Evaluation under REACH
Progress Report 2016

Evaluation in ECHA's Integrated Regulatory Strategy

Disclaimer:

The report includes recommendations to potential registrants to improve the quality of 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 2016

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

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Foreword from the Executive Director

Dear reader,

This is the ninth evaluation progress report. This report covers the progress made in dossier and substance evaluation in 2016 and provides recommendations to registrants who have already registered or are still preparing their registration dossiers for the next deadline on 31 May 2018.

2016 was a year of major progress in ECHA's integrated regulatory strategy. It has been further refined with the aim of contributing to meet the United Nations' chemicals management goal set by the World Summit on Sustainable Development (WSSD) in 2002. It aims to ensure that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and environment by 2020.

ECHA's strategy is based on screening all information from the various databases that the Agency manages, to prioritise safety information requests and risk management measures on substances that can have adverse effects on our health or the environment. Evaluation plays a major role in implementing this strategy, and many other measures support the regulatory strategy, as illustrated in this report.

The quality of the data on chemicals needs to be improved and dossiers need to be updated whenever there is a material change or where new information comes to light. The five-year report on the operation of REACH and CLP published in June 2016 showed that, whilst companies are clearly responding to the legislation, a significant proportion of registration dossiers are still not of a sufficient quality and the majority of the dossiers have never been updated since their first submission.

As changes occur both in the chemicals market and the scientific knowledge on the chemicals progresses, companies need to keep their dossiers up-to-date. The most innovative and front-running companies integrate the provision of high quality information on their substances in their business strategies and keep it updated to ensure their substances can be used safely.

In December 2016, we marked 10 years of the REACH Regulation. In June 2017, we will also mark ECHA's 10th anniversary. A lot has been achieved but a lot of work also remains, for both companies and authorities. To understand the safety of the chemical universe faster, authorities and industry are investing in collaborative ways of addressing groups of substances instead of single substances that should lead to higher compliance and should mean that the right substances are targeted for further risk management.

In preparing for the final 2018 registration deadline, our evaluators have spent a great deal of time and effort in making REACH more understandable for SMEs and providing more practical guidance to registrants on how to avoid unnecessary animal tests.

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 the compliance of their registration dossiers. Remember that we rely on you to achieve a safer world by 2020.

Geert Dancet
Executive Director

Executive summary

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

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

Implementation of ECHA's integrated regulatory strategy

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

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

Outcomes of compliance checks

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

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

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

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

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

For 152 dossiers, ECHA adopted decisions, mainly based on the draft decisions issued in the previous year. These decisions contained 597 standard information requests. The

non-compliances most commonly addressed in these decisions were prenatal developmental toxicity, short- and long-term aquatic toxicity, substance identification and composition, mutagenicity or genotoxicity and issues relating to the chemical safety reporting including DNELs, PNECs and PBT assessment.

Testing proposals

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

Follow-up evaluation of compliance check and testing proposal decisions

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

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

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

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

Progress in substance evaluation

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

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

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

Extended one-generation reproductive toxicity study (EOGRTS)

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

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

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

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

Avoiding unnecessary animal testing

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

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

Use of other measures

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

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

In 2016, ECHA launched a targeted letter campaign on 270 shortlisted substances, informing registrants that their substance is shortlisted, i.e. the substance is under Member States competent authorities' scrutiny. The letters invited registrants to improve the dossier quality in advance of any compliance checks or other regulatory process that may follow the common screening. These letter campaigns have proven to be quite efficient. For example, the dossiers within the scope of the 2016 shortlist, 40 % were updated within four months of the letters being sent. Based on the common screening, ECHA regularly publishes a list of substances that may be subject to compliance check.

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

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

Ensuring availability of key information on priority chemicals

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

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

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

Key recommendations to registrants

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

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

EXPOSURE ASSESSMENT AND RISK CHARACTERISATION MUST COVER ALL HAZARDS

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

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

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

[1] Decision of the Board of Appeal of 28 June 2016 in Case A-015-2014, *BASF SE.*

[2] See also ECHA Guidance part B and part D
https://echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf/7e6bf845-e1a3-4518-8705-c64b17cecae8
https://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df

PREPARE YOURSELF FOR THE REACH 2018 REGISTRATION

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

[3] https://echa.europa.eu/-/reach-2018-assess-your-substance-to-show-safe-use
[4] https://echa.europa.eu/practical-guides

1. Evaluation in ECHA's integrated regulatory strategy

In 2016, ECHA further advanced the implementation of its integrated regulatory strategy (previously called the compliance check strategy). This strategy brings together the processes under the REACH and CLP regulations and is based on the experiences and lessons learnt from the first years of ECHA's operation.

It has been further refined with the aim of contributing to meet the chemicals management goals set by the World Summit on Sustainable Development (WSSD). This means that by using transparent, science-based risk assessment and risk management procedures, regulators aim to ensure that chemicals are used and produced in ways that minimise significant adverse effects on human health and the environment by 2020.

ECHA's ambition by the end of 2020 is to address all registered substances that are manufactured in or imported to Europe in quantities of 100 tonnes or more per year, through a number of actions. These actions are intended to reduce the pool of substances of potential concern and conclude on the need for specific action or whether they are of lower priority for further regulatory work.

Together with the Member States, ECHA continued to implement and refine a common screening process in 2016, which identifies substances that have the greatest potential for adverse impact on human health and the environment.

The common screening allows a conclusion to be reached on which dossiers and substances need further compliance check and/or substance evaluation, and which substances can be directly earmarked for EU-level risk management measures.

Under dossier evaluation, priority is given to full registrations of chemicals produced in volumes over 100 tonnes per year, and with potential concern that may require substance evaluation or risk management measures.

Based on the regulatory strategy, the main focus in the evaluation is on the higher tier (REACH Regulation Annex IX and X) human health and environmental standard information requirements, which are relevant for identifying carcinogenic, mutagenic and reprotoxic (CMR) and persistent, bioaccumulative and toxic/very persistent, very bioaccumulative (PBT/vPvB) substances.

If the concern is confirmed in the evaluation, a risk management option analysis (RMOA) usually follows. This first confirms if regulatory risk management measures need to be explored. Further, it checks which process is the most suitable: harmonised classification and labelling, restriction, or, for substances of very high concern, applications for authorisation. The analysis can also lead to the conclusion that a substance is currently of low (or no) concern, or that actions under other legislation than REACH or CLP are needed.

In brief, ECHA's integrated regulatory strategy aims to:

- Efficiently select substances that raise potential concern, generating standard or equivalent information for assessing their safety through a compliance check or other means so that any remaining concerns can subsequently be addressed through the most suitable risk management regulatory instrument;
- Improve the transparency of relevant outcomes of the different steps of the evaluation and risk management processes, for the benefit of Member States, stakeholders and registrants;

- Provide confidence amongst stakeholders and the public that registrants meet REACH and CLP information requirements, resulting in an improved basis for communication on safe use in the supply chain; and
- Ensure appropriate and timely intervention from relevant actors (ECHA, Member States, industry and the European Commission) within the different REACH and CLP processes so that chemicals of concern are addressed as soon as possible.

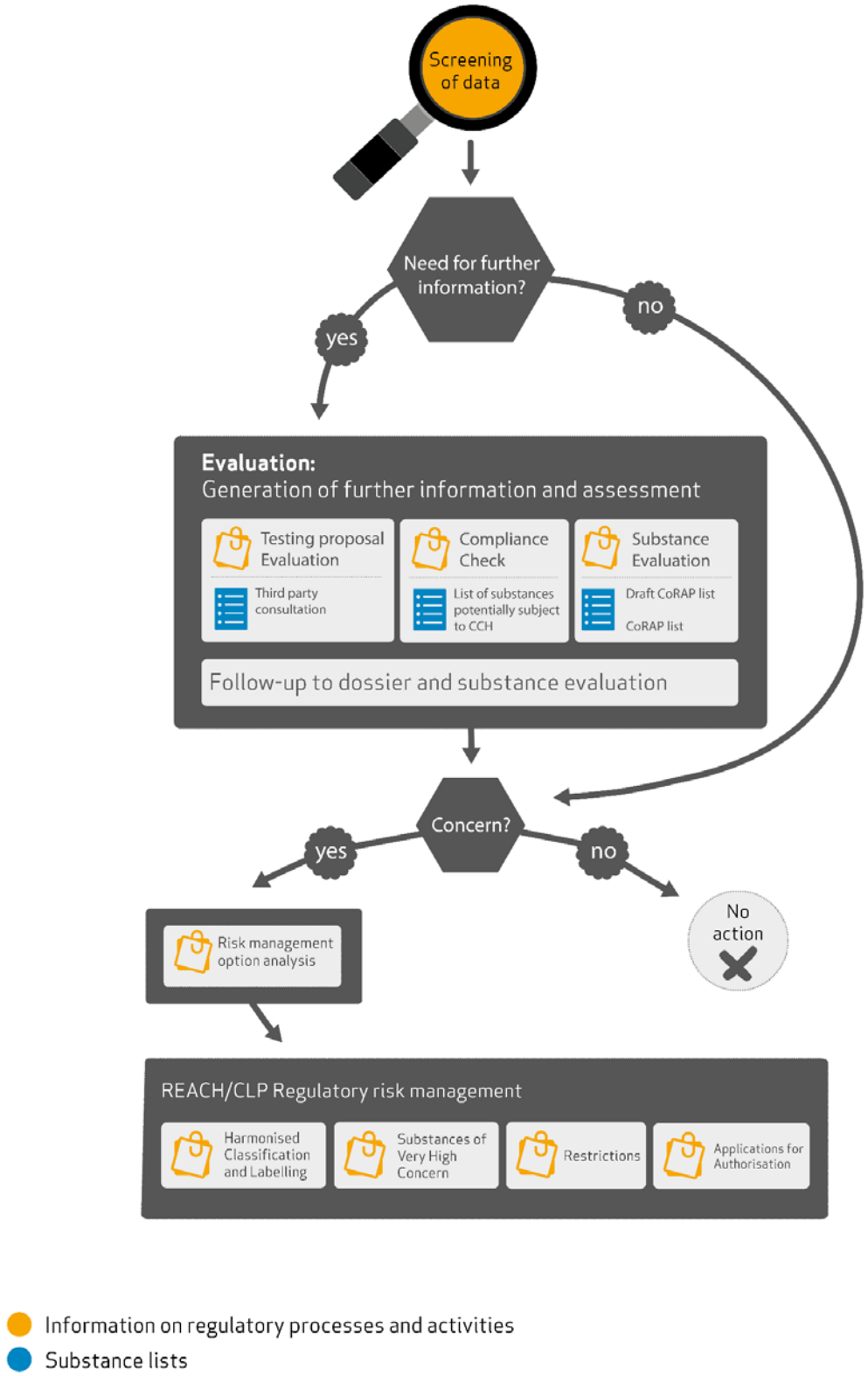


Figure 1. Evaluation in ECHA's integrated regulatory strategy.

2. Evaluation progress in 2016

ECHA's evaluation work is divided into dossier evaluation and substance evaluation.

There are two processes under dossier evaluation: compliance check (CCH) and testing proposal examination (TPE).

The outline of evaluation processes is shown in Figure 2, below. Further details of the evaluation processes are provided in previous evaluation reports[5] and the ECHA web section on evaluation[6].

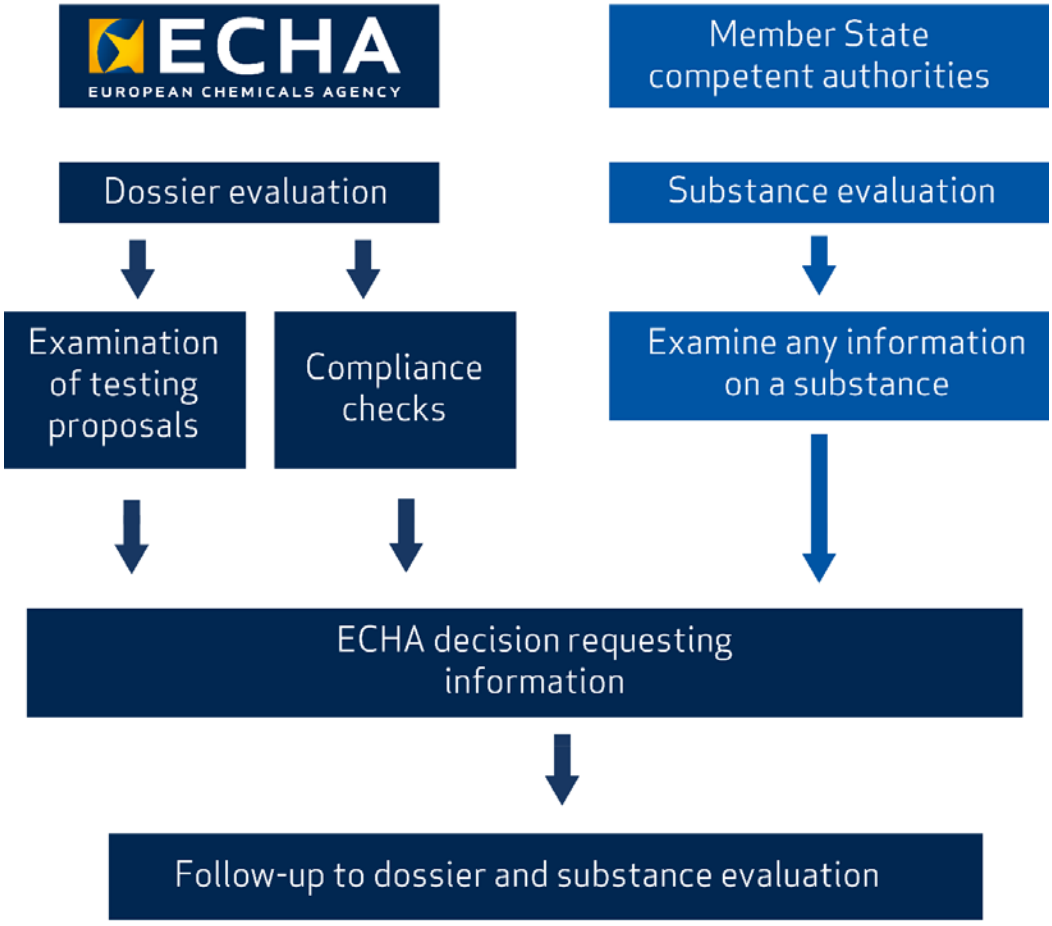


Figure 2. An overview of the ECHA evaluation processes.

