly, a framework for environmental properties is being developed and further engagement with the stakeholders on the matter is expected.

**Observation**
The RAAF does not replace the official guidance on read-across for registrants but complements it by showing how ECHA assesses read-across cases.

The RAAF will also provide the regulatory science community with a standard means of examining the quality of read-across cases. For example, the first day of the 2016 ECHA Topical Scientific Workshop on New Approach Methods (NAMs) examines how evidence from new approach methods can enhance read-across justifications. Two studies will be taken from SEURAT-1[48]. The RAAF will be used to examine the 'added value' of this evidence from SEURAT-1, ToxCast[49] and other sources, by assessing the cases both with and without it.

[47] http://echa.europa.eu/documents/10162/13628/raaf_en.pdf
[48] http://www.seurat-1.eu
[49] http://www.epa.gov/comptox/toxcast

### 2.5.3 Reproductive toxicity

In March 2015, amended Annexes VIII, IX and X to the REACH Regulation to incorporate the extended one-generation reproduction toxicity study (EOGRTS) (EU B.56, OECD TG 433) in the REACH information requirements entered into force.

This information requirement enhances the possibility to identify certain endocrine disrupting modes of action *in vivo* with parallel assessment of adverse effects on reproduction. In addition, further information on adverse effects on reproduction in the offspring and, as new aspects, information on developmental neurotoxicity and developmental immunotoxicity can be obtained during the same study when needed.

The design of the EOGRT study is flexible and modular. Chapter R.7a of ECHA's Guidance on information requirements and chemical safety assessment (October 2015)[50] was updated to reflect the amended regulation and address the challenges of this amended information requirement. An *ad hoc* advisory expert working group consisting of experts nominated by Member State competent authorities and the Commission was set up in 2015 to support ECHA in addressing the new elements of the amended information requirement.

The standard information requirement is an EOGRT study without expansion to assess the functional fertility of the offspring (extension of Cohort 1B), developmental neurotoxicity or developmental immunotoxicity cohorts. However, if the conditions described in Annex IX/X, 8.7.3 column 2 are met, the registrant must propose an adapted study design accordingly. The adaptations described in column 2 of Annex IX/X, section 8.7.3 concern the extension of Cohort 1B to mate the offspring to produce the second filial generation and/or inclusion of developmental neurotoxicity and/or developmental immunotoxicity cohorts.

The level of information, the number of animals, and the number of animal days (duration of study for the animals) required depends on the design of the study. It is therefore essential that registrants justify the study design and the need to include/not include any expansions of the study (extension of Cohort 1B or inclusion of developmental neurotoxicity or developmental imunotoxicity 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 Chapter R.7a of ECHA's Guidance on information requirements and chemical safety assessment (October 2015).

**Observation**

Registrants submitting a testing proposal for this endpoint are responsible for proposing and justifying the adequate study design of a EOGRT study. If a EOGRT study is already available in the dossier, the registrant must also adequately justify the choice of design for the study.

The amended information requirement affects all testing proposals and compliance checks for the registration dossier where there is no valid data for this endpoint yet. The existing appropriate two-generation reproductive toxicity studies started before 13 March 2015 will fulfil the new standard information requirements.

Any new testing proposals for this endpoint must be assessed against the amended information requirement. Consequently, ECHA has addressed the EOGRTS information requirement in dossier evaluation and a batch of 34 draft decisions were sent to

[50] http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

registrants in 2015. It is expected that the majority of the 216 cases referred to the Commission for decision making will be re-submitted as testing proposals to ECHA during 2016.

ECHA commissioned a study[51] on global laboratory capacities to conduct EOGRTS. Compared with a similar study in 2012[52], the global laboratory capacity to conduct EOGRTS has increased.

### 2.5.4 *In vivo* mammalian alkaline comet assay (OECD 489)

The Member State Committee recently concluded to refine the approach on requesting the *in vivo* mammalian alkaline comet assay (OECD 489) in rats, oral route, in particular, the MSC concluded to:

1) Request examination of a site of contact tissues by default for all types of substances.

2) Prefer glandular stomach over forestomach.

3) As a default, analyse two site-of-contact tissues (glandular stomach and duodenum/jejunum), in addition to liver.

