ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH: Progress Report 2017

10 years of experience

Disclaimer

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FOREWORD

Dear reader,

This is ECHA's tenth report on progress in evaluation under REACH – and for me the first one as ECHA's Executive Director. I am thrilled to continue the important work assigned to our Agency under this very challenging legislation. This includes the core tasks on evaluating dossiers and substances under REACH, the area where ECHA has been given significant powers – and the high responsibility coming with such powers.

Three months from the publication of this report, the 11-year-long transitional period comes to its end: after 31 May 2018, all so-called phase-in substances that are manufactured or imported in the EU in amounts of more than 1 tonne per year must have been registered. This last registration deadline will complete the database on existing substances, and it will also bring a whole new challenge for evaluation. In addition to examining the testing proposals in the last phase-in dossiers, ECHA will have to select at least 5 % of the dossiers for compliance check also from the newly submitted low-tonnage registrations, which may mean over 3000 dossiers. At the same time, the frequent non-compliances found when evaluating higher tonnage (>100 tn/year) dossiers mean that we need to continue to address the inadequate adaptations and waiving statements in those dossiers and to request the missing data. This work forms an essential part of ECHA's Integrated Regulatory Strategy and is key to meeting our ambitious global goal on chemicals management.

The forthcoming Commission communication on the review of REACH will take stock of the overall effectiveness and efficiency of the legislation and its implementation. Dossier and substance evaluation are such a core part of the regulation that we can expect recommendations also regarding their further improvement. I firmly believe that together with the Member States we can indeed further speed up and increase the impact of our joint evaluation work and ensure that the necessary information on substances is being generated, allowing authorities to conclude on whether further regulatory measures are needed.

For the key audience of this report, the REACH registrants, we again bring a set of recommendations. After the phase-in period is over, the focus of registrants needs to turn to ensuring that their dossiers are kept up to date, in terms of tonnages, uses, exposure and hazard information. As this report also briefly describes, a large part of dossiers have not been updated since they were first submitted, which raises questions on the incentives (or lack of them) for complying with obligations regarding updates. ECHA is screening all dossiers and, together with Member States, prioritises those where we have reasons to suspect exposure and hazards not being properly addressed. Take care that your dossier is ready to be scrutinised and is not prioritised because of inaccurate or missing information!

This tenth annual progress report on evaluation is also the last one in its current format. From next year onwards we will merge this report with the annual report on implementing the SVHC Roadmap. This illustrates the learnings of the past 10 years: effective and efficient implementation of REACH needs to continue forcefully and the various processes and actors need to come together to step up the efforts for meeting the ambitious objectives set by the legislator!

Bjorn Hansen

Executive Director

EXECUTIVE SUMMARY

This is ECHA's tenth progress report on evaluation under the REACH Regulation. It summarises 10 years of experience from the evaluation activities carried out so far, and gives a more detailed account of ECHA's evaluation activities in 2017. It also provides recommendations to new and existing registrants deriving from this experience.

Trends in ECHA's evaluation activities since 2008

During the first years of evaluation, from 2008 to 2010, the ECHA Secretariat picked dossiers for compliance check based on random selection, IT screening and manual prioritisation. During these years, 105 dossiers were checked and 12 decisions were adopted. Altogether these decisions addressed compliance deficiencies on 23 information requirements, mainly on physico-chemical properties, screening for reproductive/developmental toxicity and the quality of the chemical safety report. At the same time ECHA, its Member State Committee and the Member States gained important experience on all aspects of the dossier evaluation process and built the capacity and skills necessary for addressing a higher volume of cases.

Over the three years following the first registration deadline of 2010, ECHA focused compliance checks increasingly on dossiers picked up by systematic IT screening. Selected information requirements were addressed in a standardised manner. This led to total of 1 464 targeted[1] and overall checks and 329 adopted decisions, each often containing one or two information requests. The first 5 % target[2] on 2010 dossiers was thereby also met at the end of 2013.

In 2014, ECHA moved to addressing also dossiers from the second phase-in deadline. With the help of improved screening tools, the Agency started selecting dossiers of substances of potential concern, i.e. those substances for which (i) the hazard profile for higher-tier (eco)toxicity information requirements[3,4] indicates a potential concern (or the hazard profile is unclear and needs to be further examined) and (ii) there is significant exposure potential. The focus was put on the key information requirements that could help to clarify if the substance is likely to be carcinogenic, mutagenic and reprotoxic (CMR) and/or (very) persistent, bioaccumulative and toxic (PBT/vPvB). Those information requirements are key in enabling the identification of a substance as being of very high concern. Since 2015, this approach has formed a core part of ECHA's Integrated Regulatory Strategy[5]. Compared to the previous approach, the number of compliance checks and decisions is lower, but the number of information requests has increased to an average of five requests per decision taken in 2017.

Overall, during the 10 years of evaluation, ECHA checked, to various degrees, the compliance of 1 350 (7.33 %) dossiers in the >1000 tn/a tonnage band and 430 (3.79 %) of the dossiers in the 100-1000 tn/a tonnage band. Due to the selection based on screening of suspected data gaps, in the vast majority of the cases (69 % and 77 % respectively), the compliance checks have confirmed one or more non-compliances and resulted in ECHA (draft) decisions.

By the end of 2017, altogether 2 586 information requests were made in the compliance check decisions. Of these requests, 420 (16 %) have targeted substance identification, 178 (7 %) physico-chemical properties, 955 (37 %) human health hazards, 662 (26 %) ecotoxicity and

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[1] For same registration more than one compliance check could have been opened to address different targeted concern scenarios or incompliances.

2 The 5% target is calculated by using number of unique registration dossiers checked for compliance (see Table 1.)

[3] Genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

[4] https://echa.europa.eu/documents/10162/17208/echa_cch_strategy_en.pdf/607b157b-a35d-4d1c-8e62-ce8668324b1a

[5] https://echa.europa.eu/documents/10162/22837330/mb_44_2016_regulatory_strategy_en.pdf/

fate, and 367 (14 %) the quality of the chemical safety reporting. The most common non-compliances related to human health have been found in pre-natal developmental toxicity (first and second species), sub-chronic toxicity (90-day study), *in vitro* studies for gene mutation and/or cytogenicity in mammalian cells and in the *in vitro* gene mutation study in bacteria. For the environmental information requirements, the most commonly found non-compliances have been in the long-term toxicity in fish, identification of degradation products, growth inhibition in the aquatic plants, bioaccumulation and effects in terrestrial organisms. In relation to physico-chemical properties, the partition coefficient, water solubility, vapour pressure and the dissociation constant were the most often requested information requirements in the decisions.

In parallel to the work on compliance checks, ECHA successfully met the two deadlines set in REACH, 2012 and 2016, for the examination of the phase-in substances' testing proposals and issued 806 decisions. The total number of requests made in the testing proposal decisions over the years is 1 588 – 964 (61 %) regarding toxicological testing, 494 (31 %) testing on ecotoxicology and environmental fate, and 130 (8 %) regarding physico-chemical testing. Registrants proposed testing mostly for pre-natal developmental toxicity, the 90-day sub-chronic toxicity study and the long-term toxicity testing on invertebrates.

The first cases in follow-up to dossier evaluation were processed in 2012, and a structured approach was fully established in 2013. Currently, the number of follow-up evaluations carried out annually is between 300 and 350, with approximately 55 % originating from compliance check decisions and 45 % from testing proposal decisions. Since 2013, ECHA has notified the Member States competent authorities and the Commission of 73 cases where substances are possible candidates for harmonised classification and labelling, and flagged 11 cases for substance evaluation. After setting the Integrated Regulatory Strategy to focus on substances of potential concern, ECHA has also considered more systematically whether further regulatory risk management processes are needed based on the follow-up evaluation.

The other main evaluation process, substance evaluation, started effectively with the publication of the Community rolling action plan (CoRAP) in February 2012. ECHA coordinates the work and collaborates with the evaluating Member States throughout the substance evaluation process, aiming to achieve consistent and scientifically robust decisions and to ensure that the necessary information is requested using the most viable route to clarify the concerns and inform regulatory risk management.

Between 2012 and 2017, a total of 221 substances were evaluated by Member States, who considered that 159 (72 %) of these required further information to clarify the suspected concerns; the remaining 62 substances could be concluded on without the need for further information. Of the 159 substances requiring further information to clarify the concern, 147 are currently at the process stage of either further information being requested (decision-making) or newly submitted information being evaluated (follow-up). The remaining 12 substances were concluded on following the submission and evaluation of requested information. Consequently, a total of 74 substances have been concluded on, and in 43 % of these cases the evaluating Member States considered that further regulatory risk management may be needed.

ECHA's evaluation activities in 2017

In line with the Integrated Regulatory Strategy set in 2015, ECHA continued to check the compliance of dossiers for registering substances in amounts of more than 100 tonnes per annum, addressing relevant higher-tier hazard endpoints for substances of potential concern. In addition, ECHA started a pilot focusing on selected groups of priority substances on which registrants are using read-across or grouping approaches for the key endpoints, and initiated informal interaction to more effectively ensure that such a grouping approach is in compliance with the information requirements. In addition, ECHA continued to use other measures – including letter campaigns and sector-specific approaches – to work together with industry to help to increase the overall compliance of the registration dossiers and improve the quality of chemical safety reports.

Outcome of compliance checks

In 2017, 185 (83 %) out of the 222 compliance checks concluded were done on substances of potential concern. ECHA issued 151 new draft decisions addressing non-compliances; the most common information requests were in relation to pre-natal developmental toxicity, mutagenicity/genotoxicity, reproduction toxicity, and long-term aquatic toxicity. In addition, ECHA adopted 139 compliance check decisions. Altogether, 679 standard information requests were made in ECHA decisions, with an average of five information requests per decision. The most common non-compliances addressed in the compliance check decisions were: pre-natal developmental toxicity, mutagenicity/genotoxicity, simulation testing (water, soil and sediment), long-term aquatic toxicity, reproduction toxicity, and repeated dose toxicity. These information requirements enable the identification of a substances of very high concern.

Testing proposal examination

Overall, 58 testing proposal decisions were adopted in 2017, comprising 127 requests for testing. The most common human health-related testing proposals were for pre-natal developmental toxicity and the sub-chronic 90-day toxicity study. On the environmental side, the most frequent information gaps identified by the registrants were on short- and long-term effects on terrestrial organisms and long-term aquatic toxicity. The results of these tests will inform the identification of substances of very high concern, but will also complete the information on the hazards of a substance to enable its safe use.

Follow-up evaluation of compliance check and testing proposal decisions

In 2017, 327 dossier follow-up evaluations were concluded. The outcome of the follow-up evaluations shows that of the endpoints originally identified as being non-compliant with the information requirements or where a testing proposal was submitted, 639 (85 %) are now compliant as a consequence of dossier evaluation. For the remaining 117 (15 %) endpoints, the ECHA Secretariat sent a statement of non-compliance (SONC) for 109 endpoints and launched a new decision-making process according to Article 42(1) for 8 endpoints.

Of the concluded follow-up evaluations, 67 cases were flagged as candidates for further regulatory processes, i.e. classification and labelling, substance evaluation or a new compliance check. As the first decisions based on ECHA's Integrated Regulatory Strategy's focus on selected key endpoints were made only in 2015, the first of such cases reached the follow-up stage at the end of 2017.

Progress in substance evaluation

The 2017-2019 CoRAP update, adopted on 21 March 2017, consists of 115 substances, of which 22 were scheduled for evaluation in 2017. Following the common screening round in 2017, ECHA proposed to include 107 substances in the draft CoRAP for 2018-2020 to be evaluated by the Member States.

From the previous round of substance evaluations, the evaluating Member States prepared draft decisions for 27 substances to request further information to clarify suspected concerns. For the remaining 12 substances, the evaluating Member States considered the available information sufficient to conclude on the identified concerns.

The substance evaluation process is shifting more towards follow-up assessment, and the timing depends on the deadlines set in the decisions for the registrants to submit the data. In 2017, 26 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.

ECHA adopted 31 substance evaluation decisions and published 25 substance evaluation conclusions: for 13 substances it was concluded that the risks are sufficiently controlled with existing measures, and for 12 substances it was concluded that EU-wide risk management measures are necessary.

KEY RECOMMENDATIONS TO REGISTRANTS

The following are ECHA's key recommendations to registrants based on the evaluations carried out in 2017. All recommendations and advice are available in chapter 5 of this report and on ECHA's web pages on evaluation[6].

UPDATE YOUR REGISTRATION DOSSIER WITHOUT UNDUE DELAY WHEN RELEVANT NEW INFORMATION IS AVAILABLE

- According to Article 22 of the REACH Regulation, you are responsible for updating your registration with relevant new information on your own initiative and without undue delay and submitting it to ECHA, for example in the following cases:
  - there are changes in your status as registrant;
  - there are changes in the composition of your registered substance;
  - there are changes in the annual or total quantities manufactured or imported, resulting in a change of tonnage band;
  - you have identified new uses or new uses advised against;
  - you have new knowledge of the risks of substance to human health and/or the environment;
  - there are changes in the classification and labelling of the substance;
  - you have updated or amended the chemical safety report or guidance on safe use;
  - you have identifed the need to perform a new test listed in Annex IX or Annex X to the REACH Regulation;
  - there is a change in the access granted to information in your registration.
- The new information may have an impact on the protection of human health and the environment.

JUSTIFY AND DOCUMENT YOUR WEIGHT OF EVIDENCE APPROACH

- If you propose an adaptation based on weight of evidence, the individual lines of evidence and the justification should provide a sufficient confidence level when compared to information expected with the default test. Documentation of the weight-of-evidence adaptation should be transparent and conclusions justified.
- You need to document the quality and relevance of the pieces of evidence, as well as their consistency and completeness, in relation to the standard information requirements.
- You should also address the associated uncertainties and their impact in a way that allows ECHA to assess and verify all the pieces of evidence provided in the technical dossier.

[6] https://echa.europa.eu/regulations/reach/evaluation

PROVIDE ROBUST GROUPING AND READ-ACROSS ARGUMENTS

- Use ECHA's Read-Across Assessment Framework (RAAF[7]) to check the robustness of your read-across adaptation. The RAAF describes the aspects of grouping and read-across justifications that ECHA considers to be crucial for both human health and environmental endpoints.
- In March 2017, a technical document[8] was published on ECHA's website on assessing the complexity of grouping and read-across for multi-constituent and UVCB substances. It describes the additional key issues proposed to be considered when predictions based on grouping and read-across cases involving multi-constituent substances and/or UVCBs are used to adapt standard information requirements.
- Justify the grouping and read-across approach by showing how structural similarity and dissimilarity are connected to the prediction and create a data matrix, allowing side-by-side comparison of properties of the source(s) and target substance(s).

[7] ECHA Read-Across Assessment Framework (RAAF): https://echa.europa.eu/documents/10162/13628/raaf_en.pdf.

[8] Read-Across Assessment Framework (RAAF) - Considerations on multi-constituent substances and UVCBs: https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316.

1. THE EVOLUTION OF EVALUATION AND ECHA - 10 YEARS OF EXPERIENCE

This chapter summarises the evolution, progress and achievements of evaluation activities during this 10-year reporting period, including information on the number of registration dossiers submitted to ECHA and their rate of update by industry.

1.1 Objectives of the legislation

The European Chemicals Agency (ECHA) was established in 2007 and the REACH Regulation (hereinafter REACH) entered into force on 1 June 2007. The purpose of REACH is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the European internal market while enhancing competitiveness and innovation.

REACH is based on the principle that manufacturers, importers and downstream users should ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

ECHA and the Member States of the European Union evaluate the information submitted by registrants in their registration dossiers. Dossier and substance evaluation processes are fundamental in REACH to instil confidence registrants meet their legal obligations, to ensure that unnecessary testing on animals is avoided, and to make sure that sufficient information is provided to assess and manage risks related to chemicals. After evaluation, if ECHA or a Member State competent authority considers that further information is needed, a decision requesting the missing information is issued. When the deadline set in an ECHA evaluation decision has passed, a follow-up to dossier or substance evaluation takes place, and if the dossier is found to be non-compliant, national enforcement action is initiated.

1.2 Registrations

Under REACH, there have been two registration deadlines so far, in 2010 and 2013. By the third and last registration deadline on 31 May 2018, substances produced or imported in the European Union in relatively low volumes (1 to 100 tonnes per year), such as speciality chemicals, will also have been registered.