[5] https://echa.europa.eu/regulations/reach/evaluation?panel=evaluation-reports#evaluation-reports
[6] http://echa.europa.eu/regulations/reach/evaluation

2.1. Summary of the evaluation progress in 2016 in numbers

The following is a summary of the evaluation progress according to the main outputs.

Dossier selection

After systematic screening for substances of potential concern in the REACH registration dossiers and other databases, almost 290 dossiers were scrutinised as candidates for compliance check and about 130 were selected for further processing, in addition to the dossiers which are planned to be subject to substance evaluation.

Dossier evaluation

184 compliance checks concluded, resulting in 168 new draft decisions. Of the 184 compliance checks concluded in 2016, 156 (85 %) were performed on the dossiers of high priority substances and involved the evaluation of over 1 200 higher tier human health and environment endpoints.

As an outcome of these evaluations, 805 standard information requests were made, 550 focusing of higher tier human health and environment endpoints. Other compliance check draft decisions were either targeted to substance identity or on substances not specifically shortlisted for high priority.

164 testing proposal examinations concluded. ECHA finished examining all the testing proposals originating from the 2013 by the 1 June 2016 legal deadline.

268 dossier evaluation decisions adopted. ECHA adopted 152 compliance check decisions and 116 decisions on testing proposals containing 860 standard information requests.

355 dossier evaluation follow-up evaluations were concluded. In dossier follow-up evaluations, ECHA examines whether the information provided by registrants, in response to decisions adopted by ECHA, complies with the REACH requirements.

Substance evaluation

Adoption of the 2016-2018 Community rolling action plan (CoRAP) update. The 2016-2018 CoRAP update was adopted on 22 March 2016, consisting of 138 substances, of which 39 substances were scheduled for evaluation in 2016.

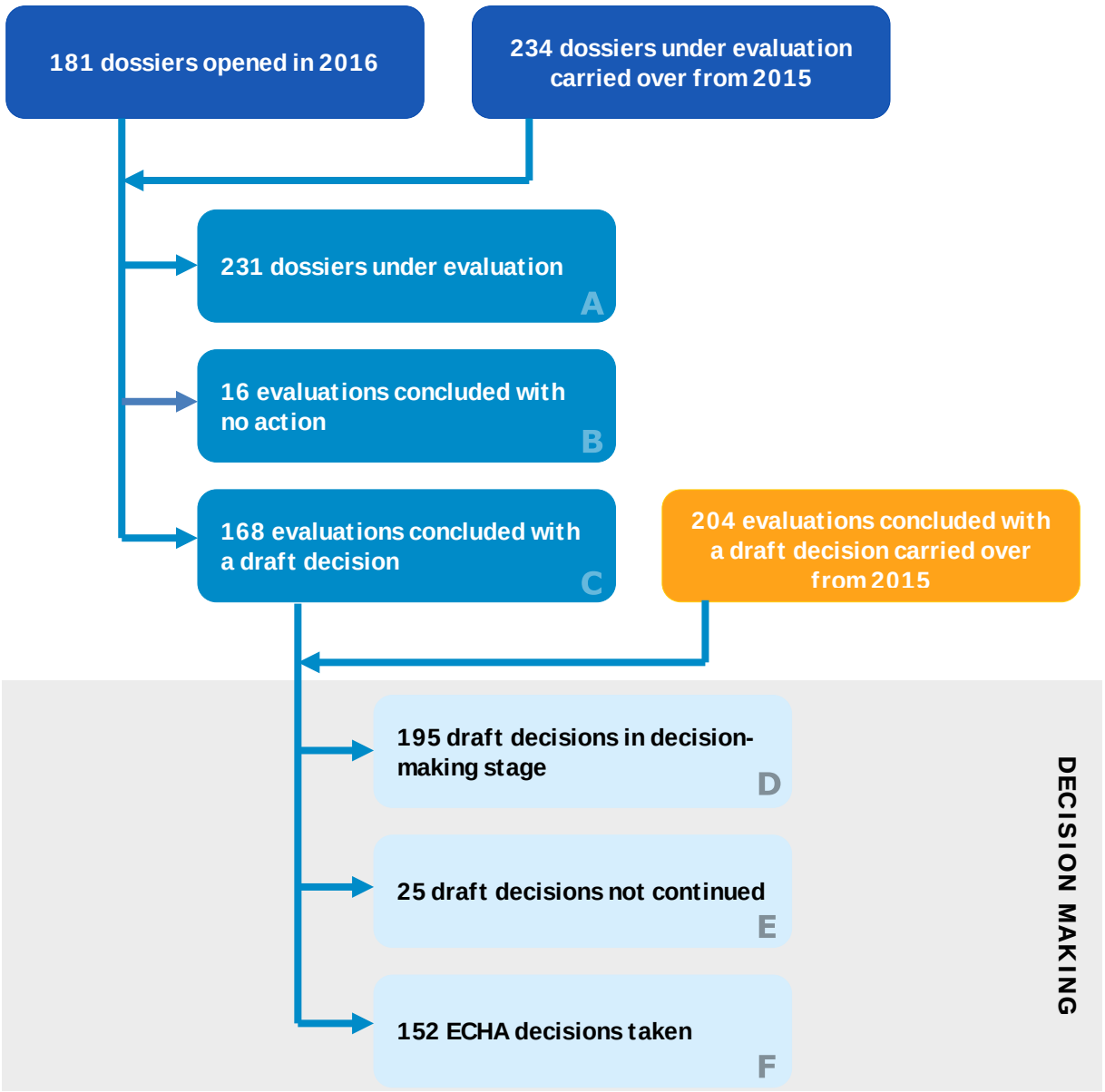
48 substance evaluations conducted in 2016. The evaluating Member State competent authorities (evaluating MSCAs) prepared draft decisions for 32 substances to require further information to clarify suspected concerns. For the remaining 14 substances, the evaluating MSCAs considered the available information was sufficient to conclude on the concerns.

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

20 substance evaluation conclusions published, completing the substance evaluation, 11 of them concluding that the risks are sufficiently controlled with existing measures, and 9 concluding that EU-wide risk management measures are necessary.

2.2. Compliance checks

Compliance check (CCH) determines whether the information submitted within a registration dossier is compliant with the requirements of the REACH Regulation. Figure 3 below highlights the overview of the compliance check evaluations during 2016.



[A] Scientific and legal evaluation stage.
[B] No formal action towards the registrant is deemed necessary.
[C] Formal action to request further information from the registrant is deemed necessary.
[D] 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).
[E] Scientifically-relevant data or important administrative changes lead to termination of the ongoing decision-making procedure.
[F] 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 3: Number and outcome of compliance checks in 2016.

Dossier selection and pre-processing

In line with the integrated regulatory strategy, ECHA's compliance check (CCH) focuses on standard registrations in the two highest tonnage bands (over 1 000 and 100-1 000 tonnes per year respectively).

Selection of new dossiers for compliance check is closely integrated with the other REACH and CLP processes, namely substance evaluation (SEV), harmonised classification and labelling, identification of substances of very high concern (SVHCs) and restriction.

Under the common screening process set up by ECHA together with Member States, all registered substances are screened, making full use of all REACH and CLP data and incorporating information from other regions and sources (including hazard prediction methods, structural similarities and work of regulatory bodies and assessment groups outside the EU).

Indications of potential exposure of workers, consumers or the environment due to wide dispersive uses and potential hazards of highest concern (CMRs, sensitisers, EDs, PBTs) are searched for.

In the manual verification of the IT-screening outcome, substances which are potential candidates for substance evaluation or regulatory risk management processes are prioritised for compliance check when standard information is missing from the related registration dossiers.

Candidates for compliance check are also selected from other sources. A large proportion of the cases (35 %) selected for concern-based compliance checks in 2016 (see Figure 4 for the breakdown of sources) were identified as candidates in the previous years during processing of testing proposals, evaluation of targeted compliance checks, follow-up evaluation of dossier evaluation or indicated as urgent candidates for evaluation by Member States.

Before opening a compliance check, ECHA pre-checks the dossier to ensure that the case is relevant and matches the priority criteria laid down in the integrated regulatory strategy. In 2016, almost 290 dossiers were scrutinised as candidates for compliance check and about 130 were selected for further processing, in addition to the dossiers which are planned to be subject to substance evaluation.

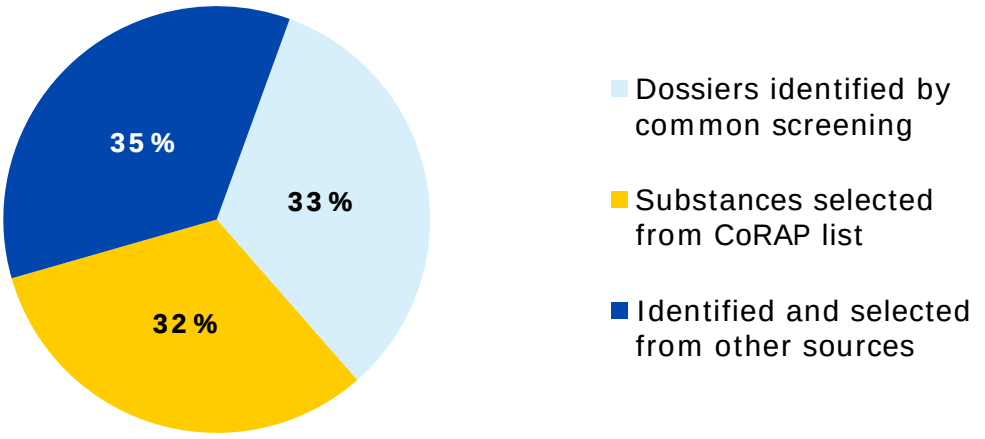


Figure 4: Breakdown of sources for the 156 concern-based compliance check selections in 2016.

Scientific and legal assessment

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 compliance check proceeds to the next phase of addressing REACH information requirements on physicochemical and hazard data in the technical dossier.

However, if the substance identity information is not clear enough for ECHA to meaningfully assess the rest of the dossier, ECHA will issue a substance identity-targeted compliance check decision (see Table 1). In the context of the evaluation process in 2016, substance identity issues were addressed in around 70 draft decisions, of which 21 are related to a compliance check targeted on substance identity.

Overall, ECHA checked a total of 184 dossiers[7] for compliance during 2016. In 91 % (168) of these[8], ECHA concluded that the non-compliances found were severe enough to require further action and generation of new information. This result merely reflects the effectiveness of the screening and selection of dossiers and cannot directly be used to assess the overall rate of compliance of all registration dossiers. For these dossiers, ECHA prepared draft decisions within the 12-month legal deadline of the start of the compliance check requiring registrants to submit the missing information.

In 9 % (16) of the cases[9], ECHA concluded that the generation of new information was not needed or requesting it was not proportionate and therefore no further action was required. Table 1 below summarises the compliance check conclusions during 2016.

Table 1: Compliance checks (CCH) concluded in 2016 with a draft decision or without action, by tonnage band. The lower tonnage evaluations were dossiers evaluated from the CoRAP list.

Tonnage band	Targeted CCH	Overall CCH		All
	Concluded with DD*	Concluded with DD	Concluded without action	Total
≥ 1 000 t/a	8	72	6	86
100 to 1 000 t/a	12	67	8	87
10 to 100 t/a	1	5	1	7
1 to 10 t/a	0	3	1	4
Total	21	147	16	184

*All the targeted compliance checks were concluded with a draft decision in 2016.

Focusing on the substances that matter most

The integrated regulatory strategy and common selection process of dossiers for compliance check is effectively addressing the dossiers and substances of concern. Since 2015, compliance checks have been focused on eight key standard information requirements of Annexes IX and X, which are outlined in the compliance check strategy. These are mutagenicity/genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

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

[7] B+C within Figure 3
[8] C within Figure 3
[9] B within Figure 3

Out of the 184 compliance checks, 156 (85%) were done on priority substances and 142 of these resulted in draft decisions. The number of compliance checks on priority substances was significantly (ca. 50 %) higher than in the previous year.

Overall in these draft decisions, ECHA made 805 requests, of which 550 were focused on the eight key standard information requirements of concern (see Table 2). The most common suspected concerns were addressed in the ECHA draft decisions with the following information requests: pre-natal developmental toxicity, mutagenicity/genotoxicity, reproduction toxicity, and long-term aquatic toxicity.

These results confirm that there are also important data gaps in the dossiers of substances of potential concern.

Table 2: Outcome on higher tier human health and environment endpoints in the overall compliance checks on cases concluded draft decisions issued in 2016.

Endpoint	CCH outcome	
	Concluded with draft decision	Concluded without action
Repeated-dose toxicity	63	84
Mutagenicity/genotoxicity	106	41
Pre-natal developmental toxicity	125	22
Reproduction toxicity*	88	59
Carcinogenicity	0	147
Long-term aquatic toxicity	79	68
Biodegradation	63	84
Bioaccumulation	26	121
Total	550	626

* 24 of these were requests for Annex VIII, 8.7.1 screening studies.

Decision making

In 2016, 84 % of the registrants used their right to comment on ECHA draft decisions. As part of the commenting process, registrants who received an ECHA compliance check draft decision are also offered the opportunity to informally discuss the scientific rationale behind the draft decision with ECHA during their 30-day commenting period.