4) Consider justifications of the registrant to justify waiving or adapting analysis of any site-of-contact tissue.

[51] http://echa.europa.eu/documents/10162/13630/echa_sr26_eogrts_en.pdf
[52] http://echa.europa.eu/documents/10162/13628/survey_report_worldwide_cros_en.pdf

### 2.5.5 Increasing transparency

In 2015, ECHA developed new dissemination web pages, which contain brief summaries of substances to allow their properties and main uses to be understood at a glance. In addition, the new pages provide a more integrated view of the regulatory information for each substance and enable information to be more easily downloaded, providing better access to key registration data.

To provide registrants and third parties with a greater insight into ECHA's evaluation processes, ECHA continued to publish non-confidential versions of adopted decisions[53] that have been sent to registrants. The new dissemination web pages allow these decisions to be more visible in the substance pages.

Before publication of any decision, ECHA systematically consults the addressee on the non-confidential version it intends to publish. 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.

**Observation**
Upon receipt of a non-confidential version of a decision for consultation, registrants should carefully check the content of their decisions, to ensure that no confidential content may be published by ECHA.

The first consultations occured in November 2012, and since then 1 037 (75 %) out of a total of 1 390 adopted decisions, have been published by ECHA.

It should be noted that 2015 saw the establishment of a new dissemination portal to provide a higher rate of automation in the publication of final decisions. As a consequence of the technical developments associated with this, there was a halt in the publication of decisions from October – December 2015. During the first nine months of 2015, 250 decisions were published, which represented 82.5 % of the cumulative decisions adopted.

To increase the efficiency and transparency of CCh, ECHA started in 2015 to publish a list of substances which will be potentially subject to CCh[54]. This list is developed in accordance with ECHA's current compliance check strategy and is based on the results of the common screening approach that has been developed by ECHA together with the Member States.

**Observation**
Registrants are advised to regularly check the list of substances potentially subject to CCh 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.

The list of substances potentially subject to CCh will be updated a few times per year. This list is only indicative and not exhaustive: ECHA may at any time open a CCh on any dossier to verify if the information submitted by registrants is compliant with the legal requirements.

[53] http://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions
[54] http://echa.europa.eu/documents/10162/13628/substances_compliance_checks_2015_en.pdf

### 2.5.6 Appeals

During 2015, 24 new appeals against ECHA evaluation decisions were announced by the Board of Appeal – see Table 9.

Of these, one concerned a TPE decision, and five concerned substance evaluation decisions.

**Table 9: Appeal cases related to evaluation announced in 2015**

| Case number | Keywords | Date of publication |
|---|---|---|
| A-012-2014 | Compliance check | 21 January 2015 |
| A-013-2014 | Substance evaluation | 04 February 2015 |
| A-014-2014 | Compliance check | 27 January 2015 |
| A-015-2014 | Compliance check | 27 January 2015 |
| A-016-2014 | Compliance check | 27 January 2015 |
| A-017-2014 | Compliance check | 25 Febriary 2015 |
| A-018-2014 | Substance evaluation | 03 March 2015 |
| A-001-2015 | Compliance check | 04 May 2015 |
| A-002-2015 | Compliance check | 04 May 2015 |
| A-003-2015 | Compliance check | 03 June 2015 |
| A-004-2015 | Compliance check | 03 June 2015 |
| A-006-2015 | Compliance check | 03 June 2015 |
| A-007-2015 | Compliance check | 03 June 2015 |
| A-008-2015 | Compliance check | 16 July 2015 |
| A-009-2015 | Compliance check | 16 July 2015 |
| A-010-2015 | Compliance check | 16 July 2015 |
| A-011-2015 | Compliance check | 16 July 2015 |
| A-013-2015 | Compliance check | 08 July 2015 |
| A-014-2015 | Substance evaluation | 19 August 2015 |
| A-015-2015 | Substance evaluation | 19 August 2015 |
| A-016-2015 | Testing proposal | 11 August 2015 |
| A-017-2015 | Compliance check | 04 August 2015 |
| A-018-2015 | Substance evaluation | 23 October 2015 |
| A-021-2015 | Compliance check | 30 November 2015 |

The Board of Appeal'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[55].