By the end of 2017, 12 242 companies had registered their chemicals and the ECHA registration database contained a total of 67 005 registrations[9] covering 17 143 unique substances. Of these, 2 495 were manufactured in or imported to the EU in quantities of over 1 000 tonnes per year. After the 2018 registration deadline, the REACH database will contain information on all chemical substances that are manufactured and/or imported in the European Union in amounts above one tonne per year. Figure 1 presents the number of initial registrations submitted to ECHA between 2008 and 2017 by tonnage band.

[9] Comprising registrations for phase-in and non phase-in substances as well as notifications made under the previous European chemicals legislation (NONS).

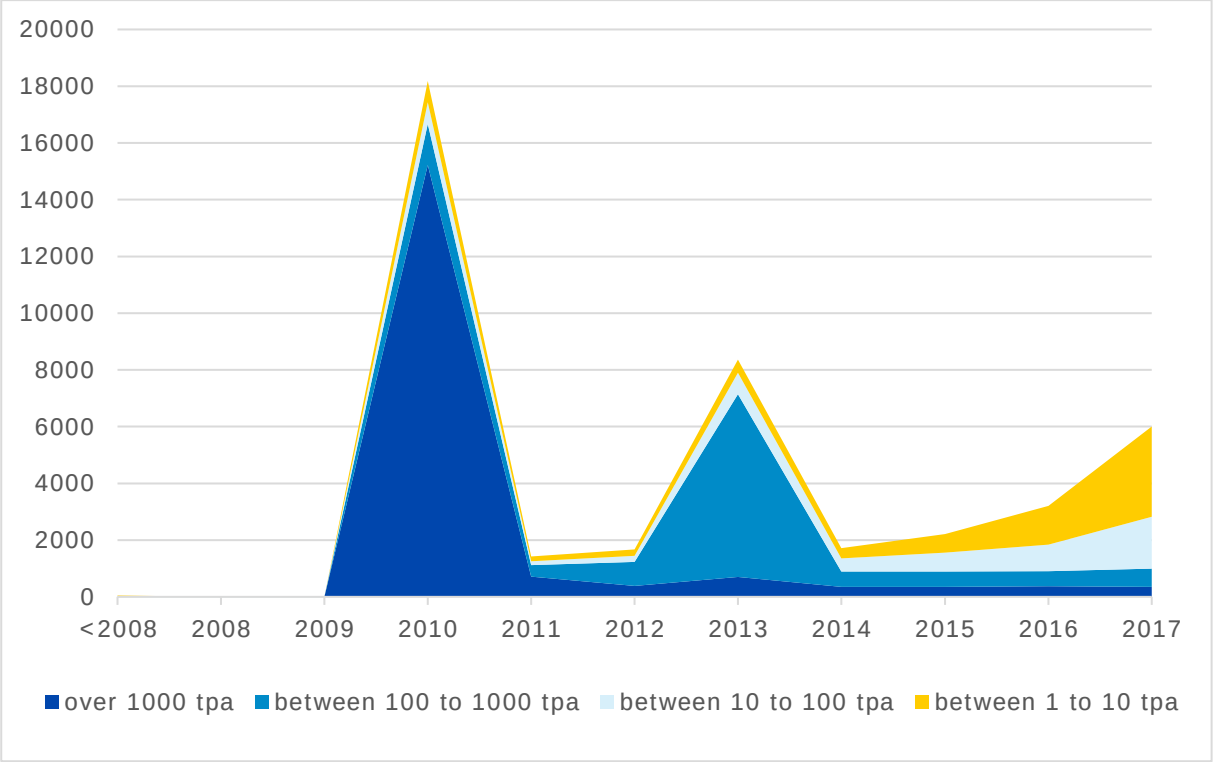


Figure 1: Initial registration dossiers submitted to ECHA in 2008-2017 grouped by tonnage band (excluding information on intermediates and NONS). The total number of initial full registrations in the ECHA database by the end of the 2017 was 56 364.

1.3 Compliance of information and the safe use of chemicals

ECHA's evaluation activities, and compliance checks in particular, are not only a legal duty but also an integral part of ECHA's strategy to improve the availability and quality of the information provided by registrants in their REACH dossiers and to ensure the safe use of chemicals in the European Union. In addition to evaluation activities, ECHA uses a range of tools to try to improve the compliance and quality of data in REACH registrations and to coordinate the development of regulatory measures to manage the risks posed by the registered substances.

1.3.1 Compliance checks

During the first years of REACH implementation, ECHA focused on establishing and building capacity in relation to the main REACH processes. The selection of dossiers for compliance checks was based on IT-screening, manual prioritisation and random selection. From 2011 to 2014, the majority of checks targeted specific parts of dossiers, so-called "areas of concern", such as substance identity, physico-chemical properties or missing environmental and human health information. The focus was on targeting easily identifiable data gaps and addressing them in a standardised manner.

By the end of 2013, ECHA reached the first regulatory milestone by meeting the 5 % target for compliance checks for the dossiers submitted for the 2010 deadline[10] (i.e. dossiers for substances that are manufactured or imported in quantities of 1000 tonnes or more per year). The experience gained from this work gave ECHA better insight into the overall quality of the information in the registration database and influenced the design and implementation of the

[10] https://echa.europa.eu/-/target-met-for-5-percent-compliance-checks-of-the-2010-registration-dossiers

Integrated Regulatory Strategy in 2015, which was developed to meet the United Nations chemicals management goals set by the World Summit on Sustainable Developments (WSSD).

The Integrated Regulatory Strategy brings all the REACH and CLP processes coherently together to achieve the aims of these two regulations. Together with Members States, ECHA has developed a common screening process, which aims to identify the substances that have the greatest potential for negative impact on human health and the environment. The common screening helps reach conclusions on which substances need to have further information submitted about them and may need to go through the compliance check, as well as on cases where there is enough information available to conclude on a concern and the substances can, where necessary, be directly earmarked for substance evaluation or for EU risk management measures. Furthermore, in 2016-2017 the focus on screening has shifted towards addressing groups of substances.

Dossier evaluation is the main tool to require further generation of hazard data when the dossier is not complying with information requirements. Under compliance check, priority is given to substances of potential concern, i.e. those substances where (i) the hazard profile for higher tier (eco)toxicity information requirements[11,12] indicates a potential concern (or the hazard profile is unclear and needs to be further examined) and (ii) where there is significant exposure potential for workers, consumers or the environment. The focus is on the key information requirements that could help to clarify if the substance is likely to be carcinogenic, mutagenic and reprotoxic (CMR) and/or (very) persistent, bioaccumulative and toxic (PBT/vPvB).

The change in strategy and moving from targeted, area-of-concern-based compliance checks towards evaluating the selected substances of potential concern is reflected in the number of concluded cases, adopted ECHA decisions and the information requests made within them. The targeted compliance checks resulted in more decisions, the typical decision containing one or two information requirements. Under the current concern-based approach, the complexity of the evaluation has increased, and also the number of information requests made in one decision has increased to five or more requests per decision in 2017 (see Figure 2). More importantly, the majority of the information requests are now more targeted for higher-tier tests, like pre-natal developmental toxicity, mutagenicity or genotoxicity, reproduction toxicity and long-term aquatic toxicity. As a consequence, the time given to registrants to comply with a decision has increased. It now takes on average two or three years from the date of issue of ECHA decision for registrants to update their dossier with the results of the requested studies. This means that the bulk of the information requested under the new integrated strategy can only be assessed by ECHA from 2019 onwards.

[11] Genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

[12] https://echa.europa.eu/documents/10162/17208/echa_cch_strategy_en.pdf/607b157b-a35d-4d1c-8e62-ce8668324b1a

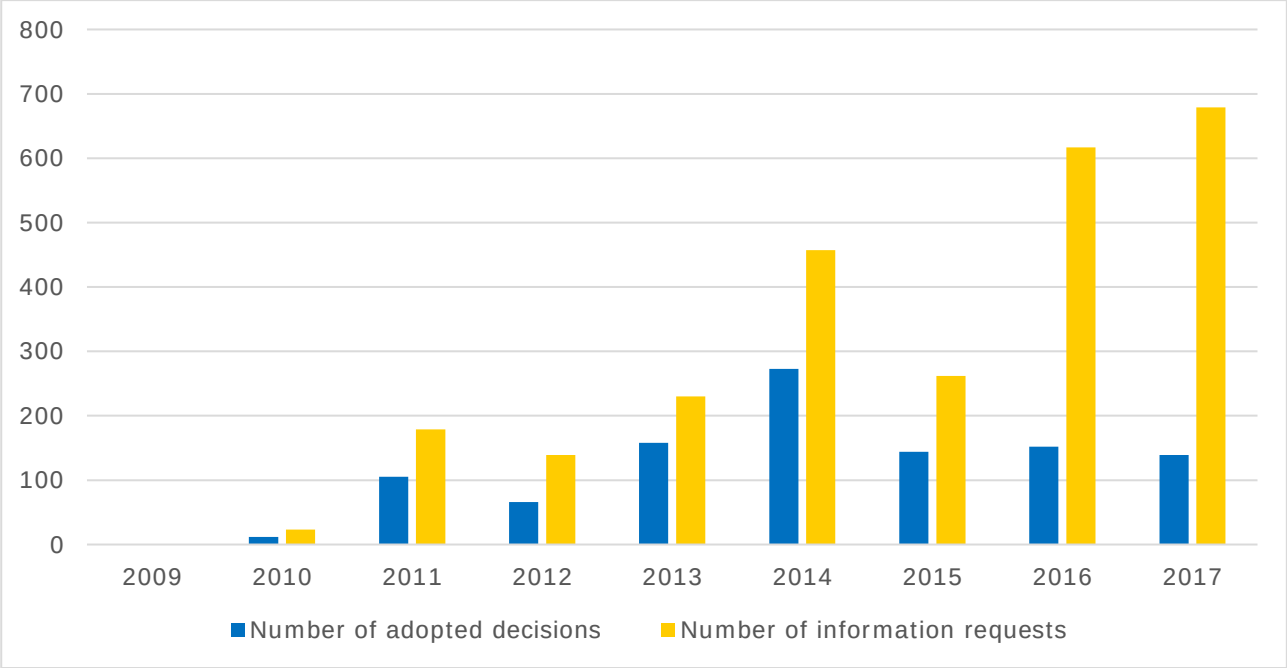


Figure 2: Concluded compliance check decisions by ECHA in 2009-2017 and the number of information requests that they contained.

Figure 3 shows the number of requests made over the years on different groups of information requirements. As explained above, under the current strategy and from 2015 onwards, the number of requests made for human heath and environment-related higher-tier tests have increased, in absolute terms and relative to other requests (e.g. in relation to substance identity), as ECHA started actively selecting and addressing dossiers with substances of potential concern. The total number of requests made in ECHA compliance check decisions by the end of 2017 was 2 582.

Non-compliance in the human health-related information requirements was most common for pre-natal developmental toxicity (first and second species), sub-chronic toxicity (90-day study), *in vitro* studies for gene mutation and/or cytogenicity in mammalian cells, and the *in vitro* gene mutation study in bacteria. For environmental information requirements, data gaps were commonly found in long-term toxicity in fish, identification in degradation products, growth inhibition in aquatic plants, bioaccumulation, and the effects in terrestrial organisms. For physico-chemical properties, the partition coefficient, water solubility, vapour pressure and the dissociation constant were the most often addressed information requirements in the ECHA decisions.

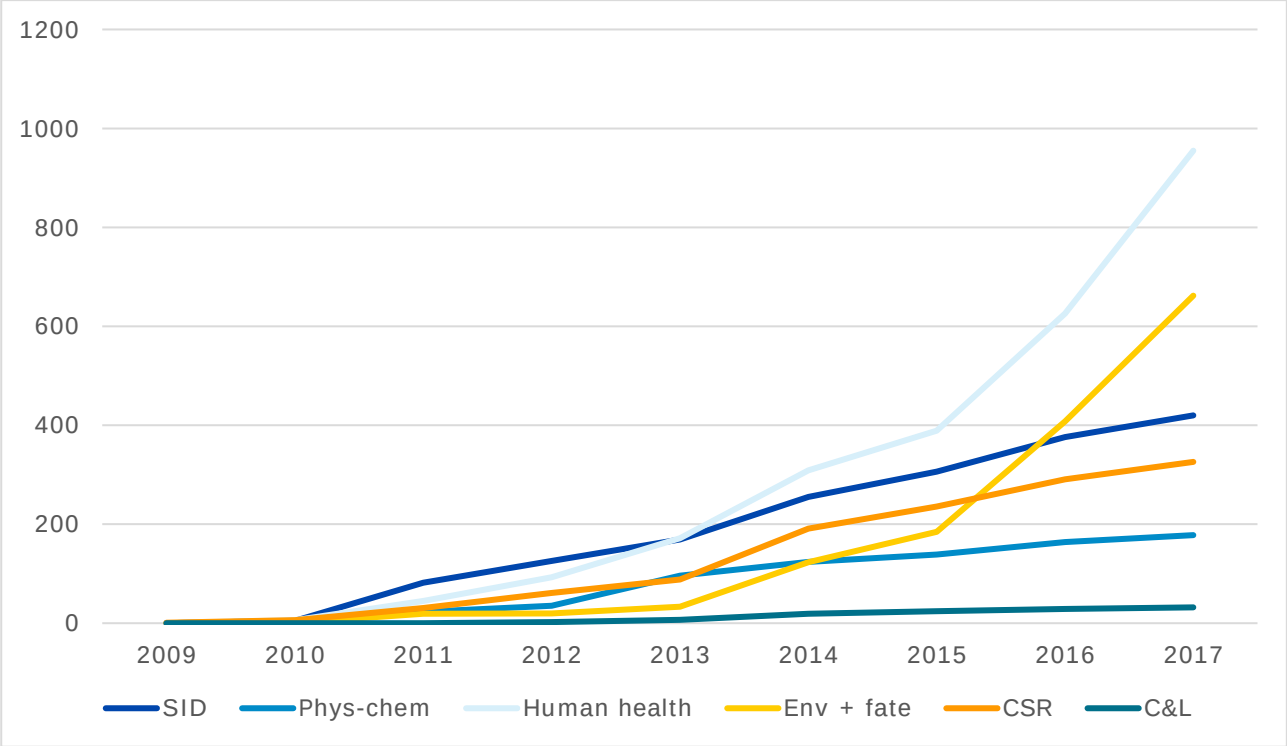


Figure 3: Cumulative number of standard information requests in the adopted compliance check decisions in 2009-2017.

Overall, ECHA has checked, to various degrees, the compliance of 1 350 (7.33 %) dossiers in the >1 000 tn/a tonnage band and 430 (3.79 %) of the dossiers in the 100-1 000 tn/a tonnage band (see Table 1 below). Due to the selection based on screening of suspected data gaps, in the vast majority of the cases (69 % and 77 % respectively), the compliance checks confirmed one or more data gaps and resulted in a ECHA (draft) decision.

Table 1: Number of compliance checks performed by tonnage band.

Tonnage band	Performed unique compliance checks				
	Concluded with DD	Concluded without DD	Total	Registration dossiers*	Percentage of registrations checked for compliance (%)
≥1 000 t/a	934	416	1 350	18 408	7.33
100 to 1 000 t/a	332	98	430	11 342	3.79
10 to 100 t/a	45	26	71	5 714	1.24
1 to 10 t/a	31	70	101	6 929	1.46
Total	**1 342**	**610**	**1 952**	**42 393**	**4.60**

* Number of unique registration dossiers; registrations of intermediates and NONSs excluded from the count.

1.3.2 Testing proposal examinations

A testing proposal needs to be included in the registration dossier if the registrant or downstream user identifies a need to perform a test that belongs to the standard information requirements for substances manufactured or imported in annual quantities of 100 tonnes or more. ECHA examines all testing proposals received. Furthermore, ECHA publishes information on its web pages on all the testing proposals that involve tests on vertebrate animals, and invites third parties to submit scientifically valid information and studies that address the relevant substance and the hazard endpoint that is subject to the testing proposal. ECHA takes

into account all information submitted and based on the information available will accept, reject, modify or ask for additional testing as necessary.

So far, ECHA has successfully met the two deadlines set in REACH (in 2012 and 2016) regarding the examination of phase-in substances' testing proposals. In the case of non-phase-in substances, ECHA examines and prepares a draft decision within 180 days of receiving a registration or downstream user report containing a testing proposal.