After the draft decision is notified to them, the Member State competent authorities can submit their proposals for amendments (PfAs) to the ECHA decision. When PfAs are submitted, the Member State Committee seeks a unanimous agreement through a written procedure or in plenary meetings (for the latter, registrants can attend the open sessions). The registrant concerned is always invited to comment on the PfAs within 30 days and the Member State Committee takes those into account.

If the Member State Committee does not reach a unanimous agreement on the draft decision, the case is referred to the Commission for decision making.

During 2016, ECHA adopted 152 decisions[10] under compliance checks and closed 25 cases[11] after a draft decision. Two draft decisions were referred to the Commission for decision making in 2016, one as the Member State Committee did not reach an agreement on whether to accept adaptations to information requirements and another related to the design of the extended one-generation reproductive toxicity study. Table 3 summarises the ECHA decisions adopted during 2016.

[10] F within Figure 3
[11] E within Figure 3

Table 3: Compliance check (CCH) decisions adopted in 2016

Type	CCH decisions adopted		All ECHA adopted decisions
	Without proposals for amendment (PfAs)	Unanimous agreement in the MSC	Total
Targeted CCH	83 %	17 %	36
Overall CCH	44 %	56 %	116
Total	53 %	47 %	152

The number of compliance check draft decisions agreed by the Member State Committee through written procedure continued to be relatively high (53 %). Furthermore, registrants have continued to be active in the Committee phase by increased commenting on Member State competent authorities' proposals for amendments and participation in the Member State Committee plenary meetings.

Information requested in ECHA decisions

Figure 5 below provides a summary of the types of information requested in ECHA's 152 adopted compliance check decisions in 2016. Altogether, ECHA adopted decisions contained 597 standard information reguests.

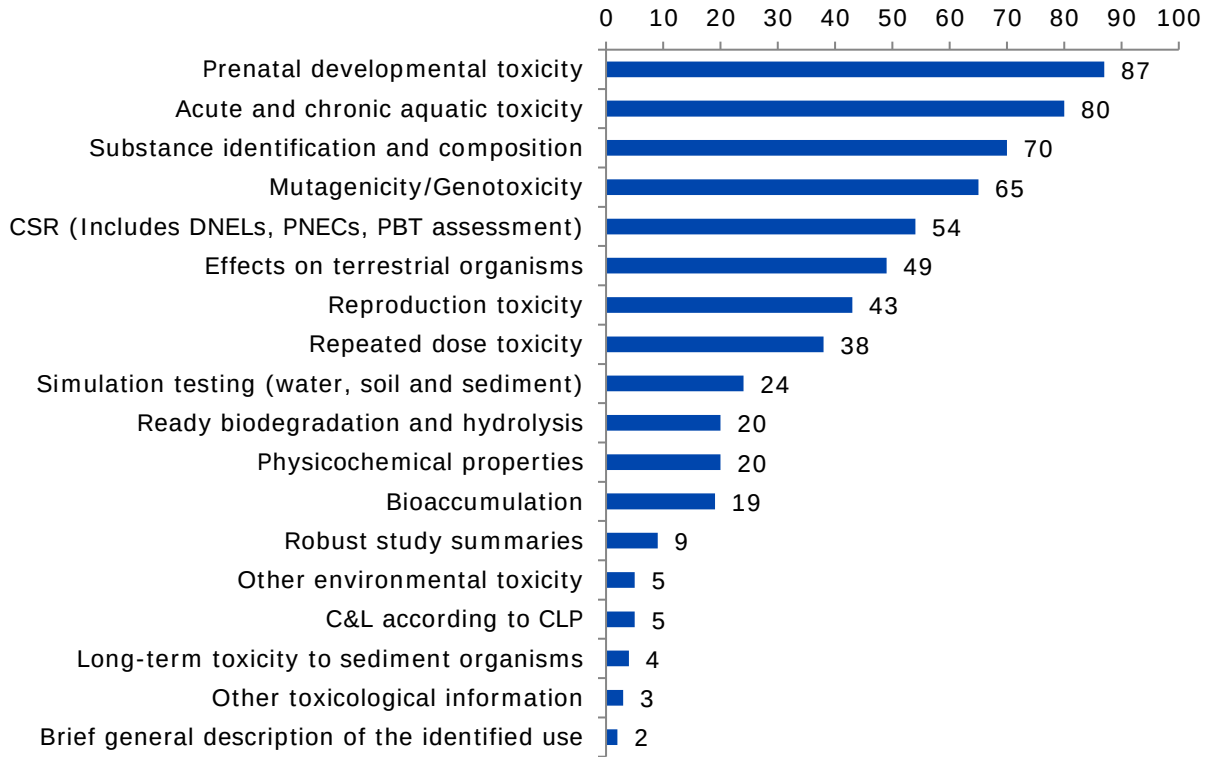


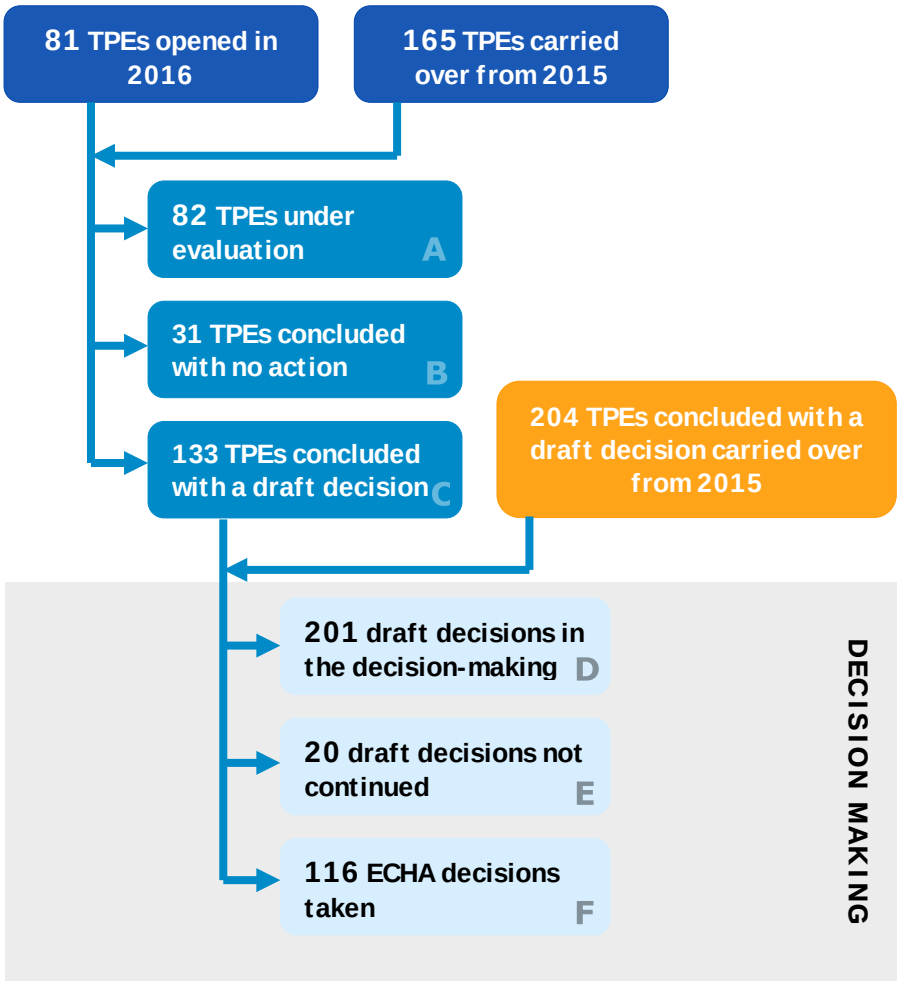
Figure 5: Information requested in the 152 adopted ECHA compliance check decisions taken in 2016.

2.3. 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.

ECHA prepares a draft decision on each valid testing proposal and can either accept, modify, request additional testing or reject the testing proposal. The legal text sets a deadline for ECHA to prepare a draft decision for certain types of testing proposals.

ECHA finalised the examination of all testing proposals from the 2013 registration deadline by 1 June 2016, as required by REACH, and prepared the remaining draft decisions. Figure 6 highlights the number and outcome of testing proposal examinations (TPEs) processed during 2016.



[A] Scientific and legal evaluation stage.
[B] Testing proposal is deemed inadmissible by ECHA or is withdrawn by the registrant.
[C] A draft decision on the proposed testing is deemed necessary.
[D] 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).
[E] Scientifically-relevant data or important administrative changes led to termination of the decision-making procedure.
[F] ECHA testing proposal 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 6: Number and outcome of TPEs processed during 2016.

Alternatives to animal testing

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 testing proposal to make sure that reliable and adequate data will be produced, and to prevent unnecessary animal testing. Since September 2015, registrants must include their considerations on alternatives to their proposed vertebrate animal testing.

ECHA publishes[12] every testing proposal that involves vertebrate animals. Furthermore, ECHA invites third parties to submit scientifically-valid information or studies addressing the substance and hazard endpoints in question that could be taken into account when ECHA evaluates and prepares its decision on the testing proposal.

The registrants' considerations on alternatives to their proposed vertebrate testing is published as part of the third party consultation or, if the dossiers were submitted after June 2016, in the testing proposal information inside the disseminated dossier.

During 2016, third party consultations were launched for 54 substances. As a response to these consultations, ECHA received only one contribution.

Scientific and legal assessment

ECHA concluded a total of 164 testing proposal examinations[13] during 2016. For 81 % (133) of these[14], ECHA sent draft decisions to the registrants, whilst in 19 % (31) of the cases[15], no further action was necessary because the registrant withdrew the proposal after ECHA started to examine it, or because the proposal was not admissible.

Table 4 lists the type of tests included in the TPE draft decisions submitted for registrants' comments. Altogether, 325 requests were included in the 133 draft testing proposal decisions that were sent to registrants during the past year.

[12] http://echa.europa.eu/information-on-chemicals/testing-proposals
[13] B+C within Figure 6
[14] C within Figure 6
[15] B within Figure 6

Table 4. List of requests made in the ECHA TPE draft decisions during 2016.

Endpoint	Total
Prenatal developmental toxicity (Annex IX, 8.7.2)	72
Sub-chronic toxicity study 90-day (Annex IX, 8.6.2)	60
Effects on soil micro-organisms (Annex IX, 9.4.2)	25
Long-term toxicity to invertebrates (Annex IX, 9.1.5)	20
Short-term toxicity to invertebrates (Annex IX, 9.4.1)	19
Short-term toxicity to plants (Annex IX, 9.4.3)	19
Pre-natal developmental toxicity study (Annex X, 8.7.2)	15
Long-term toxicity to fish (Annex IX, 9.1.6)	13
Extended one-generation reproductive toxicity study (Annex X, 8.7.3)	11
Growth inhibition study aquatic plants (Annex VII, 9.1.2)	9
Mutagenicity, in vivo (Annex IX, 8.4)	8
Two-generation reprotoxicity study/ EOGRTS (Annex IX, 8.7.3)	8
Long-term toxicity testing on invertebrates (Annex X, 9.4.4)	8
Short-term toxicity to invertebrates (Annex VII, 9.1.1)	6
Short-term toxicity testing on fish (Annex VIII, 9.1.3)	6
Long-term toxicity testing on plants (Annex X, 9.4.6)	4
Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2)	3
Soil simulation testing (Annex IX, 9.2.1.3)	3
Sediment simulation testing (Annex IX, 9.2.1.4)	3
Bioaccumulation in aquatic species, preferable fish (Annex IX, 9.3.2)	3
Viscosity (Annex IX, 7.17)	2
Identification of degradation products (Annex IX, 9.2.3)	2
Mutagenicity (Annex X, 8.4)	2
Testing proposal according to Annex VIII, 8.4, column 2	1
In vitro cytogenicity study in mammalian cells or micronucleus study (Annex VIII, 8.4.2)	1
Screening for adsorption/desorption (Annex VIII, 9.3.1)	1
Short-term repeated dose toxicity study (Annex IX, 8.6.1)	1
Total number of requests	**325**

Decision making

As with the compliance check process, registrants who receive an ECHA draft decision on testing proposals are given the opportunity to not only comment on the draft decision but also informally discuss the scientific rationale behind the draft decision with ECHA during their 30-day commenting period.

In 2016, 84 % of registrants used the possibility to have an informal communication with ECHA and/or commented on the ECHA draft decision.

After the draft decision is notified to them, the Member State competent authorities can submit their proposals for amendments (PfAs) to the ECHA decision. In 2016, 70 % of ECHA testing proposal draft decisions did not receive any PfAs and were adopted without

amendment. The 30 % of the draft decisions that received PfAs were all unanimously agreed by the MSC.

In 2016, ECHA adopted 116 decisions[16] under testing proposal examination and closed 20 cases[17] after draft decision. In the decision, ECHA can accept, modify, request additional testing or reject the testing proposal. Additional testing is requested if there is non-compliance of the testing proposal with Annexes IX, X and XI to the REACH Regulation and it can relate to either acceptance, modification or rejection of the original testing proposal. Table 5 below summarises the types of testing requested and the TPE decisions adopted during 2016. It is important to note that a decision may contain more than one request.

Table 5: Summary of ECHA TPE decisions adopted in 2016, by endpoint.

Endpoint	TPE adopted decisions				
	Accepted under Article 40(3)(a)	Modified under Article 40(3)(b)	Rejected under Article 40(3)(d)	Additional testing requested under Article 40(3)(c)	Total number of requests evaluated
Pre-natal developmental toxicity	71	3	6	12	92
Sub-chronic 90 day toxicity	42	7	5	8	62
Mutagenicity/genotoxicity	5	3	4	4	16
Extended-one generation study	2	1	1	1	5
Long-term aquatic toxicity	24		4	12	40
Effects on terrestrial organisms	13		7	25	45
Bioaccumulation in aquatic species	2	1	3	3	9
Long-term toxicity to sediment organisms	2		2	2	6
Simulation tests (water, soil, sediment)	2		2	4	8
Identification of degradation products				3	3
Other aquatic toxicity				4	4
Viscosity	4				4
Total	167	15	34	78	294

[16] F within Figure 6
[17] E within Figure 6

Information requested

A total of 260 requests were made in the 116 testing proposal decisions adopted in 2016. Figure 7 provides a summary of the information requested.