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

### 2.5.7 Recent EU Ombudsman conclusion

On 11 September 2015, the European Ombudsman closed a complaint against ECHA relating to its practices in the examination of vertebrate animal testing proposals under dossier evaluation (complaint case 1606/2013/AN).

One aspect of this case concerned the obligation under Article 13(1) of the REACH Regulation that alternative methods (e.g. *in vitro* test methods, read-across) are considered and used whenever possible. Following the Ombudsman's decision, ECHA started to request additional information on the alternative methods considered by registrants, who submit new testing proposals for vertebrate animal tests.

**Observation**
From September 2015 onwards, ECHA has invited registrants to demonstrate that they have considered alternative methods for new testing proposals involving vertebrate animals.

The information received is published alongside the public consultation of the testing proposals such that third parties can comment and will be considered in the testing proposal examination. Further measures may be implemented in the future. This will help to demonstrate that the safe use of chemicals can be ensured whilst avoiding unnecessary animal testing.

ECHA has started a consultation with the Commission, Member States and stakeholders on the further practical steps to implement the Ombudsman's conclusions. The aim is for companies to be able to submit their considerations in registration dossiers following the next update of the IUCLID tool in 2016. In the meantime, registrants will be contacted through REACH-IT.

# 3. Recommendations to registrants

In this section, ECHA provides (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[56], give 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 registrations consistent and up-to-date without undue delay, and how to use adaptation possibilities correctly.

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

## 3.1 Substance identity

**Apply the 'one substance, one registration' principle**
Manufacturers and importers of the same substance are obligated to submit their registration jointly. The identity of the jointly-registered substance must be unambiguous and reported transparently within the registration dossier. Transparency can be achieved by including the substance identity profile (SIP) in the registration dossier of the lead registrant.

**Observation**
The SIP sets the boundaries of the compositions registered collectively within a joint submission. It brings transparency regarding the compositions that were agreed to be addressed in the registration dataset.

Currently, the SIP can be inserted into the registration dossier as an attachment, however, a structured way of reporting this information will be provided in the next IUCLID release in 2016.

**Be proactive in addressing potential shortcomings**
For some EINECS entries, the substance description can be quite broad and may potentially be considered to cover more than one substance. Furthermore, some EC/CAS numbers used are not representative for the substances registered (such as where a substance includes specific stereoisomeric forms). Registrants should proactively adapt any identifier that they recognise as being inappropriate for the registered substance.

Complementary measures aimed at improving dossier quality, such as the IT-based screening on substance identity information[57], aim to help industry proactively improve the quality of their dossiers. Based on the screening results, registrants might receive an information letter from ECHA, providing advice on how to address their specific substance identification shortcomings. Failure to address any potential shortcomings may lead to follow-up actions from ECHA, therefore, registrants should update their dossiers whenever SID information is incomplete or inconsistent.

**Use the available support and services to improve data quality**
The Guidance for identification and naming of substances under REACH and CLP[58] is the key document to establish the identity of the registered substance. However, the sector-specific documents prepared with the contribution of ECHA should also be taken into account[59].

ECHA developed the dossier quality assistant[60] (DQA), which is a tool available for registrants to check their IUCLID substance datasets and dossiers for common shortcomings and inconsistencies before submitting their registration to ECHA. The DQA incorporates a set of checks particulary dedicated to improving the quality of substance identity information. The DQA module is included in the IUCLID validation assistant plug-in[61], which also allows the user to verify business rules and completeness check rules that are checked during submission to ECHA.

[57] http://echa.europa.eu/support/how-to-improve-your-dossier/it-screening-campaigns-on-dossiers
[58] http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf
[59] http://echa.europa.eu/view-article/-/journal_content/title/guidance-on-substance-identification-for-essential-oils-now-available
[60] http://echa.europa.eu/support/how-to-improve-your-dossier/dossier-quality-assistant
[61] http://echa.europa.eu/support/dossier-submission-tools/iuclid/validation-assistant

## 3.2 Quantitative structure-activity relationships (QSARs)

**Consider the type of assessment when building your case**

The adaptation of REACH Annex XI, section 1.3 (QSARs) is based on the premise that the chemical structure determines the toxicological properties of substances. In this approach, the prediction should be adequate for the purposes of classification and labelling, and/or risk assessment to fulfil the requirements for replacement of standard information requirements alone.