Since 2009, ECHA has examined 1 348 testing proposals and has issued 806 decisions (Figure 4). As part of the testing proposal examination, ECHA has launched 1 087 third party consultations and has received 826 pieces of information regarding the testing proposals under consultation.

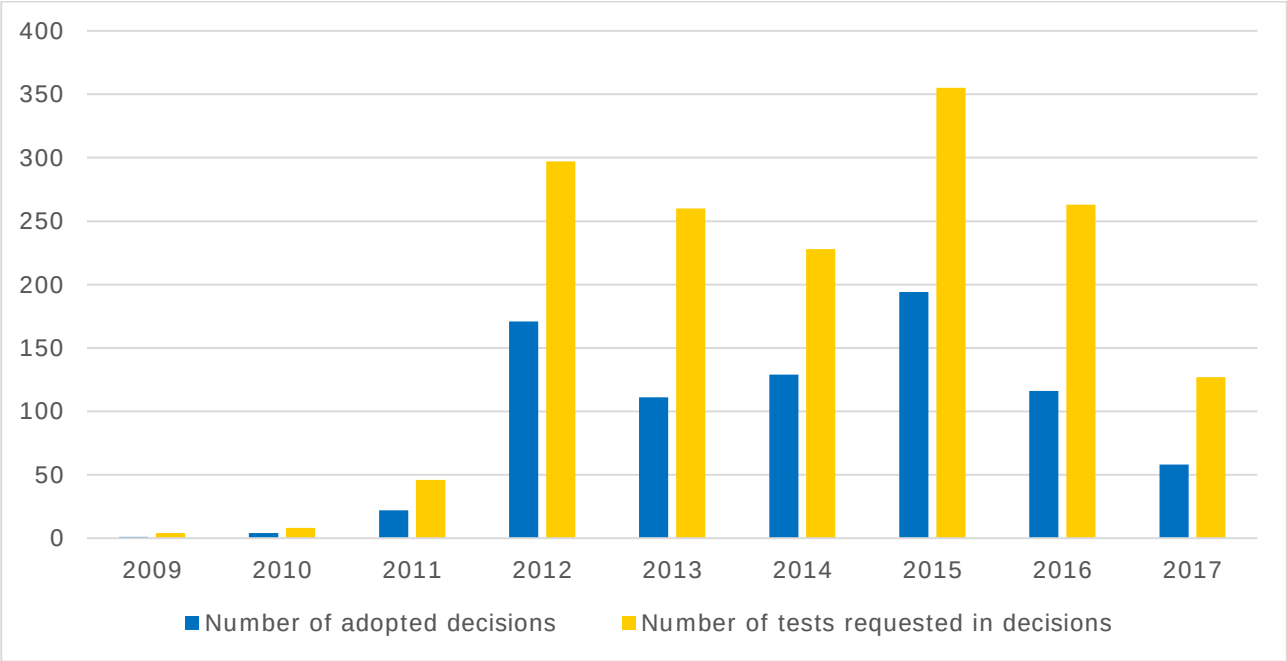


Figure 4: ECHA adopted decisions on testing proposal examinations in 2009-2017.

So far, the most common human health-related testing proposals have been for pre-natal developmental toxicity and the 90-day sub-chronic toxicity study. The most commonly proposed ecotoxicity test has been long-term toxicity testing on invertebrates. Between 2009 and 2017, the most testing proposals were submitted to ECHA to clarify the potential hazards to human health (see Figure 5 below). A total of 1 588 requests were made in the testing proposal decisions, of which 964 (61 %) were toxicological testing requests, 494 (31 %) ecotoxicological and fate testing requests, and 130 (8 %) physico-chemical testing requests.

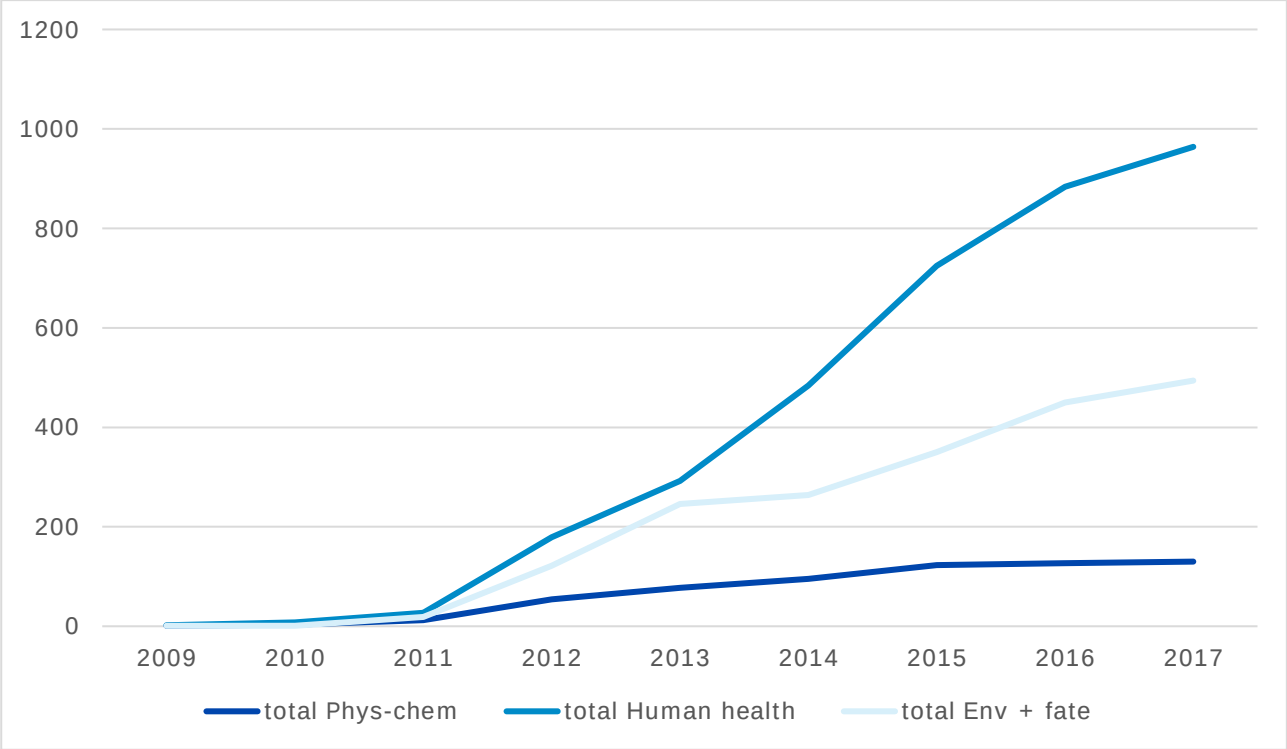


Figure 5: Cumulative number of requests made in adopted testing proposal decisions in 2009-2017 by type of test request.

1.3.3 Follow-up to dossier evaluation

Once the deadline given in the dossier evaluation decision has passed, ECHA will assess the information submitted to ECHA and verify if it complies with the decision. If it does, ECHA notifies the Commission and the Member States competent authorities of the case and the conclusions made on the received information. In the case of non-compliance, national enforcement action will be initiated.

ECHA has been adopting evaluation decisions since 2009 and the first deadlines for registrants to update their dossiers with the requested information expired in 2011. The number of decisions issued increased steadily in the first years and required a systematic approach to follow-up evaluation to be set up, which was fully established in 2013. Since then, the follow-up evaluation process has been developed further, streamlined and adapted to new and refined policies as well as newly introduced IT tools. In cases where registrants have not fulfilled the obligations set in a decision by the given deadline, ECHA has collaborated successfully with the Member States enforcement authorities to execute the decision. The annual average for such cases is around 40, including both compliance checks and testing proposal decisions. Currently, the number of follow-up evaluations carried out annually is 300 to 350 annually, with approximately 55 % originating from compliance checks and 45 % of testing proposal decisions.

In December 2016, ECHA concluded its 1000th follow-up evaluation. Since 2016 and after the Integrated Regulatory Strategy focused on substances of potential concern, ECHA has also considered more systematically if further regulatory risk management processes are needed based on the follow-up evaluation. This approach has led to notifying the Commission and the Member States competent authorities of possible candidates for harmonised classification and labelling, as well as flagging some cases for substance evaluation (see Table 2 below).

Table 2: Outcomes of the follow-up to dossier evaluation, including the flagging for further assessment and the need for regulatory risk management identified. (CCH = compliance check, TP = testing proposal.)

Outcome of the follow-up evaluation		2012	2013	2014	2015	2016	2017	Total
Article 42(2) notification*	TP	0	72	99	111	118	143	543
	CCH	2	77	136	148	201	129	692
Statement of non-compliance**	TP	2	10	27	16	17	21	93
	CCH	8	22	17	26	16	25	114
Non-compliant cases still open (recorded by the year the non-compliance was notified to the Member State authorities)***	TP	0	0	2	2	10	17	31
	CCH	1	2	2	7	8	18	38
Flags for future regulatory actions		**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Proposal for harmonised classification and labelling	TP	0	1	10	17	4	19	51
	CCH	0	0	4	1	1	16	22
Candidate for substance evaluation	TP	0	0	4	3	0	1	8
	CCH	0	0	2	0	0	1	3

* Information requirements were complied with by the deadline.
** No information provided or an unacceptable adaptation was provided.
*** No (or no adequate) information was provided by the deadline. ECHA invited MS authorities to consider enforcement actions towards the registrant. The requested information still has not been provided.

1.3.4 Substance evaluation

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

In preparation for the start of the substance evaluation process, ECHA organised workshops with, the Member State Committee (MSC) and the Commission to discuss the prioritisation criteria for inclusion of substances in the Community rolling action plan (CoRAP) as well as procedural matters. The first CoRAP was published on 29 February 2012 and contained 36 substances to be evaluated in 2012.

During 2015, a common screening process was developed in collaboration with the Member States to identify substances with the greatest potential for negative impact on human health and the environment. Furthermore, ECHA launched a review of the substance evaluation process to further reduce process time and increase time available for higher-value tasks such as expert input to cases. In addition, the first decisions by the Board of Appeal provided important feedback on the process and the substance evaluation decisions.

To provide further support in considering the best approaches to clarify the concern and any risk management measures, ECHA implemented a more structured approach for interaction with the evaluating Member State competent authorities in 2016.

Between 2012 and 2017, 221 substances were evaluated by Members State competent authorities (MSCAs). The evaluating MSCAs considered that 159 (72 %) of these required further information to clarify the suspected concerns.

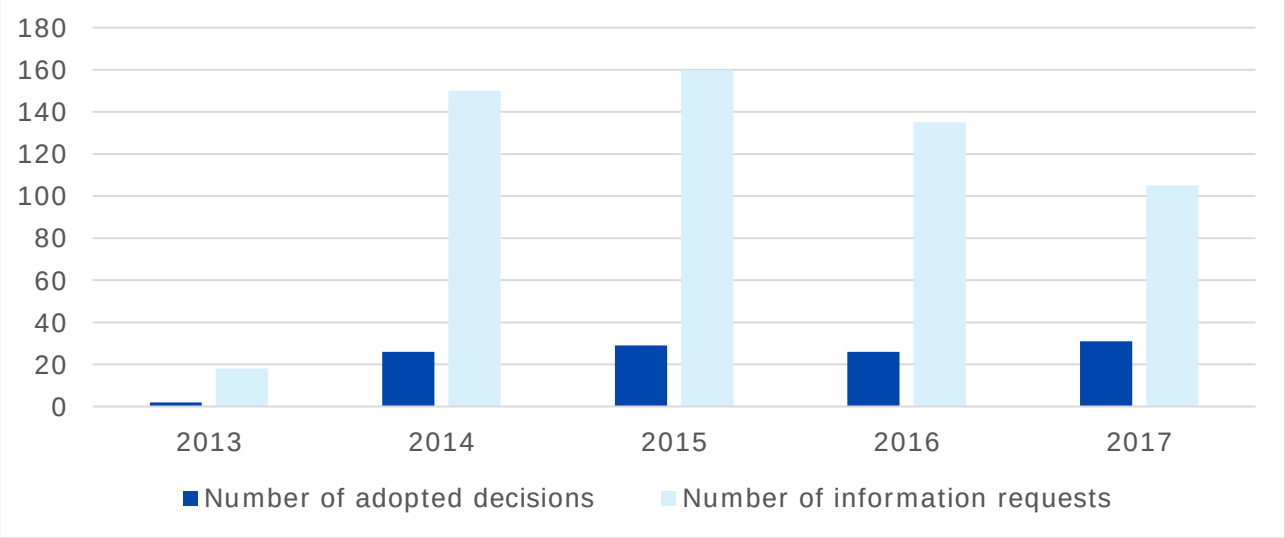


Figure 6: ECHA adopted decisions on substance evaluation in 2013-2017.

For the remaining 62 (28 %) substances, the evaluating MSCAs considered the available information was sufficient to conclude on the concerns and submitted their conclusion documents to ECHA. It is worth noting that the reported number of substance evaluations resulting in a request for further information does not take into account situations where the draft decision was subsequently terminated during the decision-making stages.

An evaluation may conclude that risks are sufficiently under control with the measures already in place (i.e. no further EU-wide regulatory action is proposed). 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.

Figure 7 below summarises the number of substance evaluation conclusions published between 2013 and 2017. These numbers include conclusions made after the evaluation of additional information requested via the decision-making process.

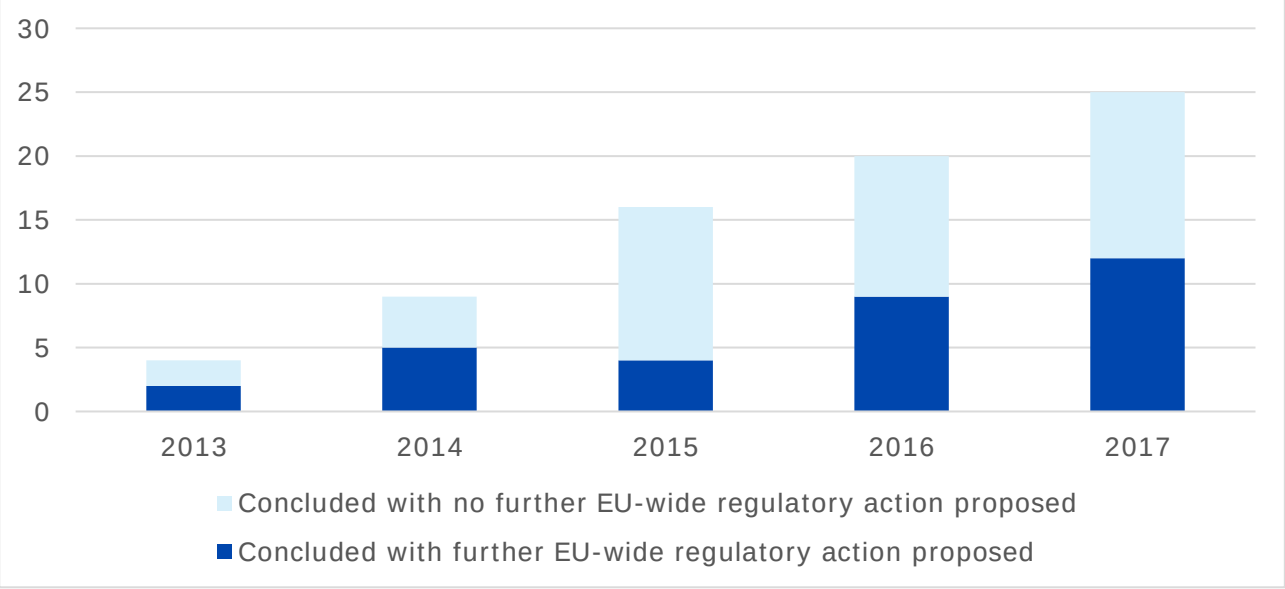


Figure 7: Substance evaluation conclusions published in 2013-2017.

Figure 8 below summarises the number and type of regulatory actions at EU level proposed within all substance evaluation conclusions published between 2013 and 2017. It is worth noting that a conclusion may propose more than one type of regulatory action at EU level.