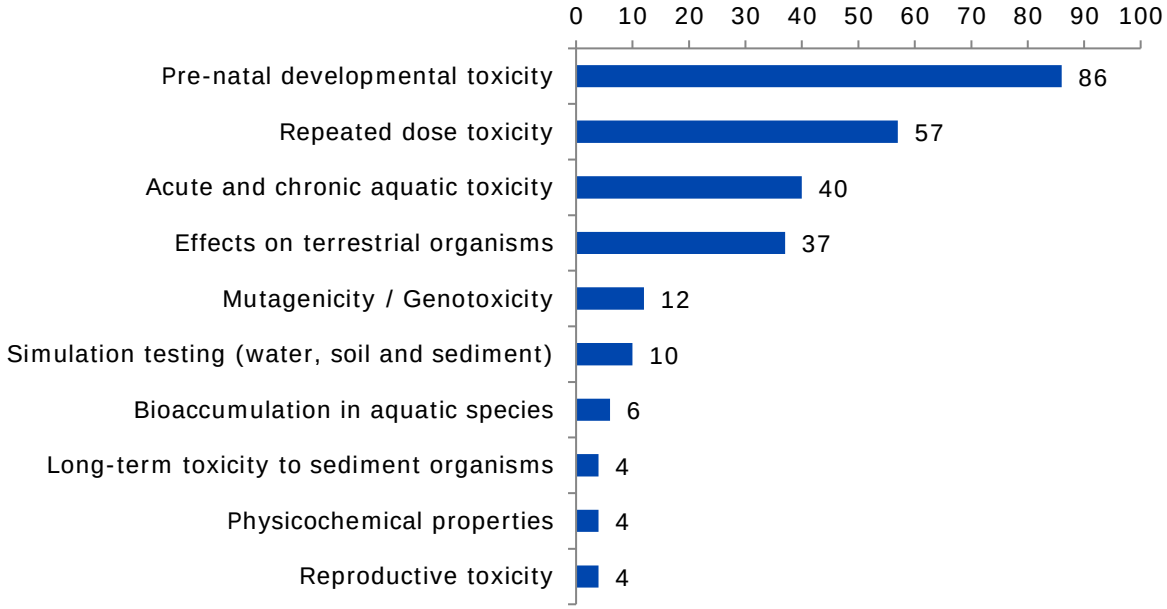


Figure 7: Types of information requested in 116 testing proposal decisions adopted in 2016.

2.4. Follow-up evaluation of dossier evaluation

Under Article 42 of REACH, ECHA examines the information provided by 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[18].

As in previous years, ECHA continued providing enforcement authorities with the statements of non-compliance (SONCs) following a dossier evaluation decision whensome or all of the requests in a dossier evaluation decision were not complied with. However, a new consultation as per Articles 50 and 51 of REACH may be initiated in specific cases where a registrant submits – in response to a decision – information which is substantial and new but still not sufficient to meet the initial request. This new element has been added to the process in response to the issues raised by the Board of Appeal decision in Case 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. This resulted in the finalisation of the interlinks guide addressed to the national enforcement authorities (NEAs).

In general, the collaboration between ECHA and the Member State competent authorities and national enforcement authorities has worked well and the majority of cases has been resolved within a reasonable time.

[18] https://echa.europa.eu/publications/fact-sheets

In 2016, ECHA concluded on an outcome in 355 follow-up evaluations, which are summarised in Table 6. A multi-annual milestone of 1 000 completed follow-up evaluation cases was reached in December 2016.

ECHA issued 33 SONCs and was able to close 37 SONCs with an Article 42(2) notification following a dossier update by the registrants after the national enforcement authorities had been involved in the cases. At the end of 2016, there were 65 unresolved SONCs that had been notified to the Member States authorities since 2012.

Table 6. Number and outcome of the follow-up evaluations conducted in 2016.

Decision Type	Outcome			
	Article 42(2) without SONC[19]	Article 42(2) after SONC[20]	SONC[21]	New CCH/TPE based on Article 42(1)[22]
TPE decisions	103	15	17	2
CCH decisions	179	22	16	1
Total	282	37	33	3

Table 7 provides a summary of the outcome of the follow-up evaluations, performed in 2016, for each endpoint/group of endpoints. It is important to note that a follow-up evaluation outcome may contain both compliant and non-compliant endpoints.

Table 7. Number and outcome of the follow-up evaluations conducted in 2016, by endpoint.

Endpoint	Outcome		
	Fully compliant	Compliant with deviations*	Non-compliant
Substance identity	90	53	4
Physical/chemical properties	23	12	3
Biodegradation	15	1	1
Bioaccumulation	0	0	1
Other environmental fate/behaviour	3	2	1
Long-term aquatic toxicity	20	9	1
Other ecotoxicological hazard	6	2	4
Mutagenicity/genotoxicity	30	15	4
Carcinogenicity	0	0	2
Repeated dose toxicity	42	8	7
Pre-natal developmental toxicity	64	35	14
Reproduction toxicity	1	1	0
Other human health hazard	3	2	0
CSR	67	61	5
Total	364	201	47

*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.

[19] All requests in the decision were complied with, without a SONC being issued.

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

[21] 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.

[22] A new draft decision under Article 42(1) was issued if a registrant provided new and substantial information, but this information was not found to be compliant.

The outcome of the 2016 follow-up evaluations shows that 92 % (565) of the endpoints originally identified (by compliance checks or submission of a testing proposal) as non-compliant with the REACH information requirements are now deemed compliant as a consequence of dossier evaluation. For the remaining 8 % (47) of endpoints deemed non-compliant, ECHA sent a SONC for 42 non-compliant endpoints to the Member State authorities for consideration of enforcement actions, and for 5 non-compliant endpoints, ECHA launched a new decision-making process according to Article 42(1).

The information received through the dossier evaluation processes is screened to identify any cases where further regulatory actions may be needed. The number of such substances is expected to increase in the future due to the adopted regulatory strategy to address substances and dossiers with a potential concern. However, as the regulatory strategy to focus on selected key endpoints was adopted in 2015, the first such cases will reach the follow-up stage only towards the end of 2017.

2.5. Substance evaluation

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

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

The evaluation may conclude that the risks are sufficiently under control with the measures already in place. Otherwise, it may lead to the proposal of EU-wide risk management measures, such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.

From the date of publication of the Community rolling action plan (CoRAP) list, the evaluating Member State competent authority has, for those substances to be evaluated in the first year[23], 12 months to conclude whether further information must be requested from the registrants to clarify the concerns. The information requested usually goes beyond the standard information requirements of REACH and may relate to the intrinsic properties of the substance or its exposure.

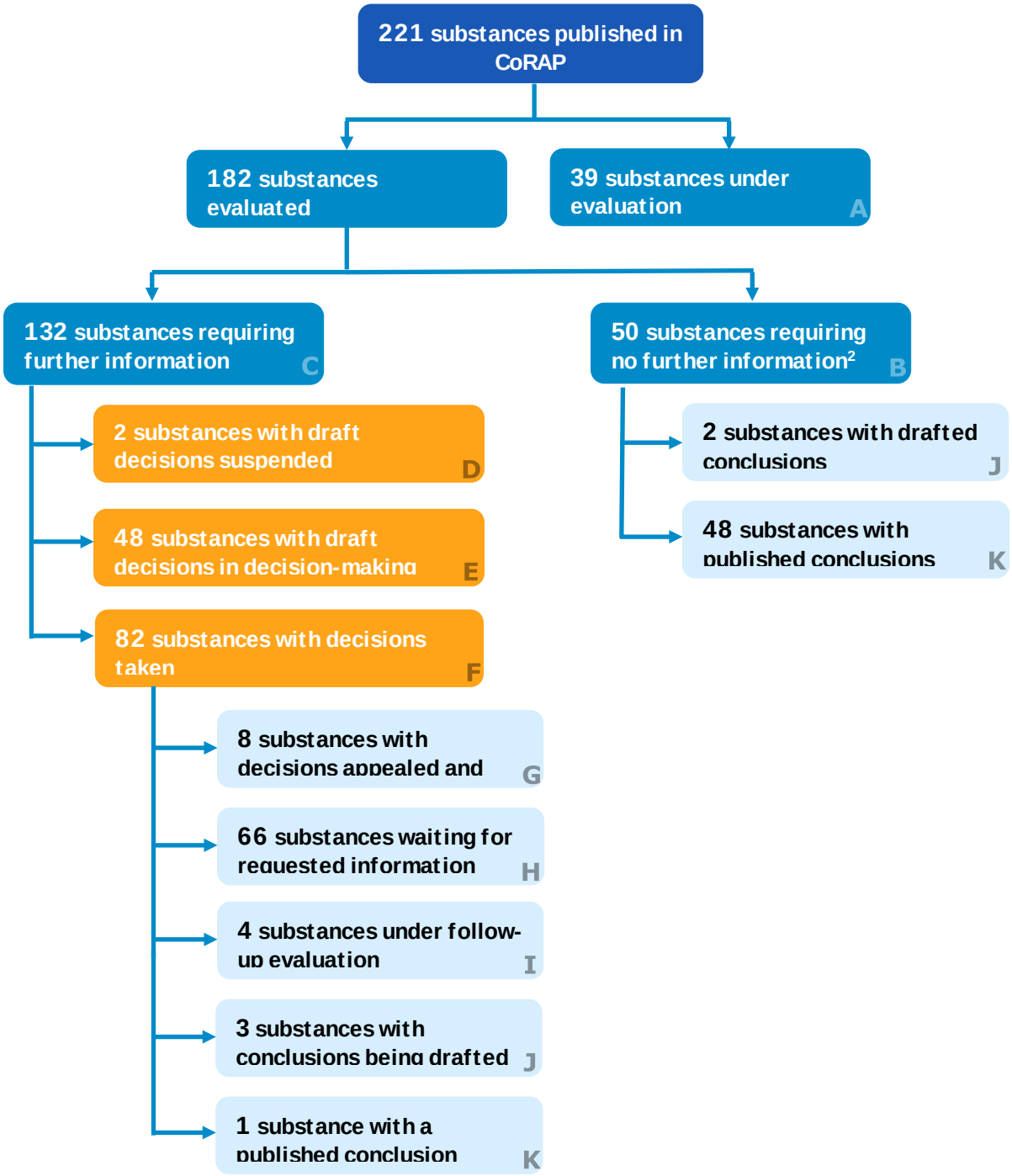
The view that further information is needed, is shared with all the other Member States and ECHA to achieve a general agreement. ECHA takes the decision to request further information, whenever necessary.

Further information on substance evaluation is provided on ECHA's website[24].

Figure 8 provides an overview of the current status of the 221 substances published within the CoRAP for evaluation between 2012-2016.

[23] The CoRAP covers 3 years, and its rolling nature means that the list of prioritised substances included for evaluation during the second and the third year may change when the updated CoRAP is annually published. In the update of the previous CoRAP, the second year's list becomes the list of the first year and a new list of substances for the third year is added.

[24] https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation



[A] Substance is currently being evaluated by the Member State competent authority (MSCA).
[B] Evaluating MSCA can conclude on the suspected risk based on the available information.
[C] A draft decision requesting further information to clarify the concern(s) is deemed necessary.
[D] Substance evaluation is suspended (i.e. no draft decision prepared) pending the outcome of a compliance check that must be performed first.
[E] Stages of processing the draft decision.
[F] ECHA evaluation decision taken.
[G] Decisions appealed before the Board of Appeal of ECHA.
[H] Registrants to submit the requested information, within the timelines specified in the decision.
[I] The evaluating MSCA will examine all new information in the updated registration.
[J] Conclusion documents are drafted and being prepared for publication.
[K] Conclusion documents are published on ECHA's web pages.

Figure 8: Status of all substance evaluations started in 2012-2016 at the end of 2016.

Selection and prioritisation of substances for evaluation

Article 44(1) of REACH provides general criteria for selecting substances for substance evaluation. In cooperation with the Member States, ECHA has refined the risk-based criteria[25], before applying them to identify substances with potential concerns. The selection of substances originates from the common screening at the basis of the integrated regulatory strategy. Such substances are screened to see whether they should already be subject to regulatory measures; if not, whether substance evaluation would be effective to clarify the concerns.

Subsequently, 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 CoRAP is adopted after consultation among the Member States and the opinion of ECHA's Member State Committee.

The CoRAP 2016–2018 update[26] was adopted on 22 March 2016 and contained 138 substances. The list contained 54 newly-selected substances and 84 substances carried over from the existing CoRAP.

ECHA forwarded the draft of the subsequent CoRAP update 2017-2019 to the Member State Committee for opinion seeking on 13 October 2016, and published the draft on 27 October 2016[27]. The draft list contained 117 substances, with 24 substances planned to be evaluated in 2017. The list contained 22 newly-selected substances and 95 substances carried over from the existing CoRAP. Depending on the opinion of the Committee, the number and order of substances may change before the list is adopted. ECHA anticipates the adoption of the CoRAP 2017–2019 update in March 2017. Further information on the CoRAP is provided on ECHA's web pages[28].

To further enhance the effectiveness and efficiency of substance evaluation, ECHA normally performs a compliance check before a substance is evaluated under substance evaluation.

These compliance checks support substance evaluation by ensuring that key information requirements for human health and the environment are adequately fulfilled. The interplay between compliance checks and substance evaluation is defined case-by-case to prevent the substance evaluation process being postponed, and consequent delays in identifying regulatory risk management.