**Observation**

It is understood that local QSARs developed for few analogues present a case of many-to-one read-across, and must be reported and justified as such. If a clear trend for many points is established (e.g. for acute aquatic toxicity), then it can be defined as QSAR and reported as such.

A pre-requisite for the use of QSARs is their accessibility, therefore, the advantages and disadvantages they offer with respect to reliability, handling complex evidence, and uncertainty must be well understood and handled carefully. Large aggregated models based on diverse data can be useful for screening but may not be suitable for addressing standard information requirements because they may fail the first OECD QSAR validation principle[62] (defined endpoint).

**Ensure that all QSARs are properly documented**

The QSAR prediction reporting format (QPRF) is needed in addition to the QSAR model reporting format (QMRF) to assess both prediction reliability and how the target is covered by the applicability domain, and to conclude on the adequacy of the prediction. The uncertainty associated with the prediction (e.g. the error of estimate) is an important component for assessing its reliability. However, the error of estimate alone is not sufficient to assess the reliability of the prediction. The REACH Guidance on information requirements and chemical safety assessment; Chapter R.6 on QSARs and grouping of chemicals (May 2008)[63] provides a detailed description of the information required in the reporting formats.

**The adequacy of the prediction needs to be properly justified**

If the tool does not offer all necessary information to justify the adequacy of the prediction, go outside the tool and try to compensate the missing piece of information. For example, several EpiSuite models provide training sets that can be taken out of the tool and mined in software to assess the structural similarity of the target to the training set, and to individual chemicals in it.

**Observation**

For large training sets, the proximity of the target to a well predicted molecule from the training set, provides additional assurance that the model works for the particular type of chemistry.

Consider the specific chemistry of the substance to highlight whether it can be difficult to predict. For example, information on reactivity or specific modes of action can highlight structures where excess toxicity would be expected, and predictions may be potentially less accurate. There are statistical techniques that need to be applied only for models where statistical pitfalls are expected. However, this test cannot make the prediction acceptable, if the endpoint is unclear, or is a broad compilation of all available data for a given endpoint.

[62] http://www.oecd.org/env/ehs/risk-assessment/37849783.pdf
[63] http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf

## 3.3 Read-across

ECHA has developed the RAAF[64] to provide experts with a transparent and structured methodology to assess read-across approaches. Applying the RAAF results in a structured assessment of the case, identifying strengths and weaknesses of a read-across approach.

**Observation**
Registrants are encouraged to familiarise themselves with the RAAF since this framework may be used to identify the critical weaknesses of their read-across adaptations and to further improve on these aspects.

Structural similarity is required for grouping and read-across approaches under REACH, however it is not sufficient on its own to establish a basis for prediction of toxicological properties between substances. The role of the structural similarities and the impact of the structural differences between the substances on the possibility to predict properties need to be established.

**Observation**
Registrants should ensure that each read-across hypothesis establishes why the structural similarities and differences between the source substances and the target substance allow for a possibility to predict properties of the target substance.

Supporting information constitute an essential part of a read-across justification. Adequate and reliable supporting evidence is necessary to verify the read-across hypothesis. However, even though read-across hypotheses are frequently based on toxicokinetic arguments, these arguments are often supported only by general considerations on toxicokinetics rather than information on toxicokinetic properties specific to the substance under consideration.

**Observation**
Providing adequate and relevant supporting information increases the robustness of the read-across approach. This information should be reported as (robust) study summaries allowing an independent scientific assessment.

[64] http://echa.europa.eu/documents/10162/13628/raaf_en.pdf

## 3.4 Substance evaluation

**Plan dossier updates effectively**

When a substance is listed within the second or third year of the CoRAP[65], registrants should take the opportunity to update their dossiers for that substance. This is particularly important for information that may fall within the scope of the initial concerns, defined in the justification document.