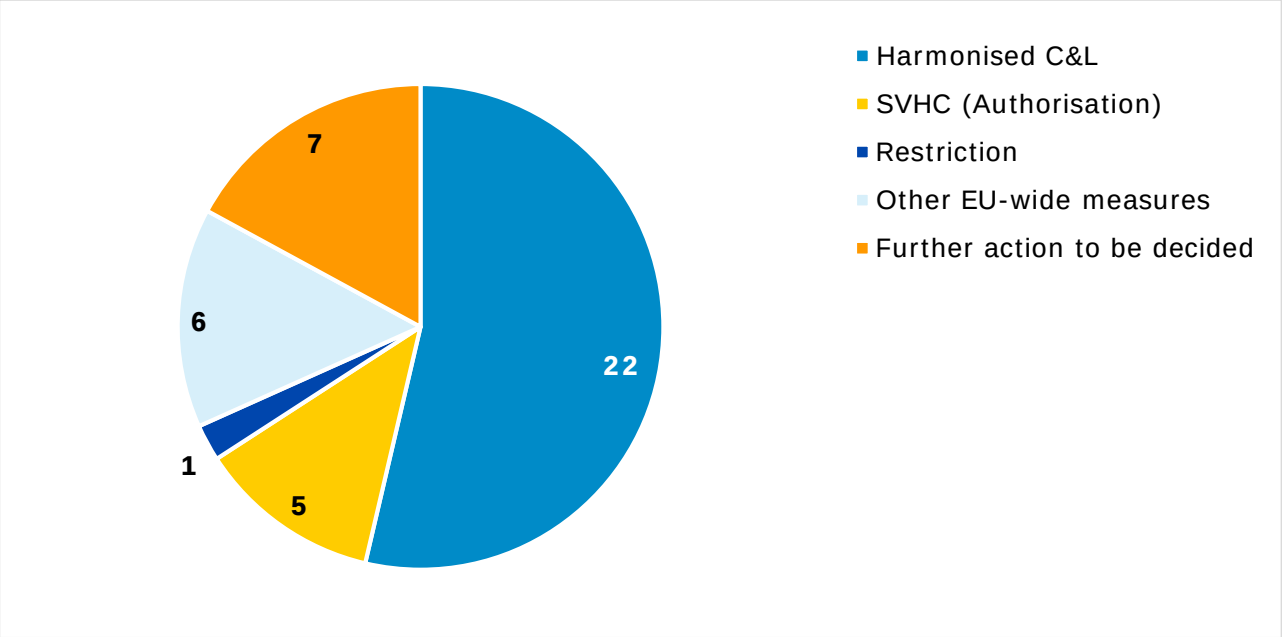


Figure 8: Regulatory actions at EU level proposed within substance evaluation conclusions published in 2013-2017.

1.4 The future of REACH evaluation

ECHA's current two main strategic objectives aim at maximising the availability of high quality information to enable safe manufacture and use of chemicals and at mobilising authorities to use information intelligently to identify and address chemicals of concern. ECHA is working towards these objectives by following its Integrated Regulatory Strategy, in close co-operation with the Member States, using common screening for selecting the dossiers and substances for evaluation and prioritising the substances of potential concern.

During the first ten years of REACH, dossier and substance evaluation have been established as the key processes for generating further information on the substances. The work continues, focusing on substances that have been registered at 100 tonnes or more and on meeting the WSSD goals. A lot of work remains to be done to maximise the availability of high-quality data and ensuring the safe use of chemicals. The focus of the screening and evaluation of dossiers and substances has moved from single substances to groups of substances and in the future ECHA will continue to strengthen this approach. ECHA will continue to improve the efficiency and effectiveness of the processes and to adapt its approaches and practices based on experience, new scientific and technical developments, including alternative methods to animal testing, learnings from litigation cases, and other feedback from its partners and stakeholders.

After the 2018 registration deadline, the new, sometimes complex and previously unknown lower-tonnage substances will bring an interesting and challenging task to ECHA and evaluation: how to identify candidates for risk reduction among the lower-volume substances with limited data available? For the 2018 registration dossiers, a new approach and plan needs to be developed. Grouping of substances is likely to play an even bigger role and due to limited standard information requirements, substance evaluation will most likely be required to request more often for data that is necessary to conclude on the key CMR and PBT properties of substances.

With this and other new challenges ahead, ECHA will continue to seek opportunities to work more closely in collaboration with Member States competent authorities and to rely on their continued investment in risk management and enforcement activities.

2. EVALUATION PROGESS IN 2017

This chapter presents the progress made in dossier and substance evaluation during 2017.

2.1 Summary of evaluation progress in 2017 in numbers

The following is a summary of evaluation progress based on the main outputs in 2017.

Dossier selection

The selection of candidates for compliance check continued to focus on substances of potential concern, in line with ECHA's Integrated Regulatory Strategy. In 2017, 315 dossiers were scrutinised as candidates for compliance check and 218 of them were selected for further processing. The other cases were for the time being not selected for compliance check due to, for example, low priority for further regulatory work or other ongoing processes. Furthermore, compliance check was opened for 25 dossiers which are planned to be subject to new substance evaluations.

New testing proposals were submitted in 104 registration dossiers. In addition, testing proposals for extended one-generation reproductive toxicity studies (EOGRTS) were submitted in 16 dossiers based on the Commission decision on the related previous testing proposal examinations or compliance checks.

Dossier evaluation

222 new compliance checks concluded, resulting in 151 draft decisions. 185 (83 %) of the compliance checks were performed on dossiers of high-priority substances. Of the 151 draft decisions, 138 were on high-priority substances, i.e. on substances of potential concern.

Overall, in all the draft decisions ECHA addressed 787 standard information requests, of which 564 were on higher-tier human health and environment endpoints. The 13 non-priority compliance check draft decisions were either targeted to substance identity or on substances not specifically shortlisted for high priority.

72 testing proposal examinations concluded. ECHA examined 72 testing proposals of which 14 were concluded with no action and 58 with a draft decision. In these drafts, 118 tests were proposed to be requested, of which 71 were tests on human health hazards, 40 on environmental hazards and fate, and 7 on physico-chemical properties.

197 dossier evaluation decisions adopted. ECHA adopted 139 compliance check decisions and 58 decisions on testing proposals, which contained 806 standard information requests in total.

327 dossier evaluation follow-up evaluations were concluded. In these follow-up evaluations, ECHA examined whether the information provided by registrants, in response to decisions adopted by ECHA, complied with REACH requirements. In 272 cases ECHA received the information requested in a compliance check or a testing proposal decision.

Substance evaluation

Community rolling action plan (CoRAP) update 2017-2019. The 2017-2019 CoRAP update was adopted on 21 March 2017, consisting of 115 substances, of which 22 were scheduled for evaluation in 2017.

For CoRAP 2018-2020, ECHA proposed to include 107 substances to be evaluated by Member States. Of these, 26 substances are expected to be evaluated in 2018, 37 in 2019, and 44 in 2020.

39 substance evaluations conducted in 2017. The evaluating Member State competent authorities prepared draft decisions for 27 substances to request further information to clarify suspected concerns. For the other 12 substances, the evaluating MSCAs considered the available information to be sufficient to conclude on the concerns.

31 substance evaluation decisions adopted. ECHA adopted 31 decisions originating from substance evaluation, requesting further information from registrants to verify the suspected concerns.

25 substance evaluation conclusions published, completing the substance evaluation. 13 of these concluded that the risks are sufficiently controlled with existing measures, and 12 concluded that EU-wide risk management measures are necessary.

2.2 Dossier selection and pre-processing

In line with ECHA's Integrated Regulatory Strategy, compliance checks continued to be opened for standard registration dossiers in tonnage bands over 100 tonnes per year which indicate high potential for exposure and have potential non-compliance in one of the eight so-called super endpoints. Moreover, in 2017 the interplay between dossier evaluation and the other REACH and CLP processes was further strengthened by focusing the compliance check selection to substances that have uncertain priority for regulatory risk management due to lacking hazard information as it was then not possible to confirm or refute that the substance is of concern.

Another enhancement was that candidates for compliance check were selected increasingly in groups or pairs of similar substances based on structural similarities and read-across, or in categories applied by the registrants or regulatory bodies. Such grouping was applied both in ECHA's own selection and in the common screening[13]. Groups of substances having uncertain priority for regulatory risk management were processed by ECHA as candidates for compliance check and groups having suspected concerns were directed to common screening. However, later the manual screening also concluded on some of the groups that a compliance check may be needed to be able to confirm or refute a suspected concern. In 2017, the majority of compliance check candidates originated from ECHA's own IT based selection and manual screening of substances having uncertain priority for regulatory risk management (83 %) (see Figure 10 for the breakdown of sources for compliance check candidates).

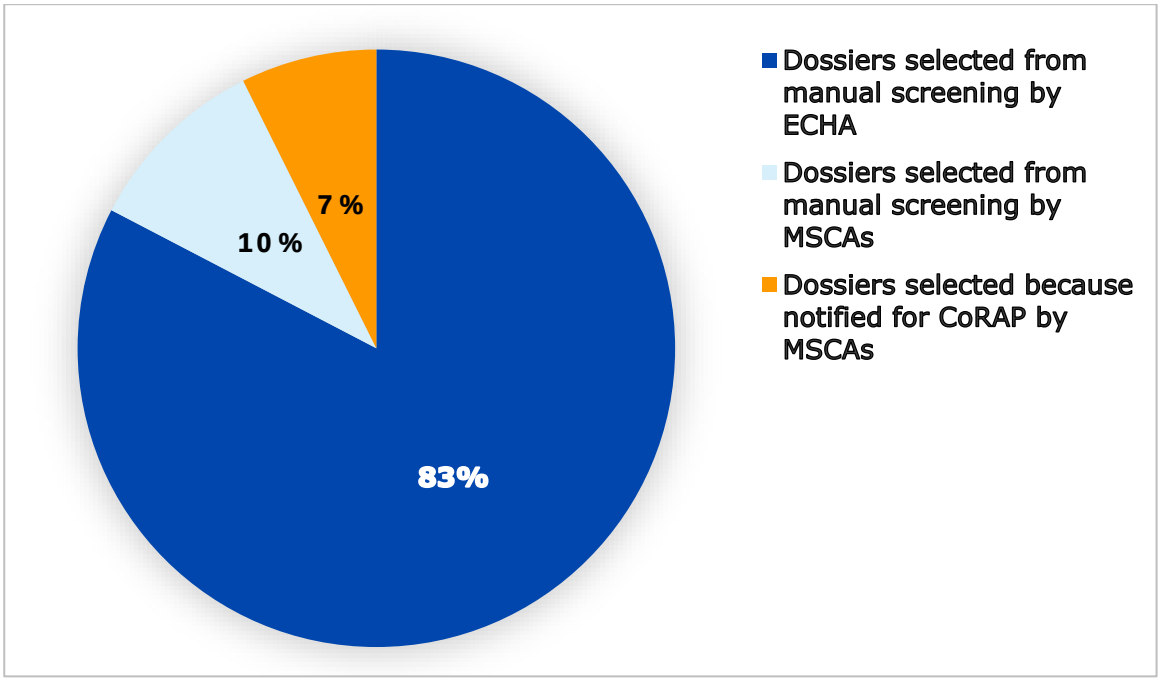


Figure 10: Breakdown of sources for 315 compliance check candidates in 2017.

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 2017, 315 dossiers were scrutinised as candidates for compliance check and 212 were selected for further processing. In addition, the dossiers which were planned to be subject to substance evaluation were directly taken for compliance check.

[13] Further information on common screening: https://echa.europa.eu/screening.

After pre-check, 50 candidate dossiers were considered to be of low priority for further regulatory work – three of them based on low potential for exposure only and 47 due to low toxicity or other low priority. An overview of the reasons for early termination of 96 compliance check candidates in 2017 are given in Figure 11. No compliance check will be currently opened for these dossiers, but the need for compliance check may be reconsidered in the future based on new information on, for example, uses and exposure.

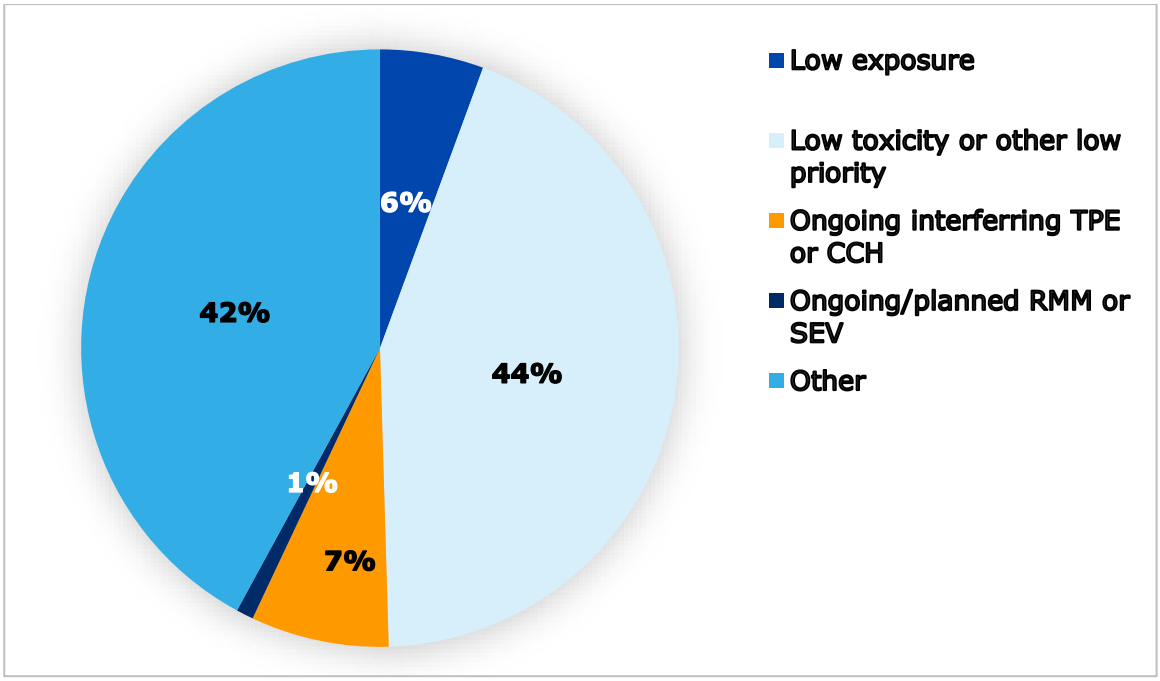
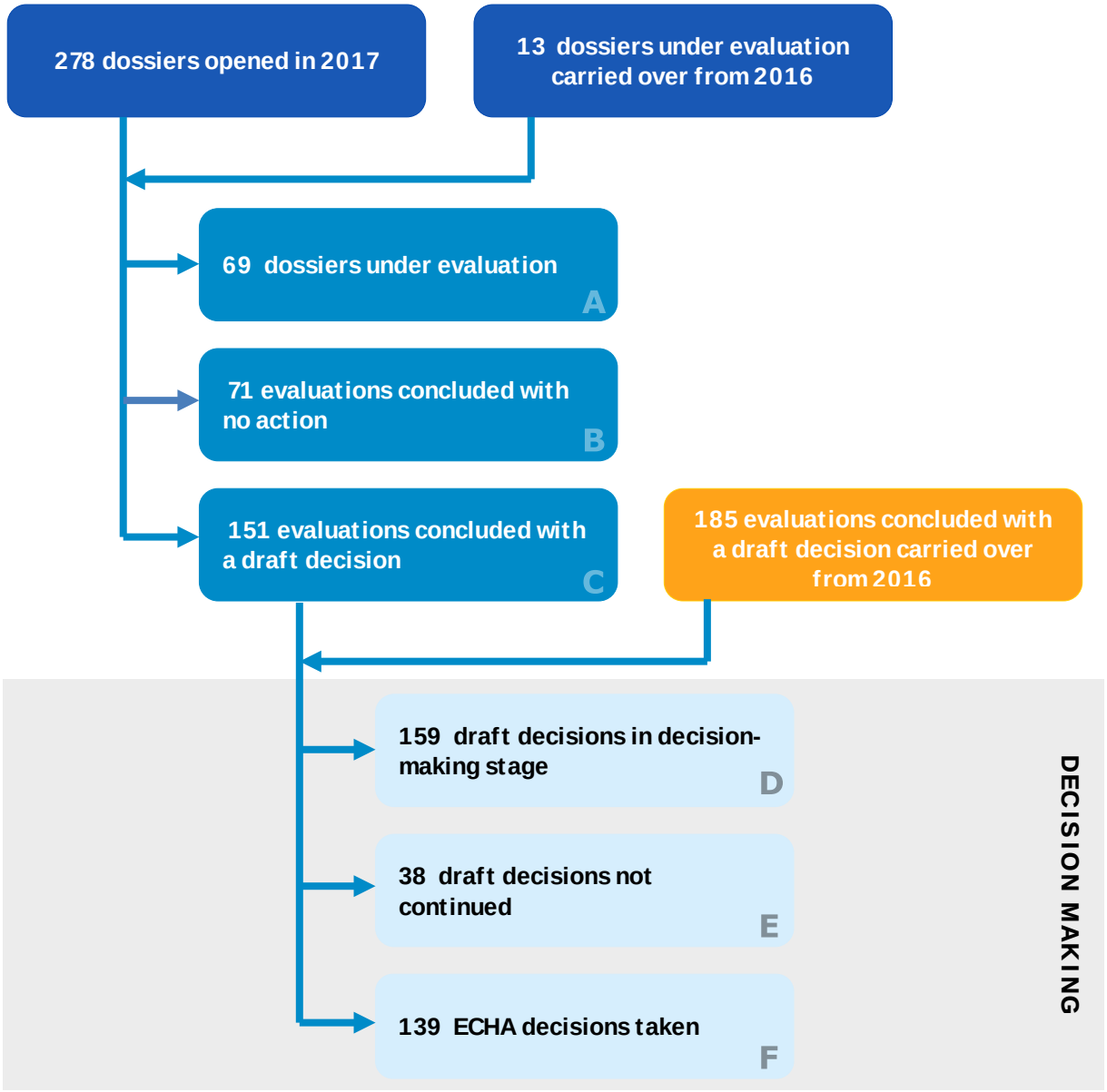


Figure 11: Reasons for early termination of 96 compliance check candidates in 2017. Other reasons include e.g. cease of manufacture, and the substance being a member of a large category to be evaluated later. Note that in a few instances several reasons may apply for the same case – for example, a reason based on human health-related endpoints may be different to one based on environment-related endpoints.