Whenever possible, a compliance check is performed before substance evaluation begins. This approach is in line with the Board of Appeal finding 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[29]). However, there are situations where the performance of compliance check and substance evaluation processes in parallel is feasible and is the preferred fastest route.

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[25] http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf
[26] https://echa.europa.eu/documents/10162/13628/corap_list_2016-2018_en.pdf/7fe9642e-3d45-4b9b-89e8-afffcef9120f
[27] https://echa.europa.eu/documents/10162/13628/corap_list_2017-2019_en.pdf/c2ea7854-606f-448f-9072-42ce2437dcd7
[28] https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan
[29] http://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

During preparation of the draft 2017-2019 CoRAP, it was apparent that for many of the candidate substances, further information related to the standard information requirements would be needed before substance evaluation. Thus, it was considered that some evaluations previously planned in the CoRAP, would have to be postponed in order to perform a compliance check first.

Consequently, a significantly reduced number of substances were allocated for substance evaluation in 2017 (24 instead of the anticipated number close to 50). After obtaining the information from the compliance check, it remains to be seen if there are still remaining concerns for those substances that need to be clarified under substance evaluation.

ECHA and Member State competent authorities maintain close collaboration and communication to ensure that the most appropriate route is taken to address the concerns.

Evaluation by Member State competent authorities

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 initial reason for selecting a substance for the CoRAP is not limiting the scope of the evaluation.

In 2016, the Board of Appeal reiterated the view that dossier evaluation should normally be conducted before substance evaluation[30]. As already held in previous decisions[31], ECHA must establish the necessity of a request for additional information by setting out the grounds for considering that a substance constitutes a risk to human health or the environment. ECHA must be able to show that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures.

The Board of Appeal also confirmed its earlier findings that requests cannot be solely based on data gaps since the latter are not evidence of a potential risk[32]. However, it clarified that concerns may be based on properties of structurally similar substances. For establishing such a similarity, no full read-across assessment is necessary.

During the evaluation, the Member State may identify other concerns that need clarification to conclude whether a substance is of concern or not. However, the Member State can focus the evaluation more on specific concerns raised about the substance.

Of the 48 substances allocated for evaluation during 2015, the evaluating Member State competent authority considered that 32 (67 %) of these required further information to clarify the suspected concerns. For 14 of the substances evaluated during 2015, the evaluating Member State competent authorities considered the available information as sufficient to conclude on the concerns and submitted their conclusion documents to ECHA.

[30] Decision of 12 July 2016 in Case A-009-2014, *Albermarle Europe Sprl a.o.*, paragraph 71.
[31] Decision of 27 October 2015 in Case A-006-2014, *International Flavors & Fragrances*, paragraph 76; Decision of 23 September 2015 in Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH a.o.*, paragraphs 59-60.
[32] See references above.

For the remaining two substances evaluated during 2015, it was considered that a compliance check of the relevant tonnage bands was required before the substance evaluation could proceed. Thus, the substance evaluation process, for making a request for possible further information to clarify the suspected concern(s), was suspended pending the outcome of ongoing compliance checks.

As soon as the information on the standard requirements is available in the dossier updates, the evaluating Member State competent authority will consider this under their continued substance evaluation, and indeed whether some other additional information would still be necessary to clarify the remaining concerns regarding those substances.

Furthermore, the evaluating Member State competent authorities started their evaluations of the 39 substances allocated for evaluation in 2016 and finalisation of all draft decisions generated as a result of this evaluation work, will be performed in early 2017.

During 2016, ECHA implemented a more structured approach for interaction with the evaluating Members State competent authorities during the 12-month evaluation period. The aim of this interaction between ECHA and the evaluating Member State competent authorities is to:

- Provide further support to evaluating Member State competent authorities in considering the best approaches to clarify the concern and any risk management measures;
- Monitor the progress of the evaluation more closely;
- Provide advice and support related to consistency, and ensure more scientifically-robust decisions.

Decision making

In 2016, ECHA sent draft decisions for commenting to 400 registrants of the 32 substances evaluated during 2015, where the evaluating Member State competent authorities considered further information was needed to clarify the suspected concerns. To date, nearly all consulted draft decisions under substance evaluation have received proposals for amendment.

When Member State competent authorities or ECHA submit proposals for amendment, the Member State Committee seeks a unanimous agreement through a written procedure or in plenary meetings. For the latter, the registrants can attend the open sessions. The number of decisions agreed through written procedure is still increasing. During 2016, the Committee agreed on 33 draft decisions for 31 substances, of which 17 (52 %) were agreed in written procedure.

If the Member State Committee does not reach a unanimous agreement, the case is referred to the Commission. To date, only one decision under substance evaluation has been referred to the Commission following no unanimous agreement being reached at the Committee. This decision was referred to the Commission in 2014, who subsequently adopted the decision[33] in 2015.

To further improve the quality of the decisions and ensure a smooth decision-making phase, ECHA started offering enhanced support to evaluating Member State competent authorities during decision making, which includes extra checks and recommendations in drafting decisions. Based on the positive results of pilot cases, the support will be continued in 2017.

[33] https://echa.europa.eu/documents/10162/e23a2e0e-d456-48f0-9d24-2fb4bbf49dca

Information requested

During 2016, ECHA took decisions on 26 of the substances evaluated. Non-confidential versions of 24 of these decisions have been published on ECHA's website and links to them have been included in the dynamic CoRAP list[34]. Non-confidential versions of the remaining two decisions will be published in due course.

Table 8 summarises the information requested to clarify hazard-based concerns, within the decisions taken during 2016. A decision may contain more than one request.

Table 8: Information requests to clarify hazard-based concerns, within decisions taken during 2016.

Suspected Concern	Types of information requested to clarify the concern	Total requests†
PBT/vPvB	Simulation biodegradation test	11
	Physicochemical test	7
	Fish, early-life stage toxicity test	3
	Analytical information on composition	3
	Freshwater Alga and Cyanobacteria, growth inhibition test	2
	Daphnia magna reproduction test	2
	Bioaccumulation in Fish: aqueous and dietary exposure test	2
	Update/revision of PBT assessment	2
	Ready biodegradability - CO_2 in sealed vessels (Headspace Test)	1
Reproductive toxicity	Extended one-generation reproductive toxicity study	1
Mutagenicity	*In vivo* Mammalian alkaline Comet assay	6
	In vitro Mammalian cell gene mutation test	5
	Bacterial reverse mutation test	3
	Mammalian erythrocyte micronucleus test	1
	Mammalian spermatogonial chromosomal aberration test	1
	In vitro Mammalian cell micronucleus test	1
	Transgenic rodent somatic and germ cell gene mutation assay	1
Endocrine disruption	Fish sexual development test	2
	Medaka extended one generation reproduction test	1
	Zebrafish extended one generation reprodution test	1
	Toxicokinetics	1
	Extended one-generation reproductive toxicity study	1
	H295R Steroidogenesis assay	1
	Stably transfected human androgen receptor transcriptional activation assay	1
	Androgen receptor binding assay	1
Sensitisation	Further information on existing data	4
	Skin sensitisation local lymph node assay	1

[34] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Suspected Concern	Types of information requested to clarify the concern	Total requests†
Other hazard-based concerns	Physicochemical test	9
	Repeated dose 90-day oral toxicity study in rodents	2
	Analytical information on composition	1
	Freshwater Alga and Cyanobacteria, growth inhibition iest	1
	Fish, acute toxicity test	1
	Daphnia magna reproduction test	1
	Soil Microorganisms: nitrogen transformation test	1
	Bioaccumulation in Fish: aqueous and dietary exposure	1
	Neurotoxicity study in rodents	1
	Total	**84**

† For many decisions, an integrated testing strategy (ITS) may be used.

Additionally, in 14 of 26 decisions taken by ECHA in 2016, the evaluating Member States considered that further information on exposure and/or risk assessment was necessary to clarify the concern(s). Examples of some of the exposure-based information requests included within the decisions taken during 2016, are:

- Information on operational conditions, exposure estimations and risk characterisation for exposure scenarios;
- Further information on personal protection equipment;
- Site-specific monitoring data;
- Justification for deviation in the use of default values in DNEL/PNEC derivation.

Follow-up evaluation of substance evaluation decisions

Upon receipt of a dossier update containing all information requested in the decision, the evaluating Member State competent authority has 12 months to complete the assessment of the substance.

Once this assessment is complete, the evaluating Member State 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 2016, 24 substances were at the stage where new information should have been submitted following an initial request for further information. The responsible evaluating Member State competent authorities are currently reviewing the newly submitted information to conclude on its suitability. For 4 substances, the evaluating Member State concluded in 2016 that the newly submitted information was suitable, and the 12-month assessment of the submitted information is ongoing.

ECHA Secretariat and the Forum, through its Working Group ‘Interlinks’ continued to work on a process for future potential enforcement of substance evaluation decisions.

The process has been adapted to align with the approach on dossier evaluation decisions and then finalised and included in the Interlinks Guide for national enforcement authorities. Thus far, there have been no cases yet where national enforcement authorities needed to enforce a substance evaluation decision.

Concluding substance evaluation

Following a review of the available and new data (where relevant), if the evaluating Member State concludes 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, e.g. a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

During 2016, 20 conclusion documents originating from substance evaluations performed in 2012–2015 were published within the dynamic CoRAP list[35] on ECHA's website. In 9 of the 20 concluded cases published, the evaluating Member State competent authority concluded that further EU-wide regulatory action is needed.

Table 9 summarises the hazard-based concerns concluded during 2016 and their outcomes. A substance may have more than one concern. Regulatory follow-up actions are not needed if the hazard concern is removed or no risk is anticipated due to changes of circumstances, like new risk management measures being in place, cease of certain uses or import/manufacture.

[35] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Table 9: Hazard-based concerns concluded during 2016 and their outcomes.

Suspected Concern	Concluded regulatory follow-up action at EU level	Total Conclusions	Concluded Substances by EC/List number
Carcinogenicity	No regulatory follow-up action needed	5	203-398-6 231-511-9 232-235-1 203-872-2 219-514-3
Mutagenicity	No regulatory follow-up action needed	2	203-872-2 219-514-3
Reprotoxicity	Concern not clarified*	1	204-278-6
	No regulatory follow-up action needed	5	203-079-1 229-912-9 217-175-6 202-804-9 219-514-3
	Harmonised classification and labelling	1	627-083-1
PBT/vPvB	Concern not clarified*	5	627-083-1 700-427-9 204-278-6 404-800-4 428-970-4
	No regulatory follow-up action needed	3	219-514-3 906-484-8 405-490-3
Endocrine disruption	Concern not clarified*	2	204-278-6 428-970-4
	No regulatory follow-up action needed	3	203-398-6 217-175-6 202-804-9
	Identification as a SVHC (Authorisation)	3	231-511-6 232-235-1 627-083-1
Sensitiser	Other EU-wide regulatory risk management measure(s)	2	203-376-6 226-394-6
	Harmonised classification and labelling	3	232-565-6 219-514-3 629-732-4
Other hazard-based concern	Concern not clarified*	2	700-427-9 204-278-6
	No regulatory follow-up action needed	5	231-511-9 232-235-1 202-804-9 203-872-2
	Harmonised classification and labelling	2	405-490-3 629-732-4

* For four substances, substance evaluation was terminated following the cease of manufacture by the relevant registrants. Consequently, the evaluating MSCAs concluded that the concern could not be presently clarified and a new assessment should be undertaken in the event of new registrations of the substance in the future. For one substance, the evaluating MSCA will conclude on the PBT concern after the ongoing substance evaluation of a constituent of concern has been concluded.

More information on the conclusion of concerns for PBT/vPvB, potential endocrine disruption, carcinogenicity, mutagenicity, and reproductive toxicity under substance evaluation is available within the annual reports for SVHC identification and implementation of REACH risk management measures[36].

[36] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

3. Other measures to enhance dossier quality

In line with the integrated regulatory strategy, ECHA applies also other measures than compliance check and formal decisions to improve the dossier quality. Some of them (3.1 and 3.2 below) are directly related to the registration process, others are additional, non-regulatory measures (3.3, 3.4, 3.7) that aim to trigger registrants to update and improve their dossier before evaluation processes start. ECHA has also repeatedly called registrants to spontaneously update their dossiers.

To analyse the effectiveness of these measures, ECHA monitors the dossier updates and the reasons given. During 2016, ECHA received just over 5 600 spontaneous updates on registration dossiers, an increase of 30 % compared to 2015. Based on the update reasons indicated by the registrants, ECHA's other measures have clearly been a major driver in this substantial increase. For example, of the 270 substances within the scope of the 2016 shortlist (see 3.4), 40 % were updated within four months of the letters being sent.

3.1. One substance, one registration

Correct application of the registration and data-sharing rules is the basis for the REACH system. In 2016, several new measures were put in place to reinforce their correct implementation.

On 26 January 2016, the Commission Implementing Regulation on joint submission of data and data-sharing entered into force. This regulation clarified that ECHA needs to ensure that the “one substance, one registration” (OSOR) principle is applied, whereby registrants of the same substance have to register the substance jointly.

Subsequently, ECHA updated the joint submission module in version 3 of REACH-IT to implement the OSOR principle and better assist registrants to find the existing joint submission, lead registrant and co-registrants for their substances. Since 26 January 2016, it is no longer possible to submit an individual registration for a substance where a joint submission exists.

These changes to REACH-IT prevent companies from registering individually, without participating in substance identity discussions and data sharing with the other registrants of the substance.

In addition, lead registrants now also have to indicate in REACH-IT whether they agree that their company name is published as the lead registrant for the substance on ECHA’s website. ECHA started to publish the list of lead registrants in September 2016. By the end of 2016, 31 % of lead registrants had accepted publication of their company name and this number is increasing.

Upholding the ‘one substance, one registration’ principle

Some 700 existing registrations are still in breach of the joint submission obligation.