In contrast, if the substance is listed within the first year of the CoRAP, where the eMSCA will begin their evaluation once the CoRAP is published, registrants should avoid submitting new dossier updates for that substance. Instead, any planned dossier update should be communicated and agreed with the eMSCA beforehand, to prevent delays in the evaluation process.

**Observation**

By default, dossier updates received after the day on which the draft decision was notified to the registrants will only be considered if agreed in advance with the eMSCA. Dossier updates received after the deadline agreed with the eMSCA will not be taken into account.

**Communicate clearly and with a 'single voice'**

It is highly recommended that registrants maintain good communication with the eMSCA during the substance evaluation process so that there is an opportunity to explain and understand the scientific issues arising from the risk assessment. In particular, registrants may provide valuable insight into any exposure-related issues.

**Observation**

Registrants should coordinate their commenting during the relevant steps of the decision-making process and provide a single set of consolidated comments. A good approach is to select a single representative who will submit comments on behalf of the whole group.

Within 90 days of receipt of the adopted substance evaluation decision, registrants should inform ECHA regarding which registrants will perform the requested experimental studies. If the decision contains requests for multiple experimental studies, registrants may nominate different registrants to be responsible for the performance of each test. If no agreement can be reached regarding who will perform each experimental study requested, ECHA will designate the responsibility of performing the tests to one of the registrants, regardless of the number of experimental studies requested in the decision.

Registrants should use the available webform[66], to notify ECHA and the eMSCA once all information requested in the decision has been delivered by dossier update. This is important since it will trigger the 12-month period for the follow up assessment.

[65] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

[66] https://comments.echa.europa.eu/comments_cms/Sedraftdecisioncomments.aspx

## 3.5 PBT/vPvB assessment

Substances that persist for long periods of time in the environment and have a high potential to accumulate are of specific concern since their long-term effects are rarely predictable.

PBT substances are persistent, bioaccumulative and toxic, while vPvB substances are characterised by a very high persistence in combination with a very high tendency to bioaccumulate.

**For recognised PBT/vPvB substances, an assessment containing a demonstration that emissions are minimised must be provided.**

The properties of the PBT/vPvB substances lead to a high uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies. For PBT and vPvB substances, a 'safe' concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way. Therefore, a separate PBT/vPvB assessment is required to take these specific concerns into account. Registrants are required to perform this specific PBT/vPvB assessment in the context of their chemical safety assessment (CSA).

A PBT/vPvB assessment is required for all substances for which a CSA must be conducted and reported in the chemical safety report (CSR). In general, these are all substances that are manufactured or imported in amounts of 10 or more tonnes per year that are not exempted from the registration requirement under the regulation.

**Observation**
Following the identification of substances as PBT/vPvB, in some cases the requirement for an exposure assessment (corresponding to emission characterisation) and risk characterisation (corresponding to demonstration of minimisation of exposure) has not been met.

**PBT properties of constituents of UVCB substances are generally not properly addressed in the registration dossiers.**

The constituents of UVCB substances need to be considered in the PBT/vPvB assessment. The assessment does not mean that all constituents must be identified by their chemical structure, but the identity needs to be sufficiently analysed to enable the PBT/vPvB assessment to be concluded. Only in cases where the constituents are similar with regard to fate properties, may it be sufficient to provide only data on the whole substance. In most cases, however, the constituents need to be assessed either one-by-one or fraction wise.

Registrants should characterise and know their UVCB substance, including the 'unknown' constituents to such a level that they can conclude whether the substance contains PBT/vPvB constituents or not. A CSA can only contain negative or positive conclusions on PBT/vPvB properties of a UVCB substance and its constituents, or testing proposals. A CSA on a UVCB substance cannot conclude that there is insufficient information on PBT/vPvB properties of some constituents, if no testing proposals are submitted.

**Observation**
PBT properties of constituents of UVCB substances should be properly addressed in the registration dossiers. The characterisation and assessment of properties of UVCB constituents need to be carried out to such a level of detail that allows an unequivocal conclusion to be derived on the PBT-properties for all constituents of the substance.

## 3.6 Chemical safety report (CSR)

**Use the available tools to make a transparent and consistent safety assessment**
In response to experience gained in generating and using exposure scenario information under REACH, ECHA together with industry and Member States launched an action programme called the CSR/ES Roadmap[67] in 2013. This programme defines the areas of improvement on CSA/ES and the corresponding actions until 2018.