2.3 Compliance checks

2.3.1 Compliance check overall

Figure 9 below presents the overall compliance check process in 2017.



[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 9: Number and outcome of compliance checks in 2017.

2.3.2 Scientific and legal assessment

In total, ECHA checked 222 dossiers for compliance during 2017. In 151 (68 %) of these, ECHA concluded that the non-compliances found were severe enough to require further action and generation of new information. Consequently, ECHA prepared draft decisions requesting registrants to submit the missing information.

Clarity of the substance identity (SID) information is a prerequisite for ensuring that the dossier complies with the information requirements. If the provided SID information allows ECHA to interpret the scope of the registration, the assessment turns to the REACH information requirements on physico-chemical and hazard data in the technical dossier.

However, if the substance identity information is not clear enough to meaningfully assess the rest of the dossier, ECHA will issue a substance identity-targeted compliance check (draft) decision. In the context of the evaluation process in 2017, substance identity issues were addressed in 36 draft decisions containing also other types of information requirements. In 22 cases, substance identification issues were clarified due to informal calls made to the registrant that resulted in dossier updates where such issues were clarified and solved.

In 71 (32%) of the compliance checks[14], ECHA concluded that the generation of new information was not needed or that requesting it was not proportionate, and therefore no further action was required. Table 3 below summarises the overall compliance check conclusions, grouped by registration tonnage band, made during 2017. This result reflects only indirectly 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.

Table 3: Compliance checks concluded in 2017 with a draft decision or without action, by tonnage band.

Tonnage band	Performed CCHs		
	Concluded with DD	Concluded without action	**Total**
≥1 000 t/a	54	34	**88**
100 to 1 000 t/a	86	29	**115**
10 to 100 t/a	9	7	**16**
1 to 10 t/a	2	1	**3**
Total	**151**	**71**	**222**

Focusing on the substances of potential concern

The Integrated Regulatory Strategy is effectively addressing the dossiers and substances of potential concern. Since 2015, compliance checks have been focused on eight key standard information requirements of Annexes IX and X to REACH. 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.

Out of the 222 compliance checks concluded in 2017, 185 (83 %) were performed on priority substances, and 138 of these resulted in draft decisions.

[14] B within Figure 9

Overall, in these 138 priority draft decisions ECHA addressed 735 information requests, of which 537 were focused on the eight key standard information requirements of concern (see Table 4). 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 the dossiers selected for compliance check in the common screening contain important data. In 2017, ECHA also issued 13 non-priority draft decisions with 62 information requirements, of which 27 were on the key information requirements. On average, in 2017 a draft decision contained over five information requests, of which three to four were for higher-tier tests.

Table 4: Information requests made in the compliance check draft decisions in 2017.

Endpoint	Priority CCH	Non-priority CCH	Total requests
	Number of requests in the 138 draft decisions	Number of requests in the 13 draft decisions	Number of requests in all the 151 draft decisions
Repeated-dose toxicity	65	6	71
Mutagenicity / genotoxicity	97	5	102
Pre-natal developmental toxicity	121	7	128
Reproduction toxicity*	83	7	90
Carcinogenicity	0	0	0
Long-term aquatic toxicity	84	2	86
Biodegradation	66	0	66
Bioaccumulation	21	0	21
Other endpoints	198	35	233
Total	**735**	**62**	**797**

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

Evaluating groups of substances

In 2017, ECHA started pilots with selected groups of priority substances for which registrants had proposed a read-across and grouping approach for the key endpoints and initiated informal interaction on how to most effectively address such groups of substances and dossiers and to ensure their compliance with information requirements. One such pilot addressed a category of 14 substances. The novelty of the approach was to involve registrants in discussion on shortcomings and data gaps and agree on the testing strategy before formal compliance check was initiated. The draft decision itself is also different from a standard case as it addresses all the substances of the category in one single document. As the decision making of this pilot is still ongoing, it is too early to report on its results. However, ECHA expects that this type of approach could help bring groups of dossiers to compliance faster, potentially using fewer resources and involving fewer vertebrate tests.

2.3.3 Decision making

The decision-making part of dossier evaluation starts when ECHA sends the compliance check draft decisions to registrants for comments. As part of the current 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. The opportunity is well received and the registrants frequently use it to discuss with ECHA the reasons behind decisions taken. In addition, during 2017, 65 % of registrants used their right to comment on ECHA draft decisions.

After the registrants' commenting period and after addressing the comments, ECHA refers the draft decision to the Member State competent authorities and they 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. In addition, the registrant concerned is always invited to comment on the PfAs within 30 days and the Member State Committee takes those comments into account in the decision making.

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

During 2017, ECHA adopted 139 decisions[15] under compliance checks and closed 38 cases[16] after a draft decision. Two draft decisions were referred to the Commission for decision making, both related to the design of the extended one-generation reproductive toxicity study design.

2.3.4 Information requested in ECHA adopted compliance check decisions

Figure 12 below summarises the types of information requested in ECHA's 139 adopted compliance check decisions in 2017. Altogether, ECHA adopted decisions contained 679 standard information reguests, on average 4.9 information requests per decision. The most common incompliances addressed in the 2017 decisions were pre-natal developmental toxicity, mutagenicity/genotoxicity, simulation testing (water, soil and sediment), long-term aquatic toxicity, reproduction toxicity, and repeated-dose toxicity.

[15] F within Figure 9.
[16] E within Figure 9.

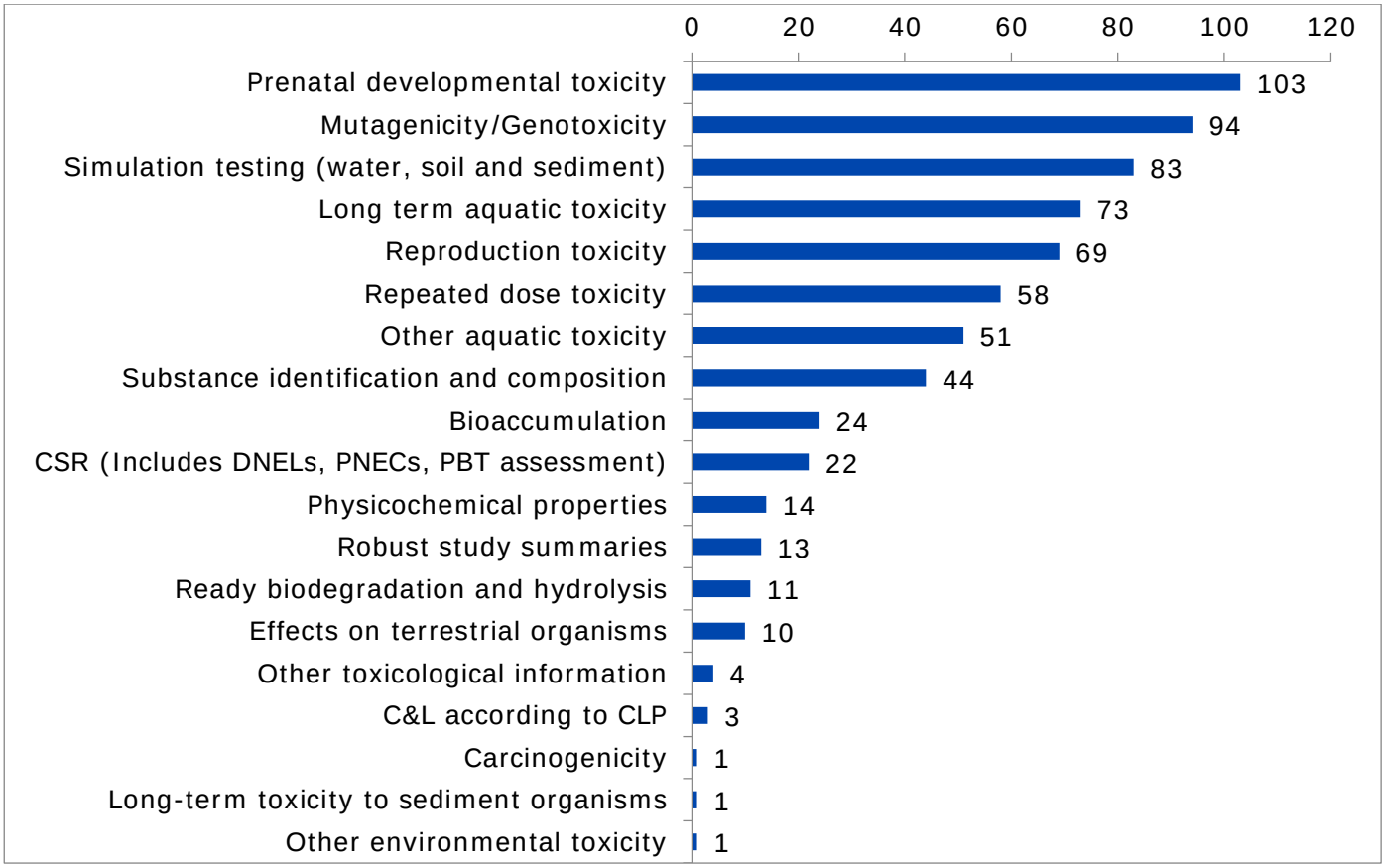


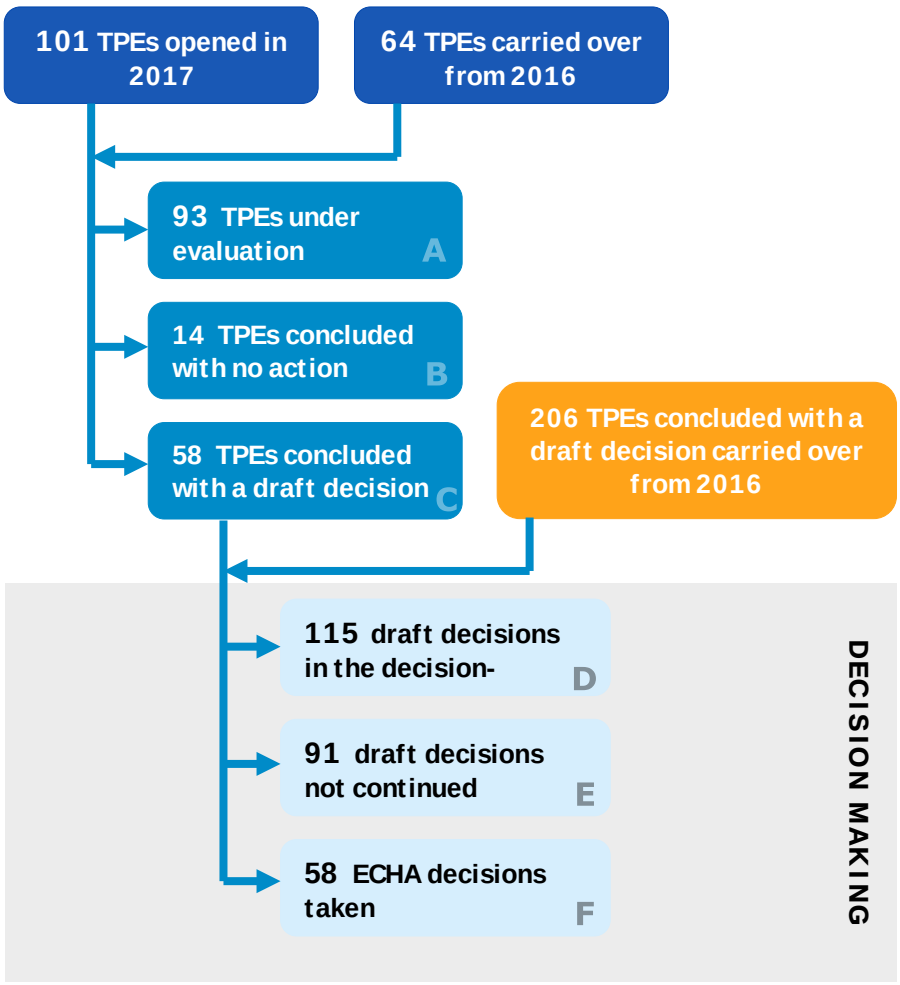
Figure 12: Information requested in the 139 adopted ECHA compliance check decisions in 2017. Altogether, the decisions contained 679 standard information reguests.

2.4 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. The legal text sets a deadline for ECHA to prepare a draft decision for certain types of testing proposals.

Figure 13 below 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. Of the 91 cases 73 were formally closing the cases that the Commission had adopted decisions on.
[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 13: Number and outcome of testing proposal examinations processed in 2017.

2.4.1 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 submit their considerations on alternatives to their testing proposals involving vertebrate animals.

ECHA publishes[17] 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. All valid information is 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 2017, third party consultations were launched for 67 substances. As a response to these consultations, ECHA received eight sets of information.

2.4.2 Testing proposal examination

ECHA concluded a total of 72 testing proposal examinations[18] during 2017. For 58 (81 %) of these[19], ECHA sent draft decisions to the registrants, while in 14 cases (19 %)[20], no further action was necessary because either the registrant withdrew the proposal after ECHA started to examine it, or the testing proposal was not admissible.

Table 5 below lists the type of tests included in the testing proposal draft decisions sent for registrants' comments. Altogether, 118 requests were included in the 58 testing proposal draft decisions that were sent to registrants in 2017. The most common testing proposals, accounting for over half (53 %) of all testing proposals examined, were for: pre-natal developmental toxicity, sub-chronic toxicity study (90-day), pre-natal developmental toxicity study, and extended one-generation reproductive toxicity study.

[17] http://echa.europa.eu/information-on-chemicals/testing-proposals
[18] B+C within Figure 13.
[19] C within Figure 13.
[20] B within Figure 13.

Table 5: List of requests made in the ECHA testing proposal draft decisions during 2017. Altogether 58 testing proposal draft decisions were sent to registrants.