During 2016, letters were sent to 157 of these individual registrants, to require them to either join the joint submission or to submit a data-sharing dispute if no agreement can be reached. Their deadline to comply is six months, and if they do not take action, their registration decision will be revoked. By the end of 2017, all priority cases (full registrations of phase-in substances) should be addressed.

Lead registrants not chosen by the SIEF members

In view of the implementation of the OSOR principle in REACH-IT, ECHA had been informed that a number of dossiers (54) have recently been submitted as placeholder dossiers with the intention to occupy the lead registrant role without agreement of the SIEF and the appropriate data-sharing discucssions.

To address these cases, ECHA contacted all the companies that had pre-registered the substances in question, and invited them to provide evidence on the election of the lead registrant. In the cases where there is no evidence that the registrant who submitted the lead dossier was elected as lead by the SIEF, ECHA will reassign the lead role to the agreed lead registrant.

3.2. Enhanced completeness check

ECHA checks the completeness of the registration dossiers systematically at the submission phase. To foster the availability of key information in the dossiers, and in accordance with the decision taken by the Management Board[37], ECHA implemented several new measures in 2016 to ensure that submissions contain all the information foreseen by REACH.

After the development work and stakeholder consultations in 2014-2016, ECHA revised the IUCLID data formats and the completeness check implementation to be able to better ensure that all the required elements are provided in a registration dossier and that the information submitted is relevant within the context of the REACH Regulation.

The enhanced completeness check entered into force on 21 June 2016. It applies equally to new registrations and updates of registrations previously submitted. The updated completeness check also includes additional manual verifications by ECHA staff[38] to ensure that when registrants waive or deviate from the information requirements they provide justifications foreseen by REACH, and that testing proposals on vertebrate animals are accompanied by considerations for why none of the adaptation possibilities under REACH could be used. The manual checks aim to establish a level playing field between registrants who follow the standard information requirements set out in REACH, and those who waive or deviate from these requirements, by ensuring that the latter provide justifications with a regulatory relevance.

Since the entry into force of the enhanced completeness check until the end of 2016, 1 297 dossiers (ca. 33 % of the incoming registration dossiers) were stopped for manual verification by ECHA staff, corresponding to 1 123 registrations. In 20 % of the verified dossiers, registrants were requested to improve the submitted information. In 95 % of these cases, registrants were able to amend the dossiers as requested, and the submissions passed the completeness check at the second attempt.

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[37] 36th MB meeting, 16-17 December 2014, Rome
AP 11: Substance identification in registration dossiers – a strategy for improvement (including completeness check); (MB/53/2014)
https://echa.europa.eu/documents/10162/13608/mb_m_04_2014_minutes_mb_36_en.pdf/9e7bff2a-ba57-4af4-86ef-783dd685d80e; 38th MB meeting, 17-18 June 2015, Helsinki
AP 11: Improved substance identity check as part of the Technical completeness check process; (MB/26/2015)
https://echa.europa.eu/documents/10162/21844190/mb_m_02_2015_minutes_mb_38_en.pdf/af58238e-c948-4de9-aba1-c8c644888e0c

[38] For information about the areas of manual verification by ECHA staff, refer to:
https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf

Figure 9 shows the areas in which the registration dossiers were incomplete upon manual verification at the first attempt.

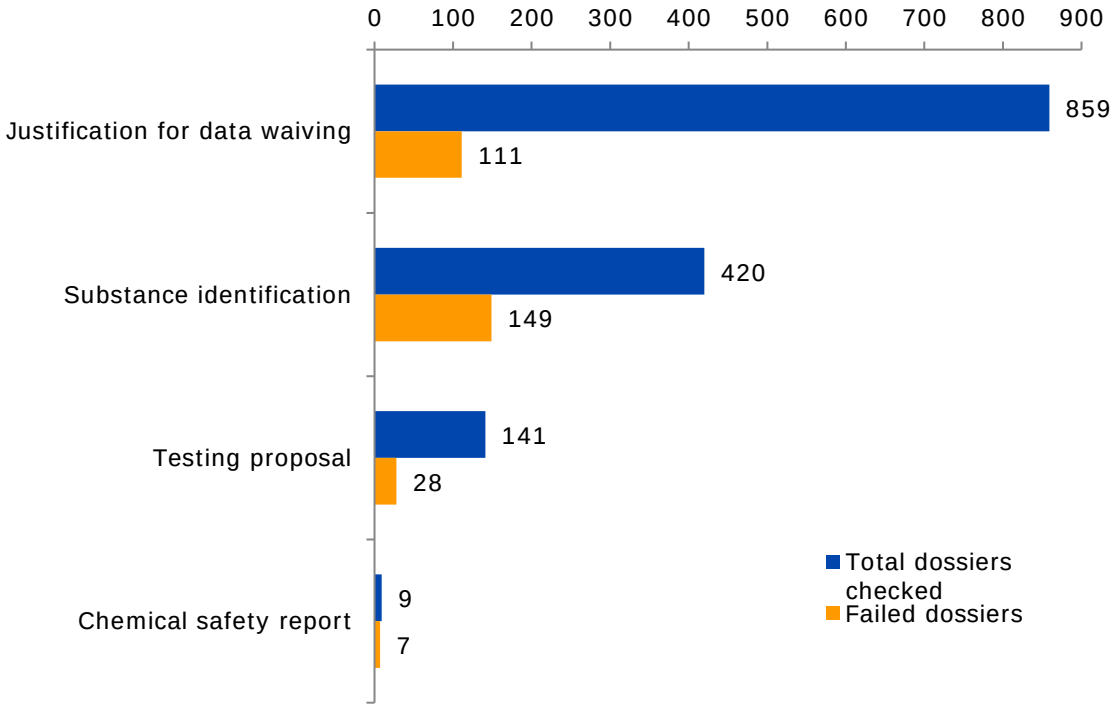

Figure 9. Types of information requested for the 267 dossiers that failed the completeness check upon manual verification by ECHA staff at the first attempt (orange). Note that one dossier may fail in one or several areas. The total number of dossiers checked are shown as blue bars.

A systematic impact analysis of the enhanced completeness check will be undertaken in 2017. However, preliminary results indicate that the manual checks done by ECHA staff have brought improvements to registration dossiers also in a broader context. In substance identification, the manual checks have led to improved manufacturing process descriptions and compositional breakdown of UVCB substances, which in turn have resulted in a clearer substance identity. For well-defined substances, the verification of deviations from the rules on naming and identification of such substances has also brought some registrants to reconsider the substance type they are registering.

The manual checks on data waivers ensure the justifications either match the provisions by Column 2 of REACH Annexes XII-X, or by Annex XI. In most cases, registrants have refined their justifications to bring them into the context of REACH. Some registrants have also decided to replace the data -waiving adaptation by study summaries on the registered substance, or by a read-across approach. The checks on justifications for omitting the chemical safety report have mostly prompted registrants to improve their reasoning in line with Article 14(2) of REACH; in some cases, the chemical safety report has ultimately been submitted.

Retroactive completeness check of existing registrations

In parallel with the entry into force of the enhanced completeness check of incoming dossiers, ECHA started to retrospectively verify the completeness of previously submitted dossiers in the database, focusing in 2016 on data waivers for hazard data that were not substantiated by justifications foreseen by REACH.

This activity targets registrations that are rarely updated and would therefore not be subject to the enhanced completeness check applied to incoming dossiers. The initiative was supported by the outcome of appeal Case A-022-2013[39], where the Board of Appeal concluded that ECHA can undertake a fresh completeness check on registrations submitted in the past.

In July 2016, ECHA sent letters to registrants to inform them that 24 lead or individual dossiers were found to be missing information. By the end of 2016, 20 of these dossiers had been updated and passed the new completeness check. For the remaining four dossiers, which contain a significant number of unfounded data waivers, updates providing the requested information had not yet been received at the end of the year. If the requested information is not provided within the given deadline, the registration decisions will be revoked. In autumn 2016, a second lot of similar letters was sent to registrants of 43 lead dossiers.

The results of the first retrospective completeness check exercise were examined in more detail to assess the impact of this initiative in a broader context. The analysis showed that the registrants of the 20 dossiers for which an update was successfully submitted had amended their dossiers by adding 15 studies carried out on the registered substance, 21 studies used in a read-across approach, and 17 data waivers that fall within the remits of REACH Column 2 or Annex XI.

These results show that the retrospective completeness check can be successfully used to target registration dossiers that are not otherwise updated and that are incomplete according to the current completeness check, to ensure that they contain the data elements that are intended by REACH as an input for subsequent regulatory processes.

3.3. Substance identification

Correct identification of the registered substance is essential for evaluating the compliance, examining testing proposals and identifying substances of concern.

From the start, incorrect substance identification has been among the most re-occurring non-compliances. In addition to formal evaluation decisions, the issue has been addressed by other measures. These have proven successful: for the vast majority of cases, the deficiencies in substance identification can be easily solved byregistrants after they have been asked to do so, for example through the letter campaigns or in informal phone calls.

During 2016, ECHA organised informal discussions with registrants to help them comply with the substance identification requirements under REACH. These discussions focused on dossiers submitted for substances that are potentially subject to the compliance check procedure[40] and for which ECHA observed the need for clarification. The discussions, usually over the telephone, gave the opportunity for registrants to address issues or challenges encountered when determining and reporting substance identity information and to avoid the need for a compliance check.

In addition, ECHA has ongoing discussions on substance identification with a variety of chemical producing sectors such as complex inorganic pigments, metals, grease thickeners and renewable fuels. ECHA also contributed to the development of the ‘OECD Guidance For Characterising Hydrocarbon Solvents For Assessment Purposes’ which was published in January 2016.

[39] https://echa.europa.eu/documents/10162/13575/a-022-2013_decision_en.pdf
[40] A list of substances potentially subject for compliance checks is available onECHA’s website at: https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

As explained in Section 3.1, REACH includes provisions that set joint submission obligations and introduces the “one substance - one registration” (OSOR) principle.

This means that registrants must collectively agree on the applicability of the data provided and must establish how far the composition of the material used for carrying out a test can be used for determining the properties of each individual imported/manufactured composition. Therefore, registrants must define the compositional boundaries covering the properties reported for the registered substance.

When submitting the lead registration dossiers, it is mandatory since June 2016 to clarify the agreed boundaries and scope of the substance identity within a joint registration - also known as the substance identity profile (SIP). The lead registrant must report the SIP in the form of one or several “boundary compositions” in the improved composition section of IUCLID 6 released in 2016.

As explained further in Section 5.3 of this report, registrants must report their own specific substance identity information in their registration dossier. Therefore, the individual compositions reported in each registration dossier within the joint submission will differ from one to another. The agreed SIP reported by the lead registrant instead will describe the overall compositions agreed to be covered by a certain set of data.

Practical advice on how to define the SIP is available in Appendix III of the *Guidance on substance identification and naming under REACH and CLP*[41].

In addition, a new format is now available in IUCLID 6 for structuring the reporting specific information on the composition of test materials. The availability of such information will provide an important contribution to the activities done in the evaluation process.

One of the elements that is considered essential in the context of the evaluation process is the use of correct identifiers (i.e. chemical name and EC/list number). To this end ECHA provides a service enabling the adaptation of numerical identifiers when needed. As a result of this adaptation, a new EC/list number is allocated to the registered substance.

Even though certain identifiers are not considered appropriate for identifying a substance according to the *Guidance on substance identification and naming under REACH and CLP*, these may be used or may have been used for other regulatory purposes. For maintaining the correlation of such identifiers with the registered substance, ECHA provides the possibility to specify other relevant identifiers in the table “Other identifiers” in Section 1.1 of the IUCLID 6 dossier as a technical solution.

In 2016, the adaptation of numerical identifiers was performed for around 40 substances. Before the service was available, registrants could not correct mistakes in the way they had identified their substance during registration and, as such, inaccurate identifiers were retained. However, the substance identifier adaptation service provides a solution to this problem.

[41] https://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

3.4. Letter campaigns

In addition to substance identity shortcomings, ECHA has also used letter campaigns to communicate to registrants on other specific improvement needs in the dossiers. As already was the case in 2015, the substances on the 2016 shortlist for manual screening were also the targets of a letter campaign. This second letter campaign on substances shortlisted in 2016 addressed 270 substances.

All registrants of the shortlisted substances were alerted to the fact that their substances might be under scrutiny by Member States and invited to review their dossiers with regard to identified potential hazards and their use and tonnage information. The aim of the campaign was to increase the transparency and predictability of the screening process by letting registrants know that their substances were shortlisted. The aim was also to trigger updates of dossiers so that authorities and registrants focus on the right substances if, for instance, some information on uses in the registration dossiers would not be up-to-date anymore.

A 40 % update (per substance) was observed within four months of the letters having been sent. The main reason for updating these dossiers was related to the inclusion of new and updated information on uses and tonnage per use. However, in certain cases, the registrants have also updated hazard information with a revision of the human health and environmental endpoints summary, improved information on the substance identification and strengthened the justification for certain adaptations from the standard information requirements.

3.5. Sectoral approach

In addition to addressing substances one-by-one, ECHA has initiated discussions with Member State authorities and industry sectors with the aim of triggering the generation of better quality data on groups of substances. Addressing substances in groups and interacting with registrants' representatives early on is important for the overall implementation of the regulatory strategy: it is expected to bring efficiency, help to avoid unnecessary animal testing and speed up the work aiming to draw conclusions on whether further action is needed or whether a substance is of low priority and can be set aside by authorities.

The way substances covered by such approaches are grouped, and hence the sectors approached, vary depending on the initial potential concerns. The substances can be from the same chemical family or, for instance, differ in their chemical structures but be used in similar materials or articles.

Consequently, the companies or sectors approached can either be all manufacturers/importers of the substances belonging to the same "chemical family", or all actors – from manufacturers/importers to downstream users – involved in a supply chain in which several types of substances are used. A sectoral approach can be used to trigger clarification on both hazard properties, and uses of and exposures to/emissions of substances. The aim is to make dossiers compliant and ensure that information is adequate for correctly identifying potential substances of concern.