In 2016, several actions under the Roadmap[68] will deliver products that will increase the efficiency, transparency, consistency and usefulness of the chemical safety assessment (CSA) under REACH. The products include:

- **IUCLID 6** which provides extended options to document and link different information elements on use and exposure within a registration dossier, in a transparent, consistent and structured way. This allows authorities to process information from REACH registrations efficiently and enhance understanding of the case.

- **Chesar 3** which supports a systematic safety assessment based on i) information on substance properties documented in IUCLID and ii) the use information of substances collected from the supply chain. Chesar[69] also enables the generation of the CSR and exposure scenarios for communication, and export of the CSA results into the corresponding IUCLID sections.

- **EScom standard**[70] was developed by industry to support efficient communication on the conditions of safe use down the supply chains. It consists of a library of standard phrases to express the conditions of safe use in a standardised way and an xml exchange format for exposure scenario information.

- **Sector use-map formats** allow sectors to provide a description of the typical activities performed with chemicals in a sector and the typical conditions under which these occur. The conditions are expressed in a way that allows the information to be easily fed into the registrant's safety assessment. There are standard formats/templates to provide information on the description of uses and conditions of use to be used as input to the exposure assessment of workers (specific workers exposure determinants, SWEDs), consumers (specific consumer exposure determinants, SCEDs) and environment (specific environmental release categories, SpERCs). Downstream user sectors are encouraged to use these templates to make the relevant information available to registrants.

- **ECHA Guidance documents on chemical safety assessment (CSA)** have been updated to include the practices and principles that have emerged over recent years. These principles will be complemented by further practical advice in the help-systems of the tools and by examples published by ECHA.

All the products are aligned with each other and support an efficient exchange and update of information, as well as consistency during the information flow within the supply chain.

[67] http://echa.europa.eu/en/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap
[68] http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf
[69] https://chesar.echa.europa.eu/
[70] http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

**The dossier should be transparent, consistent and up-to-date.**
The new IUCLID and Chesar versions support registrants in enhancing the transparency by facilitating the reference between the compositions of the substance, the related hazard profiles and the use patterns that the different compositions may have.

Transparency is also supported for cases where more than one set of data is relevant for the assessment, for example, when substances form reaction products, or when constituents in a substance are very different in terms of their hazard or their exposure behaviour.

The tool package generally facilitates consistency between the conclusions from the hazard assessment, the descriptions of use, exposure assessment and the risk characterisation. The tool package also supports IT-based updates of the CSA/CSR information.

**The use description and the exposure assessment should reflect the actual uses and conditions of use in companies**.
This is essential for generating useful information for authorities and for downstream users. Roadmap products support industry sectors by providing formats that enhance communication up the supply chain. This will contribute to making realistic assumptions for the exposure scenarios, including the operational conditions and the effectiveness of risk management.

It will also help registrants to provide customers with exposure scenarios matching the reality of their operations and products. Registration dossiers (including CSRs) are the main information source for authorities when prioritising substances for post-registration REACH processes. Registrants may wish to demonstrate that their substances are not a priority concern for substance evaluation, classification, authorisation or restrictions. For example, the substance only enters into wide dispersive use to a very minor extent, or is only used under strictly controlled conditions. The new IUCLID 6 will allow more transparent presentation of the case in the registration dossier.

**Use the exposure assessment tools within their domain of applicability and justify all deviations from defaults.**
For exposure tools integrated into Chesar, users receive some warnings when using the tool in a way that may conflict with the applicability domain.

**Improve the information on personal protective equipment**
Despite the recommendations presented in previous evaluation reports, the available information on personal protective equipment (PPE) continues to present problems during the CCh process.

**Dermal protection** requires information to be provided on the material, breakthrough time and thickness (where appropriate) of gloves, which should ideally be reported within both the CSR and Section 11 of the IUCLID dossier. The best approach is to also provide information on gloves that should not be used as this information can be very important. Predictions of skin exposure from tier 1 models can be misleading as dermal contamination is often highly variable and workers must be protected against unexpected events leading to high exposures.