Endpoint	Total
Pre-natal developmental toxicity (Annex IX, 8.7.2)	29
Sub-chronic toxicity study 90-day (Annex IX, 8.6.2)	20
Pre-natal developmental toxicity study (Annex X, 8.7.2)	7
Extended one-generation reproductive toxicity study (Annex X, 8.7.3)	7
Long-term toxicity to aquatic invertebrates (Annex IX, 9.1.5)	7
Effects on soil micro-organisms (Annex IX, 9.4.2)	7
Long-term toxicity to fish (Annex IX, 9.1.6)	6
Short-term toxicity to plants (Annex IX, 9.4.3)	5
Dissociation constant (Annex IX, 7.16)	5
Simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2)	4
Short-term toxicity to invertebrates (Annex IX, 9.4.1)	4
Mutagenicity, *in vivo* (Annex IX, 8.4)	3
In vitro gene mutation study in mammalian cells (Annex VIII, 8.4.3)	2
Long-term toxicity to invertebrates (Annex X, 9.4.4)	2
Long-term toxicity to plants (Annex X, 9.4.6)	2
Viscosity (Annex IX, 7.17)	2
In vitro gene mutation study in bacteria (Annex VII, 8.4.1)	1
In vivo mammalian alkaline comet assay (Annex VIII, 8.4)	1
Mutagenicity (Annex X, 8.4)	1
Bioaccumulation in aquatic species (Annex IX, 9.3.2)	1
Long-term toxicity to terrestrial invertebrates (Annex IX, 9.4.4)	1
Long-term toxicity to sediment organisms (Annex X, 9.5.1)	1
Total number of requests	**118**

2.4.3 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 to informally discuss the scientific rationale behind the draft decision with ECHA during their 30-day commenting period. During 2017, 45 % of registrants commented on the ECHA draft decision.

After the draft decision is notified to them, the Member State competent authorities can submit their PfAs on the ECHA decision. In 2017, ECHA notified 46 testing proposal draft decisions to Member State competent authorities and received PfAs on 15 (33 %) of them. Eight decisions which received PfAs were agreed during Member State Committee written procedure, another five decisions (33 %) were unanimously agreed and adopted in the Member State Committee meeting, while the deadline to agree on the last two decisions (14 % of the cases with PfAs) falls in early 2018. The other 31 (67 %) testing proposal draft decisions that were notified to Member State competent authorities in 2017 did not receive any PfAs and were adopted without amendment.

In 2017, ECHA adopted 58 decisions[21] under testing proposal examination and closed 91 cases[22] after draft decisions. For the closed cases, 73 draft decisions were ones that had been referred to the Commission for decision making in 2012-2014, and the evaluation process was now closed due to a decision taken by the Commission. Other reasons for closing an examination were dossier updates where the registrants removed their testing proposals (15 cases), manufacture of the substance having been ceased (2 cases), or a wrong submission number having been used (one case).

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 REACH and it can relate to either acceptance, modification or rejection of the original testing proposal. Table 6 below summarises the types of testing requested and the TPE decisions adopted during 2017. It is important to note that a decision may contain more than one request.

Table 6: Summary of ECHA testing proposal decisions adopted in 2017.

Endpoint	TPE adopted decisions					
	Accepted under Article 40(3)(a)	Modified under Article 40(3)(b)	Additional testing requested under Article 40(3)(c)	Rejected under Article 40(3)(d)	Original test rejected under Article 40(3)(d) and additional testing requested under Article 40(3)c*	Total number of requests evaluated
Pre-natal developmental toxicity	27		3		8	**38**
Sub-chronic 90-day toxicity	15	2			6	**23**
Effects on terrestrial organisms	12		3		1	**16**
Long-term aquatic toxicity	7		4	1	3	**15**
Extended one-generation study	1	3		2	3	**9**
Mutagenicity/genotoxicity	6			1	2	**9**
Other aquatic toxicity			9			**9**
Simulation tests (water, soil, sediment)	3					**3**
Viscosity	2					**2**
Short-term 28-day toxicity	1					**1**
Bioaccumulation in aquatic species	1					**1**
Dissociation constant	1					**1**
Total	**76**	**5**	**19**	**4**	**23**	**127**

*The combination of rejection and requesting additional testing may be used for example with testing proposals with an analogue test material or when a test different to the one originally proposed is requested.

[21] F within Figure 13.
[22] E within Figure 13.

2.4.4 Information requested

In the 58 testing proposal decisions that were adopted in 2017, a total of 127 requests were made (see Table 6). The most common human health-related testing proposals were pre-natal developmental toxicity and sub-chronic repeated-dose toxicity (90-day). On the environmental side, the effects on terrestrial organisms and the long-term aquatic toxicity were the most frequent data gaps identified by the registrants.

2.5 Follow-up to dossier evaluation

Under Article 42 of REACH, ECHA examines the information provided by registrants in response to evaluation decisions in their dossier updates and considers whether the information complies with 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[23].

As in previous years, ECHA continued to inform the Member States enforcement authorities with statements of non-compliance (SONCs) following a dossier evaluation decision and to invite them to consider enforcement actions towards the registrants when some or all of the requests in a decision were not complied with. In some cases, a new consultation as per Articles 50 and 51 of REACH was initiated where a registrant submitted – in response to a decision – information which is substantial and new but still not sufficient to meet the initial request.

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 frame.

In 2017, ECHA concluded the evaluation process after follow-up evaluation in 272 cases, which are summarised in Table 7. In 31 of these cases, ECHA was able to close the SONC with an Article 42(2) notification following a dossier update by the registrants after the national enforcement authorities had been involved in the case. In addition, ECHA issued 46 new SONCs, of which 35 were not resolved by the end of the year. At the end of 2017, there were 76 unresolved SONCs that had been notified to the Member States authorities since 2012.

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

Table 7: Number and outcome of follow-up evaluations conducted in 2017.

Decision type	Outcome			
	Information requirements were complied with by the deadline	Information requirements were complied with after involving national enforcement authorities*	Information requirements were not complied with**	Information requirements were not complied with and a new decision was needed***
TPE decisions	131	12	17	5
CCH decisions	110	19	18	3
Total	241	31	35	8

* No (or no adequate) information was provided by the deadline. ECHA invited MSCAs to consider enforcement actions towards the registrant. This lead to a dossier update with sufficient information.
**No (or no adequate) information was provided by the deadline. ECHA invited MSCAs to consider enforcement actions towards the registrant. The requested information still has not been provided.
***New substantial information has been provided but the information requirement was not met.

Table 8 provides a summary of the outcome of the follow-up evaluations performed in 2017, by endpoint or group of endpoints. It is important to note that a follow-up evaluation outcome may contain both compliant and non-compliant endpoints.

Table 8: Number and outcome of the follow-up evaluations conducted in 2017, by endpoint.

Endpoint	Outcome		
	Compliant endpoints after follow-up evaluation*	Compliant endpoints with adaptations (e.g. read-across, weight of evidence)**	Non-compliant endpoints after follow-up evaluation***
Substance identity	121	1	18
Physical/chemical properties	16	2	3
Biodegradation	4	0	3
Bioaccumulation	6	1	3
Other environmental fate/behaviour	3	1	4
Long-term aquatic toxicity	34	10	15
Other ecotoxicological hazard	72	7	18
Mutagenicity/genotoxicity	33	1	9
Carcinogenicity	1	0	1
Repeated-dose toxicity	94	11	15
Pre-natal developmental toxicity	129	13	22
Reproduction toxicity	1	1	0
Other human health hazard	9	6	2
CSR	62	0	4
Total	**585**	**54**	**117**

* Including "full correspondence" and "acceptable with deviations".
** The registrant did not provide the requested data, but an acceptable adaptation instead (regardless of any ECHA's pre-approval in evaluation).
*** No information provided or an unacceptable adaptation was provided. ECHA sent SONC or launched a new decision making to invite the Member States to consider enforcement actions.

The outcome of the 2017 follow-up evaluations shows that 639 (85 %) of the endpoints originally identified (by compliance checks or submission of a testing proposal) as non-compliant with REACH information requirements are now deemed compliant as a consequence of dossier evaluation. For the remaining 117 (15 %) endpoints that were deemed non-compliant, ECHA sent a SONC for 109 endpoints and launched a new decision-making process according to Article 42(1) for 8 endpoints.

Table 9: Conclusions made in 2017 based on the received information leading to possible further regulatory actions.

Endpoint	Outcome		
	Proposed cases as possible candidates for harmonised classification and labelling	Proposed cases as possible candidates for substance evaluation	Proposed cases for opening a new compliance check after follow-up evaluation*
TPE decisions	19	1	20
CCH decisions	16	1	10
Total	**35**	**2**	**30**

* Information requirements were fulfilled for the requested endpoints, but new data indicated concerns for other endpoints.

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. In 2017, 67 cases were flagged as candidates for further regulatory processes, i.e. classification and labelling, substance evaluation, or a new compliance check. However, as the regulatory strategy to focus on selected key endpoints was adopted only in 2015, the first of such cases reached the follow-up stage only towards the end of 2017.

2.6 Substance evaluation

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

The 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 MSCA has, for those substances to be evaluated in the first year[24], 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[25].

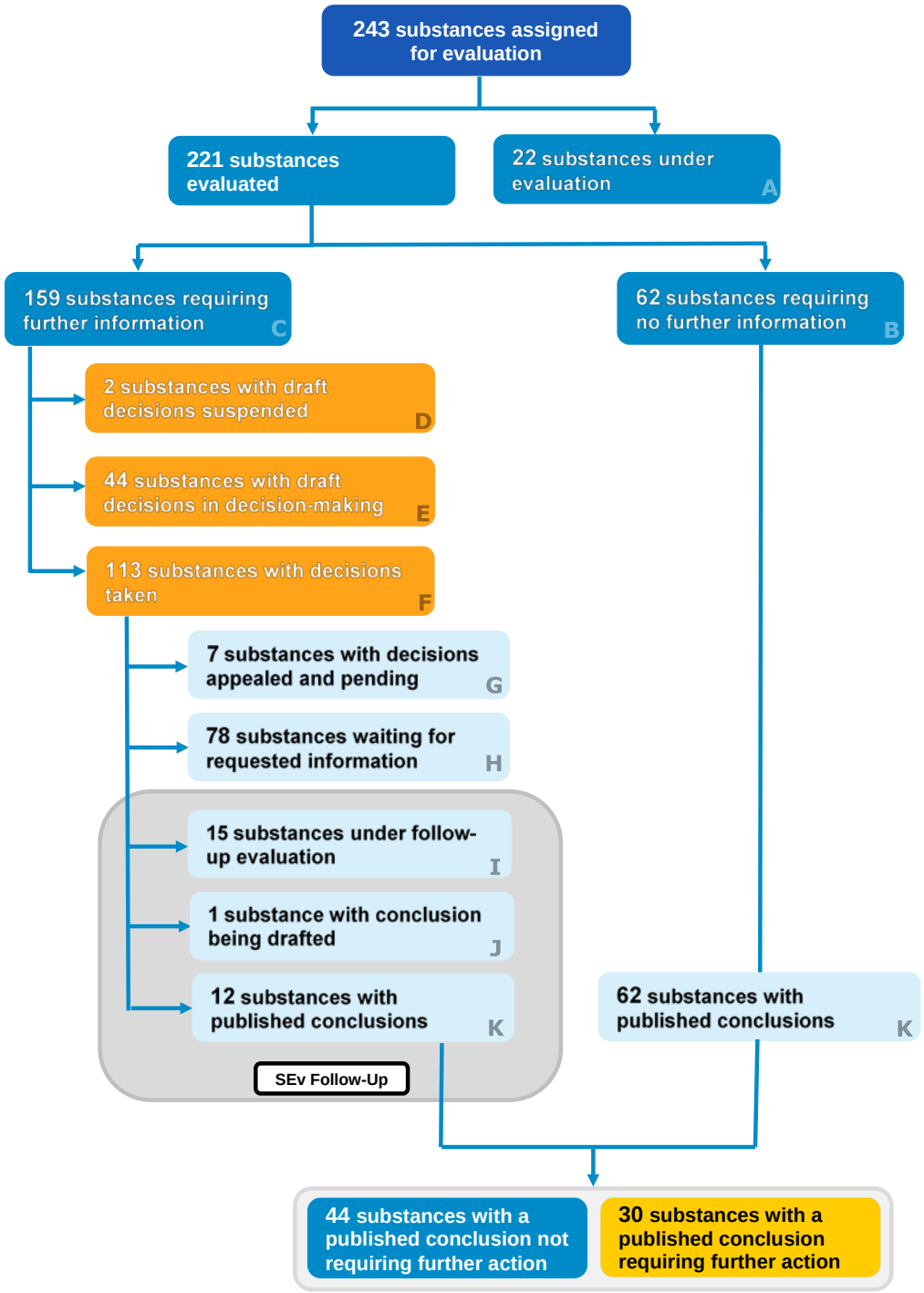
To further improve the effectiveness and efficiency of the substance evaluation process, a workshop on Substance Evaluation within the Integrated Regulatory Strategy was hosted by ECHA during October 2017. The aim of the workshop was to:

[24] 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.

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

- review the substance evaluation process and its contribution to the Integrated Regulatory Strategy;
- consider ways of amplifying the outcomes and impact of substance evaluation;
- reinforce the collaboration between ECHA, Member State competent authorities and registrants throughout the process;
- ensure efficient interplay with dossier evaluation and other regulatory processes;
- strengthen the follow-up evaluation and conclusion phases as well as the interface with regulatory risk management measures;
- discuss legal issues and learnings from appeals on substance evaluation decisions.

Figure 14 on next page provides an overview of the current status of the 243 substances published within the CoRAP for evaluation between 2012-2017.



[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 14: Status of all substance evaluations started in 2012-2017 at the end of 2017.

2.6.1 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[26], before applying them to identify substances with potential concerns. The selection of substances originates from the common screening that lies at the core 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 adopted CoRAP update is published on ECHA's website[27]. Its content is also included in the dynamic overview table of all substances[28].

The justification document prepared by the evaluating MSCA describes the scientific grounds of the initial concerns which require further clarification under substance evaluation, and it also informs on possible follow-up actions considered by the evaluating MSCA.

The CoRAP 2017–2019 update[29] was adopted on 21 March 2017 and contained 115 substances. The list contained 22 newly-selected substances and 93 substances carried over from the existing CoRAP. The lower number of selected substances is mainly due to the need to wait for important standard information gaps to be closed under a preceding compliance check. This standard information is considered necessary in deciding what further information should be requested under substance evaluation and, in some cases, it may even be sufficient to draw conclusions on the concern.

ECHA forwarded the draft of the subsequent CoRAP update 2018-2020 to the Member State Committee for opinion seeking on 13 October 2017, and published the draft on 24 October 2017[30]. The draft list contained 107 substances, with 26 substances planned to be evaluated in 2018. The list contained 16 newly-selected substances and 91 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 2018–2020 update in March 2018. Further information on the CoRAP is provided on ECHA's web pages[31].

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

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[26] http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf
[27] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
[28] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[29] https://echa.europa.eu/documents/10162/13628/corap_update_2017-2019_en.pdf/6a394595-a4e5-0e10-ec66-eabdc55ce7f6
[30] https://echa.europa.eu/documents/10162/13628/corap_list_2018-2020_en.pdf/3be44b84-5d72-01fe-f8d7-3a5a9c27951e
[31] https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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

2.6.2 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.

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.

ECHA maintains regular interaction with evaluating MSCAs throughout the intial 12-month evaluation period. This early interaction between ECHA and the evaluating MSCA was introduced to increase efficiency and transparency by:

- providing early support to evaluating MSCAs in considering the best approaches to clarify the concern and any risk management measures;
- following the progress of the evaluating MSCA's evaluation, identifying and resolving potential delays at an early stage;
- providing advice and support to ensure each evaluation is consistent and scientifically robust.

During 2017, early interaction occurred between ECHA and the evaluating MSCAs for the majority of the substances being evaluated.

Additionally, ECHA has developed example text for evaluating MSCAs to use when drafting their requests for further information. This example text provides additional support to the evaluating MSCAs and contributes to ensuring that requests for further information are consistent and transparent. Currently, example text is available for information requests related to mutagenicity, reproductive toxicity, endocrine disruption, and PBT/vPvB.

Prior to the completion of the 12-month evaluation period, the evaluating MSCAs may submit their draft decision for a consistency screening by ECHA. During 2017, ECHA performed consistency screenings on 19 draft decisions for substances allocated for evaluation during 2016. The aim of the consistency screening is to:

- ensure all requests for further information are well reasoned and appropriate for clarification of the concern;
- clarify the link between compliance check and substance evaluation, and identify the most viable route for requesting information that is necessary to clarify the concern(s) and achieve regulatory risk management.

Of the 39 substances allocated for evaluation during 2016, the evaluating MSCAs considered that 27 (69 %) of these required further information to clarify the suspected concerns. For 12 of the substances evaluated during 2016, the evaluating MSCAs considered the available information sufficient to conclude on the concerns and submitted their conclusion documents to ECHA.