Together with Member States, ECHA continued working on groups of substances with different sectors in 2016. For instance, there is work ongoing in the context of the SVHC Roadmap on developing a approach on how to identify and assess UVCB petroleum and coal stream substances (see the annual report of the SVHC Roadmap[42] for more details).

[42] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

3.6. Article 36 decisions

ECHA continued in 2016 to verify the intermediate status of registrations for on-site and transported isolated intermediates by using Article 36 decisions to ask registrants to provide information on the use of the substance as an intermediate, where necessary.

As previously, for transported isolated intermediates, ECHA also requested registrants to provide documentary evidence that, when an intermediate is supplied to a downstream user, the registrant knows that the substance is used by the downstream user as an intermediate under strictly controlled conditions (SCCs), or has received confirmation from the downstream user to that effect. During 2016, ECHA sent out 10 Article 36 decisions and handled 12 intermediate registrations in total. 11 registrants were successful in showing their intermediate use and one registrants' status is still under verification.

ECHA further considered expanding the use of Article 36 for other types of information requests before formal processes. For example, Article 36 decisions may be used to request clarification regarding exposure assessment. This would eventually facilitate the handling of cases during the subsequent formal processes.

3.7. Transparency regarding content and target of ECHA decisions

Improved transparency of relevant phases and outcomes of evaluation and risk management processes is in the core of the regulatory strategy. This benefits the Member States, stakeholders and registrants. Hence, ECHA continued its efforts to improve the systems throughout 2016.

Publication of adopted decision

To provide registrants and third parties with a greater insight into ECHA's evaluation processes, i.e. how ECHA justifies its requests for further information, ECHA continued to publish non-confidential versions of its adopted decisions.

The published documents represent decisions which were systematically consulted with the addressee registrant and where ECHA removed any personal data as well as blanking out sections deemed to possibly harm the registrants' commercial interests if disclosed.

After the establishment of a new dissemination portal in 2015 to provide a higher rate of automation in the publication of final decisions, ECHA has modified its internal publication process towards an increased automation in 2016. As a consequence of the technical developments associated with this, there was a halt in the publication of decisions from October 2015 – February 2016, and then a subsequent delay in updating ECHA's website. However by the end of the year, 1 148 (71.5 %) out of a total of 1 605 adopted decisions have been published by ECHA.

Publication of lists of substances for further action

In addition to the annual CoRAP update, ECHA has continued to publish lists of substances[43] which will be potentially subject to compliance check throughout 2016, inviting the related registrant to review and update the content of their registration dossiers. Each list has been developed in accordance with ECHA's current compliance check strategy and is based on the results of the common screening approach.

[43] https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

4. Evaluation related activities

4.1. Alternative methods to animal testing

Under REACH, animal testing is only to be conducted as the last resort. While data sharing is the primary means to achieve this, registrants are also obliged to consider generating information by means other than vertebrate animal tests. Such tests can be conducted only if there are no other scientifically reliable ways of assessing the potential effects on humans or the environment.

The availability and applicability of alternative methods to animal testing for a specific information requirement must be considered and documented. Among the alternatives, *in vitro* studies using cells, grouping of substances and read-across approach, weight of evidence, specialised computer modelling, and approaches combining or integrating various methods may satisfy the information requirement instead of an animal study. ECHA provides guidance on how to use alternatives to animal testing to fulfil REACH registration requirements.[44]

In July 2016, ECHA published two practical guides[45] to support registrants in understanding (i) how to fulfil their requirements for substances at 1-100 tonnes per year and (ii) how to use alternatives to animal testing to fulfil the requirements.

In vitro methods

In 2016, ECHA updated *Chapter R.7a of its Guidance on information requirements and chemical safety assessment* related to skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity, with clear advice on how to use *in vitro* methods and other alternatives in respect of the recent revisions of the REACH annexes.

In addition, ECHA's web pages on testing methods and alternatives were updated to reflect changes in the REACH annexes on skin and eye irritation. Also during the year, the OECD approved the third *in vitro* method for skin sensitisation h-CLAT (OECD 442e) and ECHA has accordingly updated its guidance. Furthermore, on 22 September 2016, ECHA held a webinar on the use of alternative methods to animal testing in registration that focused on the recent revision of REACH annexes in respect to skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity.

Grouping of substances and adaptations based on read-across

ECHA published the Read-Across Assessment Framework (RAAF) for human health endpoints in 2015. The first version of this framework presented the methodology ECHA uses to assess read-across approaches[46]. The RAAF does not replace the official guidance on read-across for registrants, but complements it by showing how ECHA assesses read-across cases.

In 2016, the RAAF was further developed to extend the assessment framework to assessing read-across and grouping of ecotoxicological and environmental fate properties of substances, by analogy with the concept established in the RAAF for toxicological properties published in 2015. Stakeholders and co-decision makers have been consulted in the course of this project and their input will be taken into account in

[44] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals
[45] https://echa.europa.eu/practical-guides
[46] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

finalising the framework in early 2017. In addition, ECHA has initiated a project to identify the specific scientific issues to be considered when assessing read-across approaches involving multi-constituent substances. This project will continue in 2017.

The Board of Appeal also further settled its position regarding read-across adaptations, confirming ECHA's competence to reject a read-across proposal when the latter does not comply with REACH requirements[47]. Following the rejection of a read-across, the Board confirmed that ECHA has to ask for the relevant standard information (i.e. the performance of a vertebrate test), and therefore ECHA's decision cannot be regarded as being disproportionate or breaching animal welfare provisions. The Board thereby confirmed the position adopted in earlier cases[48].

Adaptations based on weight of evidence

Registrants can use weight of evidence as an adaptation for information requirements if the conditions of Annex XI, Section 1.2. are met.

A weight-of-evidence adaptation combines evidence from several independent sources of information with the aim to assume/conclude that a substance has or does not have a particular dangerous property, while the information from each single source alone is regarded as insufficient. A weight-of-evidence adaptation needs to be substance and case-specific and needs to address the information requirement that is adapted. Adequate and reliable documentation with a rationale/justification needs to be provided by the registrant.

In the evaluation of cases, ECHA often notes that the adaptation is claimed to be based on weight of evidence but several lines of evidence are not provided or no justification is submitted. In 2016, two Board of Appeal decisions confirmed that, in compliance check, ECHA has no obligation to develop, justify or improve a weight-of-evidence adaptation to standard information requirements on the registrant's behalf[49]. In these decisions, the Board confirmed its position on the issue, as it had already been stated for read-across adaptations[50].

Scientific work on new approach methodologies

An ECHA topical scientific workshop (April 2016) addressed the use of information from so-called new approach methodologies (NAMs) within a regulatory context. These methodologies integrate information from high-throughput and high-content analyses (such as 'omics') with other information.

As reported in the proceedings[51], NAMs can be helpful to support read-across cases, especially by providing supporting evidence on toxicodynamics to increase confidence in the mechanistic hypotheses and reasoning. ECHA considers that results obtained with such methods could also be used as separate lines of evidence in weight-of-evidence adaptations.

[47] Decision of 20 October 2016 in Case A-004-2015, *Polynt SpA* and Decision of 7 October 2016 in Case A-017-2014, *BASF SE*.
[48] Decision of 19 June 2013 in Case A-001-2012, *Dow Benelux BV* and Decision of 13 February 2013 in Case A-006-2012, *Momentive Specialty Chemicals BV*.
[49] Decision of 1 August 2016 in Case A-003-2015, *BASF Pigment GmbH*; Decision of 1 August 2016 in Case A-014-2014, *BASF Pigment GmbH*.
[50] Decision of 13 February 2013 in Case A-006-2012, *Momentive Specialty Chemicals BV*.
[51] https://doi.org/10.2823/543644

Scientific work towards reducing and refining of animal tests

ECHA commissioned a study entitled "Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity test (FET) Test Guideline (OECD 236) to fulfil the information requirements and addressing concerns under REACH" and published it[52] in 2016.

The main aim of the study was to gather and analyse the publicly available data on fish embryo toxicity (FET), to compare it with available data on standard acute fish toxicity (AFT), and to set up the parameters defining the applicability domain and limitations of a FET test in comparison to AFT (OECD TG 203). The analysis focused mainly on chemical structure, mode of action and several key physico-chemical characteristics of tested compounds (e.g. solubility, lipophilicity).

In the light of this analysis, there are limitations in the use of the FET test guideline to fulfil the standard information requirements for REACH registration. Registrants intending to adapt/waive the standard AFT need to take these limitations into account.

The OECD TG 236 would not be sufficient alone as a direct 'one-to-one' replacement for the AFT to meet the information requirement of REACH Annex VIII, 9.1.3, because there is currently inadequate evidence to establish clear applicability boundaries to decide under what circumstances the FET correlates satisfactorily with the AFT.

Nevertheless, based on current knowledge, ECHA considers that the OECD TG 236 has a potential for use as part of a weight-of-evidence approach, in combination with other information, for the registrant to make a scientific justification to predict acute fish toxicity.

Integrating evidence to avoid new animal testing

The OECD has approved two guidance documents related to integrated approaches on testing and assessment (IATA) and ECHA has been actively contributing to this work.

One is a guidance on the reporting of defined approaches to be used within integrated approaches to testing and assessment[53] that provides a set of principles for reporting defined approaches to testing and assessment that can be used as one of the components within IATA. The document provides templates to enable a structured approach of documentation.

The second is a guidance on the reporting of defined approaches and individual information sources to be used within IATA for skin sensitisation.[54] This guidance document contains two annexes where the first lists case studies on the reporting of defined approaches and individual information sources to be used within IATA and the second lists individual information sources that can be used. Concerning serious eye damage and eye irritation, the IATA is being prepared by the OECD and ECHA is contributing to it.

[52] https://echa.europa.eu/documents/10162/13639/fet_report_en.pdf
[53] ENV/JM/MONO(2016)28
[54] ENV/JM/MONO(2016)29

4.2. Expert working groups

Several expert and working groups are established to provide informal, non-binding advice related to scientific challenges on specific topics, for example on endocrine disruptors or persistent, bioaccumulative and toxic substances.

These groups consist of nominated experts from Member State competent authorities, the European Commission and accredited stakeholders.

PBT Expert Group

The expert group on (very) persistent, bioaccumulative and toxic substances provides informal scientific advice on questions related to the identification of PBTs and very persistent, very bioaccumulative (vPvB) properties of chemicals.

During 2016, the expert group has supported evaluation by providing informal scientific advice for the majority of substances placed on the CoRAP for 2016 due to PBT/vPvB concerns. The discussions within the group focused mainly on the interpretation of the existing data and the most appropriate testing strategy to conclude on the concern. In addition, the group discussed the data provided in response to substance evaluation decisions for two substances listed on the CoRAP for 2012.

Endocrine Disruptor Expert Group

According to its mandate, the expert group on endocrine distruptors provides informal, non-binding scientific advice on questions related to the identification of the endocrine distruptive properties of chemicals.

The expert group has provided advice during 2016 for 17 substance cases, of which 10 were related to substance evaluation cases. 8 out of the 14 substances in the CoRAP 2016 with endocrine disruption as an initial concern were discussed by the group. The discussions in the expert group have focused mostly on the interpretation of available data, the identification of further information requirements and the most appropriate information generation and testing strategy to conclude on the concern.

4.3. Good laboratory practice

According to Article 13(4) of the REACH Regulation, ecotoxicological and toxicological tests and analyses must be carried out in compliance with the principles of good laboratory practice (GLP).

ECHA randomly verifies whether a test facility conducting such tests belongs to an OECD GLP monitoring programme. Additionally, in 2015, ECHA requested for the first time the EU GLP Monitoring Authorities to conduct GLP-study audits. In total, nine GLP-study audits were requested, which were conducted during 2015-2016.

From those nine studies, eight were found to be compliant with the principles of GLP. In one study, the EU GLP Monitoring Authorities decided that the principles of GLP were not complied with.

ECHA has informed the responsible REACH competent authority and national enforcement authority that in its opinion, the registrant is in breach of Article 13(4) of the REACH Regulation, because the study provided in the registration dossier was not conducted in compliance with GLP.

ECHA requested the REACH competent authority and the national enforcement authority to take this information into account when deciding on possible enforcement actions.

4.4. Reproductive toxicity – extended one-generation reproductive toxicity study

Since 13 March 2015, the extended one-generation reproductive toxicity study (EOGRTS) has been the new information requirement for reproductive toxicity (Annexes IX and X, Section 8.7.3.). An adequate two-generation reproductive toxicity study is only considered to meet the standard information requirement (column 1) if it was initiated before 13 March 2015.

In Annex X, the extended one-generation reproductive toxicity study is a default information requirement under REACH. In Annex IX, however, it must be fulfilled only if repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation to reproductive toxicity.

A modular design of the extended one-generation reproductive toxicity study has been implemented in REACH. The standard information requirement in Annexes IX and X is limited to the basic configuration of EOGRTS (basic study design). The basic study design only includes Cohorts 1A and 1B for reproductive toxicity. Based on specified conditions and concern-based criteria, the study must be expanded to include an extension of Cohort 1B to include the mating of the F1 animals to produce an F2 generation, the developmental neurotoxicity Cohorts 2A and 2B, and/or the developmental immunotoxicity Cohort 3.

These criteria are described in column 2 of Section 8.7.3 of REACH Annexes IX and X and further elaborated in ECHA's *Guidance on information requirements and chemical safety assessment R.7a* (version 4.1, October 2015) on reproductive toxicity (chapter R.7.6). Furthermore, the premating exposure duration and dose selection should be appropriate to meet risk assessment as well as classification and labelling purposes.

In September 2016, ECHA published a technical report which explains how the Agency identifies and concludes on the EOGRTS design under dossier evaluation and discusses the crucial information sources for defining EOGRTS design and triggering the study itself[55].