Some registrants have indicated that they consider that dermal predictions from the ECETOC TRA can be estimates for the whole body. If so, information on the appropriate protection to stop splashes and wetting events reaching the skin should be provided. Such information often requires proposing advice on the provision of chemical protective work wear. Some appropriate European Standards are:

EN 13034:2005 (Type 6), limited protection against liquid aerosol.

EN 13982-1:2004 (Type 5), protection against airborne dry particulate chemicals.
EN 14605:2005 (Type 4) protection against liquid chemical splash.

**Observation**
In general, normal work wear coveralls cannot be regarded as offering any reliable protection against chemical exposure as they are not tested for permeation and penetration.

**Respiratory protection:** exposure scenarios may appear to place a heavy reliance on the long-term performance of respiratory protective equipment (RPE). Generally, RPE is intended to address residual risk after other risk management measures have been applied. An exposure scenario can appear unrealistic when a quick calculation indicates the actual predicted external concentration (outside of the RPE) of a highly noxious or obnoxious substance is considerably above the DNEL.

In these cases, exposure scenarios that predict exposures just below the DNEL when expecting workers to wear RPE all day are not compatible with the concepts within the Chemical Agents Directive (Directive 98/24/EC). In practice, RPE may not always be entirely reliable and high workplace protection factors may not be readily achieved by an untrained workforce, which leads to a potentially unacceptable high indication of risk. RPE is usually intended for cases where the RCR is only marginally above 1 and high exposure tasks may be intermittent, so that application of RPE reduces the RCR to well below the critical long-term DNEL level.

**Observation**
Registrants suggest 8h RPE to get an RCR just below 1, without suggesting technical measures to reduce exposure. This is against key principles and would only be acceptable with an explicit justification that technical measures are not possible under the conditions of use. If >4h RPE is needed to control risks, then the type of RPE and the management system supporting proper use needs to be described in the exposure scenarios. In some cases, RPE is the primary risk management measure. For example, during car respraying operations where special arrangements are needed to ensure long-term worker protection and to avoid consequences such as occupational asthma when spraying certain formulations creating a high risk environment.

**Clearly justify the use of SpERCs for environmental exposure assessment**
The reliability of the CSA highly depends on the reliability of the input parameters used in the hazard and exposure assessments. One of the main parameters affecting the outcome of the environmental exposure assessment are the release factors to the environment. ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012)[71] suggests generic worst case release factors for each environmental release category (ERC) that registrants can use without further justification. If safe use cannot be demonstrated on this basis (because of substance hazard profile or the amounts used), registrants need to determine more appropriate release factors and the corresponding conditions of use.

It has been proposed by industry to use sector specific environmental release categories (SpERCs) as a key means to arrive at refined release estimates for the environmental assessments. The concept of SpERC is accepted in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012), provided that the operational conditions and risk

[71] http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf. Please note that at the time of publication of this report, this Guidance document is under review. Drafts are available at: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach

management measures leading to the refined release factors are sufficiently documented.

In general, SpERCs include a definition of scope (applicability domain), information on conditions of use leading to a certain expected release factor, expected release factors, and an explanation of how the release factors were derived.

SpERC developers and users should ensure that the description provided in the SpERC factsheet is detailed in a clear and accurate manner with sufficient justification, and covers all relevant activities/processes, operational conditions, and risk management measures claimed.

If environmental release factors are set lower than the defaults suggested for ERCs in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012), a proper justification for those is expected. As a minimum, this should cover:

i) the description of conditions of use under which the release factor occurs, and

ii) a description on how the release factor was derived (with underpinning data reported and explained).

Registrants often refer to SpERCs as a source of the applied release factors, however, many SpERCs do not contain sufficient background information on the release factor proposed. As a consequence, the registrant's CSR may not be convincing in demonstrating the control of risk.

Registrants using available SpERCs for their CSA must ensure that the substance and the use described in a particular dossier are in the domain of applicability of the SpERC used.