For the rest of substances evaluated in 2016, 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 information on the standard requirements is available in the dossier updates, the evaluating MSCA will consider it under their continued substance evaluation, and consider whether some other additional information would still be necessary to clarify the remaining concerns regarding those substances.

Furthermore, the evaluating MSCAs started their evaluations of the 22 substances allocated for evaluation in 2017. Finalisation of all draft decisions generated as a result of this evaluation work will be performed in early 2018.

2.6.3 Decision making

In 2017, ECHA sent draft decisions for commenting to 163 registrants of the 27 substances evaluated during 2016 where the evaluating MSCAs considered further information was needed to clarify the suspected concerns.

To further improve the quality of the decisions and ensure a smooth decision-making phase, ECHA offers enhanced support to evaluating MSCAs during decision making. After consideration of the registrants' comments, the evaluating MSCAs may submit their (revised) draft decisions to ECHA for review. In 2017, less than half of the cases were reviewed by ECHA before referral.

This review is as a continuation of the early interaction between ECHA and the evaluating MSCAs that occurs during the initial evaluation stage. The review ensures more efficient and effective handling of substance evaluation draft decisions and provides the evaluating MSCAs with additional support for formulating information requests within the draft decision.

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 increasing. During 2017, the Committee agreed on 24 draft decisions for 24 substances, of which 11 (46 %) 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 two decisions under substance evaluation have been referred to the Commission following no unanimous agreement being reached at the Committee. The first decision was referred to the Commission in 2014, which subsequently adopted the decision[32] in 2015. The second was referred to the Commission in 2017 and has not yet been adopted.

Following a consultation of the Member States in November 2017, it was agreed that registrants of certain intermediates would also receive substance evaluation decisions. Consequently, from January 2018, ECHA will send substance evaluation draft decisions also to registrants of transported isolated intermediates, but not registrants of on-site isolated intermediates.

The change in practice gives all registrants an equal possibility to comment substance evaluation decisions. The registrants of transported isolated intermediates may in the comments seek to demonstrate that the concern identified in the draft decision is not relevant to their specific strictly controlled conditions of use, as further substantiated. The evaluating

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

MSCA will take the comments into account.

2.6.4 Information requested

During 2017, ECHA took decisions on 31 of the substances evaluated. Non-confidential versions of 26 of these decisions have been published on ECHA's website and links to them have been included in the dynamic CoRAP list[33]. Non-confidential versions of the remaining four decisions will be published in due course. Table 10 summarises the information requested within the decisions taken during 2017 to clarify hazard-based concerns. A decision may contain more than one request.

Table 10: Information requests to clarify hazard-based concerns within decisions taken during 2017.

Suspected Concern	Types of information requested to clarify the concern	Total requests†
PBT/vPvB	Simulation biodegradation test	16
	Daphnia magna reproduction test	6
	Physico-chemical tests	5
	Aqueous exposure bioaccumulation fish test	5
	Ready biodegradability test	4
	Fish, early-life stage (FELS) toxicity test	3
	Sediment-water *Chironomid* toxicity test	2
	Toxicity of sediment-associated contaminants with freshwater invertebrates	1
	Aquatic toxicity test with bivalves	1
	Freshwater algae and cyanobacteria, growth inhibition test	1
	Sediment-water *Lumbriculus* toxicity test	1
Reproductive toxicity	Extended one-generation reproductive toxicity study	3
	Combined repeated dose toxicity study with reproduction/developmental toxicity screening test	1
Mutagenicity	*In vivo* mammalian alkaline comet assay	3
	Combined mammalian erythrocyte micronucleus test and mammalian alkaline comet assay	3
	Transgenic rodent somatic and germ cell gene mutation assay	3
	In vitro mammalian cell micronucleus test	2
Endocrine disruption	Fish sexual development test	3
	Larval amphibian growth and development assay	1
	H295R steroidogenesis assay	1
Sensitisation	Skin sensitisation local lymph node assay	2

[33] 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	Information on composition	7
	Sediment-water *Lumbriculus* toxicity test	1
	Daphnia magna reproduction test	1
	Sediment-water *Chironomid* toxicity test	1
	Sub-chronic 90-day toxicity study	1
	Total	**79**

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

Additionally, in 14 of 31 decisions taken by ECHA in 2017, the evaluating MSCA considered that further information on exposure and/or risk assessment was necessary to clarify the concerns. Some examples of the exposure-based information requests included within the decisions taken during 2017 are:

- clarification and detailed justification for environmental exposure scenarios;
- further information and justification on input parameters used for exposure assessment;
- improved characterisation of the tasks and processes covered in exposure scenarios.

2.6.5 Follow-up evaluation of substance evaluation decisions

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

Once this assessment is complete, the evaluating MSCA 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 2017, 26 substances were at the stage where new information should have been submitted following an initial request for further information. The responsible evaluating MSCAs are currently reviewing the newly submitted information to conclude on its suitability. In 2017, for 15 substances the evaluating MSCAs concluded that the newly submitted information was suitable, and the 12-month assessment of the submitted information is ongoing. For 11 substances, a conclusion has been published after follow-up evaluation.

To facilitate the follow-up work, ECHA provides Member State competent authorities with a monthly report on submitted dossier updates for cases where the substance evaluation decision has been issued. Furthermore, in 2017, ECHA implemented a new webform that evaluating MSCAs can use to inform ECHA on whether all requested information was provided by the registrants in their dossier updates.

2.6.6 Concluding substance evaluation

Following a review of the available data and new data (where relevant), if the evaluating MSCA 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 2017, 25 conclusion documents originating from substance evaluations performed in

2012–2016 were published within the dynamic CoRAP list[34] on ECHA's website. In 12 of the 25 concluded cases published, the evaluating MSCA concluded that further EU-wide regulatory action is needed.

Table 11 summarises the hazard-based concerns concluded on in 2017 and their outcomes. More than one concern may be indicated for a substance. 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 or cease of certain uses or import/manufacture.

More information on the conclusions on concerns in relation to 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[35].

Table 11: Hazard-based concerns concluded on in 2017 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	7	205-483-3 203-631-1 203-777-6 271-231-4 200-817-4 203-726-8 204-617-8
	Harmonised classification and labelling	1	204-820-1
	Concern not clarified*	1	212-783-8
Mutagenicity	No regulatory follow-up action needed	4	203-777-6 271-231-4 204-617-8 204-820-1
	Harmonised classification and labelling	2	203-631-1 200-817-4
	Concern not clarified*	1	212-783-8
Reprotoxicity	No regulatory follow-up action needed	6	448-020-2 205-743-6 203-631-1 210-871-0 203-777-6 203-629-0
	Harmonised classification and labelling	3	204-327-1 200-817-4 272-486-4
	Concern not clarified*	1	212-783-8
PBT/vPvB	No regulatory follow-up action needed	3	203-624-3 604-250-7** 800-353-8
	Concern not clarified*	2	448-020-2 272-486-4

[34] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[35] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

Suspected concern	Concluded regulatory follow-up action at EU level	Total conclusions	Concluded substances by EC/List number
Endocrine disruption	No regulatory follow-up action needed	3	204-327-1 200-817-4 201-248-4
	Identification as a SVHC (Authorisation)	1	201-245-8
	Further regulatory action to be decided	1	203-585-2
Sensitisation	No regulatory follow-up action needed	4	205-483-3 200-752-1 219-470-5 210-871-0
	Harmonised classification and labelling	1	204-820-1
Other hazard-based concern	Harmonised classification and labelling	7	200-752-1 203-956-9 210-871-0 203-777-6 405-040-6 204-617-8 204-820-1

* Substance evaluation was terminated due to change of the registration to only intermediate under strictly controlled conditions or inactivation of registration. Consequently, the evaluating MSCAs concluded that the concerns could not be presently clarified and a new assessment should be undertaken in the event of new registrations of the substance in the future.
** Conclusion covers two EC/List numbers (604-250-7 and 415-490-5).

3. Other measures to enhance dossier quality

ECHA also uses measures other than formal decisions to improve dossier quality. Some of them are directly related to REACH processes, such as tools used within the registration process, others are non-regulatory measures aiming to trigger and help registrants to update and to improve their registration dossiers. These measures range from simple phone calls to registrants to collaboration with industry to develop sector-specific guidelines related to, for example, substance identification, to further assist the registrants to comply with REACH requirements.

3.1 Enhanced completeness check

ECHA checks the completeness of the registration dossiers systematically at the submission phase. In accordance with the decision taken by the Management Board[36], ECHA implemented the enhanced completeness check on 21 June 2016 to ensure that submissions contain all the information foreseen by REACH. It applies equally to new registrations and to updates of registrations previously submitted. The updated completeness check also includes additional manual verifications by ECHA staff 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 justification 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.

During 2017, 4 752 registration dossiers (ca. 30 % of all incoming registration dossiers) were stopped for manual verification by ECHA staff of which 1 306 initial dossiers and 3 446 update dossiers (Figure 15). In 25 % of the manually verified dossiers (8 % of the submitted 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. This means that 0.5 % of all submitted dossiers (15 558 dossiers) were rejected at completeness check, consisting of a total of 74 dossiers, of which 22 were for initial submissions.

[36] 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.

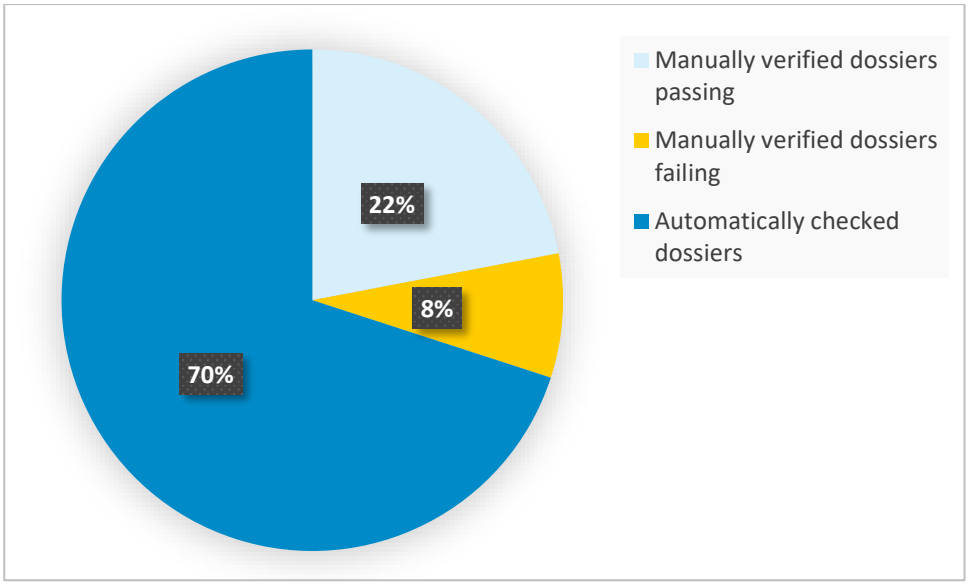

Figure 15: Breakdown between dossiers manually verified and dossiers where registrants were requested to improve the information. In 2017, 15 558 dossiers were submitted – 4 752 dossiers (30 %) were manually verified, out of which 3 541 (22 %) passed and 1 211 dossiers (8 %) failed the manual verification.

Figure 16 below shows the areas of the dossiers that were manual verified in 2017. A total of 4 752 dossiers were manually verified of which 2 182 (46 %) dossiers were checked for substance identity, 2 690 (57 %) dossiers were checked for data waiving, 523 (11 %) dossiers were checked for testing proposals and 48 (1 %) dossiers were checked for chemical safety reports (CSR). Dossiers include both initial and updated submissions with manual verification completed between 1 January 2017 and 31 December 2017.

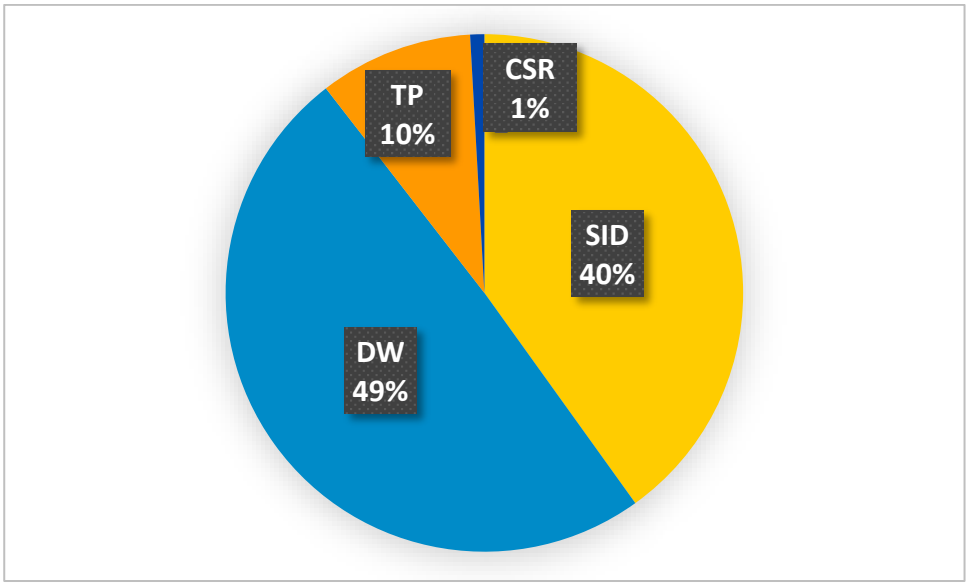

Figure 16: Distribution of verification areas in manually verified dossiers. One dossier may be checked in more than one area and for more than one item. A total of 4 752 dossiers were manually verified. Abbreviations: substance identity (SID); data waiving (DW); testing proposals (TP) and chemical safety report (CSR). Dossiers include both initial and updated submissions with manual verification completed between 1 January 2017 and 31 December 2017.

Impact of the enhanced completeness check
An impact analysis of the enhanced completeness check was undertaken in 2017, taking into account the first year of the enhanced completeness check. A sample of dossiers was further analysed to check the quality improvement of dossiers subject to manual verification. In the majority of the cases, the manual verification process had brought about significant improvements to the level of the information in registration dossiers, having a positive impact on the efficiency of subsequent regulatory processes and, indirectly, on the dossiers compliance. For example, in relation to substance identity, ECHA staff working on this topic were able to identify the substance in a clearer way (through the improvement of the manufacturing process description or UVCB composition breakdown). Similar improvements on data could be seen in the case of waiving of standard information requirements, where invalid justifications for not submitting a study were replaced by experimental data or QSARs.

3.2 Promoting dossier updates

In 2017, ECHA commissioned an external study to gain insight on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers[37]. The study found that companies lack incentives to update their REACH registrations. Furthermore, the study results suggest that more clarity is needed on how the registration process works and what needs to be updated and by whom, in order for more companies to submit new information on the safe use of their chemicals.

According to Article 22 of REACH, registrants are responsible for updating their registrations with relevant new information on their own initiative and without undue delay and submitting them to ECHA, for example when: there are any changes in a registrant's status; there is any change in the composition of the registered substance; there are changes in the annual or total quantities manufactured or imported; new uses and new uses advised against are identified; there is new knowledge of the risks of substance to human health and/or the environment; there is any change in the classification and labelling of the substance; there is an update or amendment of the CSR or guidance on safe use; the registrant identifies the need to perform new test listed in Annex IX or Annex X to REACH; and if there is any change in the access granted to information in the registration. By the end of 2017, ECHA had received a total of 67 005 registrations. Of these, 68.8 % have never been updated by industry and 33.2 % have been updated at least once. With joint lead dossiers, the update rate is slightly higher than overall: over half (53.8 %) have been updated at least once.

Updates triggered by regulatory activity

Not all the updates are based on the registrants' own initiative to update their dossier. For example, the adopted ECHA dossier and substance evaluation decisions, ECHA's requests to clarify the intermediate status for priority substances, or a decision on harmonised classification and labelling trigger the need for registrant to update their dossier by a given deadline.

To enhance data quantity and quality, in addition to dossier and substance evaluation, ECHA uses also other means to try to trigger dossier updates. Such measures include letter campaigns and the publication of pre-alert lists of substances planned to be addressed under compliance checks, thereby encouraging timely dossier updates or the use of the multiplier effect (e.g. targeting all registrants of the same substance under dossier evaluation). Furthermore, ECHA has also increased transparency by improving the dissemination of information on the registrations on ECHA's website in the form of infocards and brief substance profiles.