An advisory expert working group 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 mandate of the working group was prolonged in 2016 until the end of 2017.

Contrary to the expectation made in ECHA's 2016 Work Programme[56], ECHA did not yet receive re-submitted testing proposals resulting from the the 216 cases referred to the Commission for decision making. It is now expected that such testing proposals will be submitted to ECHA at the end of 2017 or at the beginning of 2018.

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

[56] https://echa.europa.eu/documents/10162/13608/final_mb_47_2015_wp_2016_en.pdf/

4.5. Litigation and the EU Ombudsman

The Board of Appeal

The Board of Appeal is responsible for deciding on appeals lodged against certain decisions of the Agency taken under the REACH Regulation and the Biocidal Products Regulation.

During 2016, eight new appeals against ECHA evaluation decisions were announced by the Board of Appeal. Of these, five concerned dossier evaluation decisions and three concerned substance evaluation decisions.

In 2016, the Board of Appeal closed 19 appeal cases on evaluation. Of these, 14 concerned dossier evaluation decisions and five concerned substance evaluation decisions[57].

Key rulings are summarised in the relevant parts of this report. In addition, the decisions address the definition of intermediates, substance identity of nanomaterials and procedural issues, such as the addressees of decisions and the registrant's right to be heard and comment.

At the end of 2016, seven dossier evaluation appeals and eight substance evaluation appeals were pending.

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.[58]

The European Ombudsman

In 2015, ECHA introduced measures requiring registrants who submit new testing proposals concerning vertebrate animal tests to provide their considerations of alternative methods[59]. Failure to do so could lead to the rejection of the registration.

In May 2016, animal rights NGOs complained to the European Ombudsman that ECHA does not accept that it can reject a testing proposal under dossier evaluation where a registrant has not given adequate consideration to alternative testing methods[60].

In its reply to the complaint, the European Ombudsman supported ECHA and emphasised that ECHA's role is not to put forward adaptation arguments on behalf of registrants or identify the most appropriate alternative testing method[61]. It further reiterated that "*it is for the registrants to show to ECHA, upon request, that before proposing animal testing, they have considered other methods to generate the missing information*"[62]. As there were insufficient grounds to open an inquiry, the European Ombudsman decided to close the case.

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[57] There were, in fact, four cases related to the same compliance check decision on the substance identity of nanomaterials.
[58] http://echa.europa.eu/about-us/who-we-are/board-of-appeal
[59] https://echa.europa.eu/view-article/-/journal_content/title/echa-asks-registrants-to-show-how-they-considered-alternative-methods-before-consulting-on-testing-proposals and https://echa.europa.eu/view-article/-/journal_content/title/considerations-for-alternative-methods-need-to-be-included-in-your-testing-proposal
[60] Complaint 811/2016/MDC submitted on 25 May 2016.
[61] Decision of the European Ombudsman of 29 July 2016 in Case 811/2016/MDC.
[62] Decision of the European Ombudsman of 11 September 2015 in Case 1606/2013/AN.

In the reply to the complaint, aside from supporting ECHA's position, the European Ombudsman expressed its satisfaction with ECHA's undertakings in the field of testing proposals.

There is currently one pending case related to the Joint Statement by the Commission and ECHA on the possibility to perform, under certain conditions, animal tests for substances used in cosmetics. The Ombudsman wished to have ECHA's and the Commission's views on this issue in light of the Court of Justice's recent judgment in Case *European Federation for Cosmetic Ingredients*[63] concerning animal testing performed on cosmetics ingredients for the purposes of third country legislation. ECHA has sent a first reply together with the Commission in December 2016 and is waiting for the Ombudsman to decide whether she will open an inquiry into the matter.

[63] Judgment of 21 September 2016 in *European Federation for Cosmetic Ingredients,* C-592/14, ECLI:EU:C:2016:703.

5. Recommendations to registrants

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

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

In 2016, to support future registrants, ECHA has published practical advice on information requirements and how to avoid unnecessary testing on animals as well as on ways to gather information, as part of ECHA's REACH 2018 Roadmap[64]. For an overall picture on the information requirements, we recommend reading the *Practical guide for SME managers and REACH coordinators*[65]. It covers the information requirements for registering substances from 1 to 100 tonnes per year. This guide aims to support small and medium-sized enterprises with their obligations. The content of the guide is also relevant for registrants regardless of their deadline and is available in 23 EU languages.

In addition to the advice provided in this report, the shortcomings observed in previous years of evaluation have already been highlighted in the previous evaluation reports. These reports, practical guides and illustrative practical examples are available on ECHA's website[66]. All of the advice given on the previous evaluation progress reports are still relevant, even though not repeated here.

5.1. Communication with ECHA during evaluation

Below are some recommendations on how to communicate with ECHA[67] and the Member States during the different phases of the dossier and substance evaluation processes.

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

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

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

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[64] https://echa.europa.eu/-/reach-2018-assess-your-substance-to-show-safe-use
[65] https://echa.europa.eu/practical-guides
[66] How to improve your dossier and lessons learned from dossier evaluation https://echa.europa.eu/support/how-to-improve-your-dossier/lessons-learnt-from-dossier-evaluation
[67] More details in practical guide How to communicate with ECHA in dossier evaluation: https://echa.europa.eu/practical-guides

Dossier evaluation

If you have received a draft decision for your comments:

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

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

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

Substance evaluation

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

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

Further guidance is provided in the factsheet on substance evaluation.[68]

Decision making

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

[68] https://echa.europa.eu/documents/10162/13628/fs_substance_evaluation_en.pdf

If Member States propose some amendments, you will receive them from ECHA for your comments. At this stage, only your comments on the proposals for amendment will be considered. If ECHA and the Member State Committee (MSC) puts your case for the Committee discussion, you as the case owner (i.e. a concerned registrant or a representative of a group of concerned registrants for joint submissions) may be invited to participate in the discussion as an observer when your case is addressed by the Committee. Should you accept such an invitation, you must conform to the *ECHA Code of Conduct for Case Owner Observers at MSC meetings*.[69]

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

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

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

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

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

Further guidance is provided in the factsheet on follow-up to dossier evaluation decisions.[70]

5.2. Registration and updates

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

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

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

69 https://echa.europa.eu/documents/10162/13578/code_of_conduct_msc_case_owners_en.pdf

70 https://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf

If still you do not have some of the required information (e.g. if you have ordered tests in a timely manner but have not received the results in due time), follow the instructions provided by the Directors' Coordination Group.[71] Do not simply state that you will submit the information later.

Use the validation assistant plugin for IUCLID when preparing your registration

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

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

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

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

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

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

5.3. Substance identity and physico-chemical hazard data

Provide clear information on your substance identification profile

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

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

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

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

[71] https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues

Provide precise information on the composition of the test material

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

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

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

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

Consult ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7a: endpoint specific guidance (version 5.0, December 2016)[72], which has been updated to clarify this requirement.

5.4. Good laboratory practice must be complied with in (eco)toxicological test

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

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

5.5. Testing on animals must only be undertaken as a last resort

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

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

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

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

72 https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/

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

When you have concluded that generation of new information is necessary, verify whether the endpoint requires a testing proposal and prior authorisation of the testing by ECHA. When your testing proposal involves testing on vertebrate animals, you have to include your considerations on alternatives methods in the dossier documentation. ECHA will publish this information together with the testing proposal and take your considerations into account when examining the case.

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

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

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

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

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

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

Grouping and read-across

Use ECHA's Read-Across Assessment Framework (RAAF)[73] to check the robustness of your read-across adaptation. Familiarity with RAAF is essential for adapting standard information requirements by using grouping and read-across.

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

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

- Justify the selection of the source substances proposed.
- Specify the identity of all substances involved. Consider impurities and potentially different substance compositions also when developing a read-across argument.
- Justify the prediction based on read-across adequately and provide supporting and credible information. Adequately document the scientific reasoning. Give a

[73] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

hypothesis-driven justification why the data from one substance can be used to fill the data gap for another substance. Do that for each property. The hypothesis must address why structural differences between the substances do not affect the prediction of the property under consideration.
- Make sure that the source studies used comply with the information requirement under consideration. Study results of source studies must be included in the dossier in the format of robust study summaries.
- Analyse experimental data to confirm the proposed hypothesis.
- Provide (toxico)kinetic information to make the read-across hypothesis more robust.
- Other substance-specific supporting information may be needed to support your arguments.

Weight of evidence

Registrants are advised to explain why and how the individual lines of information for a substance lead to the assumption/conclusion that is has or has not a particular dangerous property. The associated uncertainties and their impact should be addressed, e.g. related to:
- Key parameters not covered in comparison with the default test method;
- Test duration covered in the lines of evidence not adequate to cover the information requirement;
- Missing quality assurance procedures;
- Unclear substance identity of the test material used for a piece of information;
- Insufficient reporting in the sources for the information.

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

Quantitative structure-activity relationships

The practical guide on how to use and report quantitative structure-activity relationships ((Q)SARs) is available on ECHA's website[74]. This updated version contains a recommended strategy for how to use (Q)SARs, how to check the validity of the (Q)SAR model and whether it falls in the model applicability domain.

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

Despite the effort of ECHA to provide examples with different tools, there is a significant variation between the tools in terms of available databases and modelling approaches. The OECD QSAR Toolbox[75] is a good source to find experimental data and to relate it to chemical structure.

- Consult the manual "How to prepare registration and PPORD dossiers" for practical direction how to present their read-across information in IUCLID 6.
- For statistical models, which are complex by the type and number of descriptors and/or modelling algorithm, follow the recommendation of ECHA's *Guidance (Chapter R.6)* on how to check validity.
- Provide information in the (Q)SAR prediction reporting format (QPRF). The (Q)SAR model reporting format (QMRF) alone is not sufficient.

[74] https://echa.europa.eu/practical-guides
[75] https://echa.europa.eu/support/oecd-qsar-toolbox

- For complex health endpoints (e.g. reproductive and developmental toxicity, repeated dose toxicity), there is often no model to predict a result of a whole study. If such models are attempted, they can only be used for screening purposes.
- Present the prediction results accompanied by an estimated error of the prediction and description of any other possible uncertainty.

5.6. Extended one-generation reproductive toxicity study

Familiarise yourself with the technical report ECHA published in September 2016. It explains how ECHA identifies and concludes on the design of the extended one-generation reproductive toxicity study (EOGRTS) under dossier evaluation and discusses the crucial information sources for defining the EOGRTS design and triggering the study itself[76].

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

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

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

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

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

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

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

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

The test method regulation was amended[77] and the new provisions came into force in March 2016. It contains a new note relating to testing of multiconstituent, UVCB and mixtures:

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

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

The chemical safety assessment must be meaningful for the UVCB substance

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

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

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

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

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

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

[77] Commission Regulation 2016/266.

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

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

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

A CSA can only contain negative or positive conclusions on PBT/vPvB properties of a registered substance[78] and its constituents, impurities and additives or testing proposals which propose testing to reach a conclusion on the PBT/vPvB properties. A CSA on a UVCB substance cannot conclude that there is insufficient information on PBT/vPvB properties of some constituents, impurities or additives, if no testing proposals are submitted.

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

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

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

5.8. Chemical safety report

Use map information can be valuable for your dossier

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

Use maps are generated by downstream user sector organisations by collecting information on the uses and the conditions of use of chemicals in a harmonised and structured way. Therefore, use maps document information on uses in a sector and the associated exposure assessment input datasets for workers, consumers and the environment.

78 https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/

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

Five sector organisations (cleaning products [A.I.S.E], adhesives [FEICA], construction products [EFCC], cosmetics [Cosmetics Europe] and imaging and printing products [I&P Europe]) have published updated/new use map information in the harmonised format, and made their files available for the ECHA web page[79]. ECHA gives support by providing comments on the draft use maps.

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

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

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

Chesar

In 2016, ECHA released a new version of ECHA's Chemical Safety Assessment and Reporting Tool (Chesar)[80] (Chesar 3), enabling the transparent documentation of assessments for substances with a more complex behaviour (e.g. UVCBs, substances reacting on use, substances with different composition requiring different risk management) and with improved user-friendliness.

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

5.9. Publication of chemical information

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

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

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

[79] Use maps from sectors are continuously updated on ECHA's website https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library
[80] https://chesar.echa.europa.eu

5.10. ECHA's guidance updates

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

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

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

ECHA published a list of the REACH guidance documents still under consultation in June 2016. The list (which is updated occasionally with changes of status) shows the status of the documents and when the final version is expected to be published[81].

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

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

[81] REACH Guidance updates relevant to the 31 May 2018 registration deadline not finalised before 31 May 2016: http://echa.europa.eu/documents/10162/13564/list_of_reach_guidance_under_consultation_en.pdf

List of abbreviations and acronyms

AFT	acute fish toxicity
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
DNEL	derived no-effect level
DU	downstream user
ECHA	European Chemicals Agency
ED	endocrine disruptor
EOGRTS	extended one-generation reproductive toxicity study
FET	fish embryo acute toxicity
GLP	good laboratory practice
IATA	integrated approaches on testing and assessment
IUCLID	International Uniform Chemical Information Database
MSC	Member State Committee
MSCA	Member State competent authority
NAM	new approach methodologies
NEA	national enforcement authority
PBT	persistent, bioaccumulative and toxic
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
REACH	Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals
REACH-IT	A central IT application that supports industry, Member State competent authorities and the ECHA to securely submit, process and manage data and dossiers
RMOA	risk management option analysis
SEV	substance evaluation
SID	substance identity
SIEF	substance information exchange forum

SIP	substance identity profile
SONC	statement of non-compliance following a dossier evaluation decision
SVHC	substance of very high concern
t/a	tonnes per annum (year)
TPE	testing proposal examination
UVCB	a substance of unknown or variable composition, complex reaction product or biological material
vPvB	very persistent and very bioaccumulative
WoE	weight of evidence

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