## 3.7 ECHA's guidance and tools

**Consult the guidance material on the ECHA website when preparing and maintaining your registration**

The Data Submission Manuals (DSMs)[72] and the REACH-IT Industry User Manuals (IUMs)[73] give definitive instructions for preparing and submitting dossiers. These manuals will be reviewed and integrated in the tools in the context of the release of the next versions of IUCLID and REACH-IT.

ECHA has continued to develop REACH guidance in 2015. The following updated guidance documents, particularly relevant to evaluation, were published on the ECHA website during the year (see ECHA website for all publications):

- An update of the Guidance on information requirements and chemical safety assessment; Chapter R.7a: Endpoint specific guidance, Section R.7.6 related to reproductive toxicity and Section R.7.2 related to skin and eye irritation/corrosion (October 2015)[74].

- An update of the Guidance on information requirements and chemical safety assessment; Chapter R.12 on Use description (December 2015).

- An update of the Guidance on the compilation of safety data sheets (August 2015)[75].

- A corrigendum to the Guidance on the Application of the CLP Criteria - Part 2 Physical Hazards and Part 3: Health Hazards (June 2015)[76].

- An update of the Introductory Guidance on the CLP Regulation (July 2015)[77].

A number of Guidance documents are still under review, notably those dealing with chemical safety assessment. Final versions are expected to be published throughout 2016. Drafts and consultation processes can be followed here: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach

ECHA invites you to take note of these new/updated resources and to update the relevant parts of your dossiers, where appropriate. ECHA will consider the new approaches described in the guidance in on-going and future dossier evaluations.

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

In addition to verifying business rules and completeness check rules, the plugin hosts the dossier quality assistant module that warns the user of deficiencies and inconsistencies found within their dossier. It is strongly encouraged that registrants run the plugin on their substance datasets and dossiers and correct all reported issues before submitting them to ECHA.

[72] http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-manuals
[73] http://echa.europa.eu/support/dossier-submission-tools/reach-it/industry-user-manuals
http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf
[75] http://echa.europa.eu/documents/10162/13643/sds_en.pdf
[76] http://echa.europa.eu/documents/10162/13562/clp_en.pdf
[77] http://echa.europa.eu/documents/10162/13562/clp_introductory_en.pdf

# List of acronyms and abbreviations

| | |
|---|---|
| AE | assessment element |
| CCh | compliance check |
| Chesar | chemical safety assessment and reporting tool |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures |
| CoRAP | Community rolling action plan |
| CSA | chemical safety assessment |
| CSR | chemical safety report |
| DD | draft decision |
| DNEL | derived no-effect level |
| DSMs | data submission manuals |
| DU | downstream user |
| ECHA | European Chemicals Agency |
| EINECS | European inventory of existing commercial chemical substances |
| eMSCA | evaluating Member State competent authority |
| EOGRTS | extended one-generation reproductive toxicity study |
| ERC | environmental release category |
| EU | European Union |
| GLP | good laboratory practice |
| IUCLID | International Uniform Chemical Information Database |
| IUMs | REACH-IT Industry User Manuals |
| MSC | Member State Committee |
| MSCA | Member State competent authority |
| NAM | new approach methodologies |
| NEA | national enforcement authority |
| PfA | proposal for amendment |
| PPE | personal protective equipment |
| OECD | organisation for economic cooperation and development |
| QMRF | QSAR model reporting format |
| QPRF | QSAR prediction reporting format |
| QSAR | quantitative structure–activity relationship |
| RAAF | read-across assessment framework |
| RCR | risk characterisation ratio |
| REACH | Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals |
| RMM | regulatory risk management |
| RMOA | risk management option analysis |

| | |
|---|---|
| RPE | respiratory protective equipment |
| SEURAT | safety evaluation ultimately replacing animal testing |
| SID | substance identity |
| SIEF | substance information exchange forum |
| SIP | substance identity profile |
| SONC | statement of non-compliance following a dossier evaluation decision |
| SpERC | specific environmental release category |
| SVHC | substances of very high concern |
| t/a | tonnes per annum (year) |
| TPE | testing proposal examination |
| WoE | weight of evidence |

**EUROPEAN CHEMICALS AGENCY**
**ANNANKATU 18, P.O. BOX 400,**
**FI-00121 HELSINKI, FINLAND**
**ECHA.EUROPA.EU**

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