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37 https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/

In order to assess the impact of the other measures to trigger dossier updates, a substance-level analysis was conducted on their effectiveness between 2015 and 2017. The analysis showed that the average update rate was 13.4 % of the substances receiving at least one update each year. However, when a substance was added on a compliance check pre-warning list or included in a letter campaign from manual screening, the update rate increased. Based on the analysis, adding a substance on the pre-warning list on ECHA website made an update approximately 2.5 times more likely to happen, and sending a targeted letter under manual screening made an update 3 times more likely compared with the baseline. This analysis shows that the measures taken have an impact and can help to increase the update activity. However, in this analysis only the update activity was studied and therefore it is not known if these updates actually had an impact on the data quality in the registeration dossiers.

3.3 Substance identification

Informal discussions with registrants

ECHA continued to organise informal discussions with the registrants of dossiers where critical issues concerning the substance identity have been observed. ECHA has received very positive feedback from the registrants for handling problematic dossiers this way. In fact, during the informal discussions, not only are such issues highlighted, but ECHA may provide support for improving dossier quality from the substance identity point of view. The outcome of these informal discussions is usually the update of the dossier, with substance identity issues solved and with no need to send a substance identity-targeted draft decision.

ECHA also continued organising informal discussions with registrants in anticipation of the common screening work conducted in cooperation with Member State competent authorities on substances of potential concern[38]. This approach was initiated in 2016 and resulted at that time in informal discussions with registrants for 17 substances. For 2017, nine substances were selected. These substances are temporarily removed from the shortlist of substances for manual screening until the substance identity information is clarified.

Substance identity profile

In order to facilitate the clarification of the identity and composition of the substance that is intended to be covered in a joint registration, information on the substance identity profile (SIP) is part of the lead registration dossier. Advice on how to define the SIP is available in Appendix III of the Guidance on substance identification and naming under REACH and CLP[39]. Also a set of Questions and Answers on the SIP have been published on ECHA's website[40]. In addition, a new format is now available in IUCLID 6 for structuring the reporting of specific information on the composition of test materials. The availability of such information will provide an important contribution to activities done in the evaluation process.

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[38] Further information on screening is available at: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening. Different outcomes may follow the manual screening work carried out by MSCAs, one of them being the need to request for further information under the evaluation provisions.

[39] Guidance for identification and naming of substances under REACH and CLP: https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d.

[40] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Substance+identity+profile?_journalqadisplay_WAR_journalqaportlet_INSTANCE_70Qx_backURL=https%3A%2F%2Fecha.europa.eu%2Fsupport%2Fqas-support%2Fbrowse%3Fp_p_id%3Djournalqadisplay_WAR_journalqaportlet_INSTANCE_70Qx%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_pos%3D2%26p_p_col_count%3D3

Substance identity adaptation

An essential element in the context of the evaluation process is the use of the correct numerical identifiers. In 2017, the service provided by ECHA to facilitate the change of the numerical identifiers remains a well-used solution to correct substance identification mistakes observed during the dossier evaluation process. Many of these requests were initiated due to a compliance check and after the informal discussions with the registrants. ECHA has implemented a new customer-friendly webform and template to facilitate submissions of requests.

In addition, ECHA provides a technical solution for maintaining the correlation with other identifiers relevant for the substance (such as those used for other regulatory purposes, or previously used to identify the substance). Such related identifiers can be added to the field "Other identifier" in section 1.1 of the IUCLID 6 dossier.

Substance identification in the sectoral approach

ECHA has collaborated with specific industrial sectors to develop sector-specific guidelines on substance identification to further assist registrants in complying with the REACH substance identification requirements. In particular, ECHA collaborated with the relevant industry associations – Eurocolour, a sector group of the European Chemical Industry Council (Cefic), and the Inorganic Pigments Consortium – in developing the Guidance for characterising complex inorganic coloured pigments. The Guidance is now published on Eurocolour's website and linked to ECHA's website.[41]

Substance identity defined for joint registration and the test material composition

The first set of lead registrant dossiers updated or submitted after the release of IUCLID 6 in April 2016 are now available in the ECHA registration database. For substance identity, there are two new key records available: the boundary composition record and the test material record. The boundary composition record reports the joint constituent concentration profile. The name and other identifiers defined for the jointly registered substance – under the 'one substance, one registration' principle – are derived from this information. The test material record reports the constituent identities and concentration values of the test material used to generate the jointly reported REACH Annex VII-XI data.

Full use of the reporting options by the registrants will bring transparency to the link between the jointly defined substance identity and the test material used to generate the data to meet the REACH Annex VII-XI standard information requirements in the registration. ECHA is providing support for reporting in the Q&A section of ECHA website.[42] Transparent reporting in these fields will facilitate in particular testing proposal examination and substance evaluation. ECHA encourages all registrants to make full use of the reporting fields available so it is clear what is being registered and how the reported test data has been generated.

3.4 The collaborative approach pilots

The consideration of regulatory actions based on groups of similar substances rather than single substances was endorsed as part of ECHA's Integrated Regulatory Strategy[43] at the CARACAL meeting in March 2017. The assessment of groups of substances requires adaptation of the approach applied to individual substances and is an opportunity for testing new forms of collaboration between ECHA, Member State competent authorities and relevant registrants or industry groups. The expectation is that the assessment work, the generation of further

[41] https://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/complex-inorganic-pigments
[42] Q&As section: https://echa.europa.eu/support/qas-support/browse; browse by topic "Substance identity profile".
[43] https://echa.europa.eu/documents/10162/22837330/mb_44_2016_regulatory_strategy_en.pdf/

information and the conclusion on risk management actions for groups of related substances can enhance consistency and efficiency in all REACH and CLP processes and have an amplified impact on a wider number of substances.

As indicated in section 2.2.1 above, manual screening in 2017 involved many groups of related substances. Three of the groups for manual screening and two other groups with already ongoing regulatory actions were selected to test an enhanced collaborative approach ("COLLA"). The so-called COLLA pilot projects differ from the regular manual screening by offering registrants an early opportunity to contribute to the clarification of identified concerns and further testing needs. The registrants are able to contribute with additional information and provide proposals on necessary actions to generate missing information and address identified concerns. At the end of the pilot projects, ECHA and the authorities will decide on the necessary further actions on the related substances, or eventually conclude that no further action by authorities is required for the time being for certain substances.

Table 12: The five COLLA groups, initial concern, and the Member States involved in assessment with ECHA.

COLLA group	Initial concern	Lead MS	Contributing MS
EDTA derivatives	Human health, reproduction toxicity	UK	Sweden
Antimony compounds	Human health	Germany	Lithuania
Polyol acrylates	PBT	Germany	Ireland
Substituted diphenylamines	PBT, mutagenicity	France	Slovenia
Subset of organotin compounds	Reproduction toxicity	The Netherlands	Bulgaria and Sweden

The Member State competent authorities involved did a manual screening of all the group members. All related registrants (leads and individuals) as well as industry groups and other accredited stakeholder organisations were contacted. ECHA organised a webinar for the relevant registrants and stakeholders in May 2017, to further explain the COLLA approach. Kick-off meetings of the five pilots were held between mid-June and September with the participation of assessing Member State competent authorities, ECHA and registrants. Within each COLLA group, registrants appreciated this initiative and agreed to provide better information to address issues raised in the manual screening by Member State competent authorities, and to provide a draft testing strategy to clarify concerns found. These testing strategies will be finalised by the end of the five projects in March 2018.

A comprehensive review of the pilot projects and the collaborative approach will be performed in spring 2018. The experience gained so far with screening of groups of related substances shows that moving from screening of single substances to screening of groups takes time, as most actors do not have previous experience. Some re-organisation of the work is also needed. The development of integrated strategies that take into account ongoing and already-planned regulatory actions on similar substances with different timelines is complex but there are already indications of benefits. In all COLLA groups, authorities and registrants have now a better picture of all the ongoing or envisaged regulatory actions. These pilot projects show how actions on individual substances can be magnified to cover the whole group, including future registrations, while ensuring better consistency. Finally, the COLLA projects have also brought together registrants that were otherwise not collaborating.

3.5 Working with sectors

Another way to foster the improvement of dossier data quality and to identify and address substances of concern is to work with industry sectors. As examples of such work, in 2017 ECHA carried out activities with the sectors related to petroleum and coal stream substances (PetCo; see annual report of the SVHC Roadmap for more details on PetCo work), metals, and plastic additives.

Metals sector approach

Eurometaux, with input from ECHA, has started a sector approach that aims to improve the overall chemicals management of metals and metal compounds by creating an overview of the reported hazard, use, exposure and risk management information, starting action to fill data gaps and, based on that, assess where either company or regulatory action might be needed. Meanwhile, also some cross-cutting technical issues and assessment methodologies that have a direct impact on hazard and risk assessment are being further developed (such as read-across and grouping, environmental classification and addressing inorganic UVCBs).

The approach is a voluntary scheme that aims to include as many metals and inorganic industry organisations or consortia as possible. In 2017, a reporting scheme was developed and tested that gives a snapshot of the data available for groups of metals that will allow consortia to set priorities for generating further data and keep track of the progress.

The sector approach will be of help in resolving the main outstanding issues regarding dossier quality and focus on how the chemicals management in the metals sector can be specifically improved in a transparent and more effective way. The metals sector approach is not a substitute for compliance with legal obligations and for regulatory action. ECHA and Member States will continue regulatory actions as necessary.

Plastic additives

A sector approach for plastic additives was started in November 2016 in cooperation with manufacturers of plastic additives (Cefic sector groups, Eurocolour, Eurometaux, BSEF), and compounders and converters of plastics (EuPC and PlasticsEurope). The project aims to foster registration dossiers updates by generating a better understanding on the uses and exposure potential of substances used as plastic additives, to improve the quality and compliance of hazard information and the way chemical safety aspects are covered in registration dossiers, and to facilitate priority setting for regulatory action.

In 2017, ECHA, together with industry, established an overview of substances used as plastic additives. This illustrated how more appropriate use descriptions could be provided in registrations, in particular for article service life. The work so far has also demonstrated that an approach to determine high and low release potential of additives in plastic matrices would be needed, both for industry to develop better exposure estimates as part of their registration dossiers and for authorities to identify substances for regulatory priority setting purposes.

3.6 Letter campaign on shortlisted substances

ECHA uses informal letters to communicate to registrants that their substances are shortlisted for manual screening by Member State competent authorities to confirm or dismiss suspected hazard and exposure concerns. The third letter campaign in 2017 (the previous campaigns were held in 2015 and 2016) addressed 72 substances, considerably fewer than previously.

The lower number of substances addressed by the 2017 campaign is due to the pilot approach of manual screening of groups of related substances. In fact, as also explained in the screening

webinar of 14 February 2017[44], from round four of common screening, some of the shortlisted substances were associated with other registered substances because of structural similarity and presence of read-across or category information. ECHA believed that, by considering related substances, authorities can ensure consistency in their actions and act in a similar way when dealing with substances that pose similar risks. As ECHA and Member State competent authorities were piloting the manual screening of such groups, in 2017 it was decided to address the letters only to the so-called 'group seeds', i.e. the substances identified by the screening algorithms and around which these groups were formed. Hence, members of such groups were not addressed by these informative letters. It was in fact not known how many of these additional substances the Member State competent authorities would have screened. Based on the outcome of this pilot, in 2018 ECHA intends to extend the letter sending to all group members.

Therefore, only registrants of the shortlisted substances identified by the screening algorithms were addressees of this campaign and invited to review their dossiers with regard to the identified potential hazards and their uses and tonnage information. The aim of the campaign was to inform these registrants of the screening process and to trigger updates of dossiers where potential concerns with hazard and exposure information were identified. The response to this campaign was quite positive. Approximately 40 % of shortlisted substances received dossier updates within four months of the letters having been sent. The main reason for updating, as in the previous campaigns, was to include new or updated information on uses and tonnage per use. However, in certain cases, the registrants also updated hazard information with a revision of the human health and environmental endpoint summaries, improved information on the substance identification, and strengthened the justification for certain adaptations from the standard information requirements.

3.7 Intermediate status verification

The activity of verifying the intermediate status of registrations for on-site and transported isolated intermediates continued in 2017. The scope of this activity, initially set to support relevant REACH risk management processes, such as prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List, has been further expanded to support users of substances included in Annex XIV of REACH, in order to assess whether authorisation applies to their processes and to support Member State authorities to assess intermediate uses.

In 2017, ECHA continued to request registrants to provide documentary evidence of the use of their substance as intermediates in their registration dossiers. ECHA also continued working with industry associations in the metals sector to gain common understanding on intermediate uses in complex processes and subsequent authorisation implications, and with Member States (through the Forum for Exchange of Information on Enforcement and National Enforcement Authorities) to clarify how to assess uses as intermediate and strictly controlled conditions. During 2017, ECHA assessed intermediate registration dossiers for five substances. No Article 36 requests were sent in 2017 as information in registration dossiers was sufficient to conclude about intermediate use in the majority of cases. In four cases the companies were contacted directly by ECHA and the registration dossiers were updated.

[44] Link to 2017 webinar on screening: https://echa.europa.eu/-/how-are-substances-screened-and-shortliste-1

3.8 Transparency regarding content and target of ECHA decisions

The information published by ECHA, before or after an evaluation is completed, allow stakeholders to contribute to the evaluation of chemical substances undertaken by ECHA.

Before evaluation starts

Prior to the initiation of the evaluation processes, ECHA publishes the following lists of substances which will be subject to its assessment:

- the list of substances potentially subject to compliance checks is updated several times per year. Although it is only indicative, registrants are advised to check this list regularly[45];
- the substances listed on the Community rolling action plan (CoRAP)[46];
- the list of testing proposal consultations[47]: in relation to testing proposals, and to ensure that information on existing vertebrate tests is best used, ECHA consults third parties on all proposals for tests involving vertebrate animals, as specified in Annexes IX and X under REACH; Subsequently, third parties have 45 days to submit scientifically valid information and studies that address the relevant substance and hazard endpoints.

After evaluation is completed

ECHA publishes the dossier evaluation decisions to ensure transparency and to offer registrants and third parties an opportunity to increase their understanding of the evaluation processes[48]. Similarly ECHA publishes the outcome of the evaluation of a substance by a Member State, including the adopted decision. This allows any third party to understand the reasoning leading to the request for information[49] to verify the suspected concern.

[45] https://echa.europa.eu/regulations/reach/evaluation/compliance-checks
[46] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[47] https://echa.europa.eu/information-on-chemicals/testing-proposals/current
[48] https://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions
[49] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

4. EVALUATION RELATED ACTIVITIES

This chapter covers the ongoing evaluation-related activities and projects that support or are direcly linked to the implementation of REACH.

4.1 Non-animal approaches

In 2017, ECHA for the third time reported to the European Commission on how companies use non-animal approaches under REACH[50]. The results of the report showed that most registrants consider and use alternatives to animal testing. One effective way is data sharing: 98 % of the substances are registered jointly. Registrants also make extensive use of existing information and alternative methods before conducting new studies.

The analysis is based on joint and individual registration dossiers submitted to ECHA between 2008 and 2016 for 6 290 substances. Out of these substances, 89 % have at least one data endpoint where an alternative was used instead of a study on animals. The most common alternative method was using information on similar substances, read-across and grouping adaptations, used in 63 % of the analysed substances, followed by combining information from different sources (weight of evidence, 43 %) and computer modelling (QSAR prediction, 34 %).

In November 2017, ECHA published a report, "*Non-animal approaches - Current status of regulatory applicability under the REACH, CLP and Biocidal Product regulations*"[51], which in addition to the current status explored the near future developments of the non-animal approaches. The aim of the report is to further improve the understanding on how the non-animal approaches can be used to meet the legal requirements. The report does not replace ECHA Guidance, which is always the main source of information for the registrants. The main findings of the report show that:

- many of the so-called lower-tier information requirements can now be fulfilled by applying non-animal approaches;
- for higher-tier endpoints, specific non-animal approaches that could directly replace vertebrate animal tests are not yet available and not foreseen within the near or even medium-term future;
- adaptations using grouping and read-across and/or weight of evidence are currently the main approaches to reduce the need for new animal testing;
- information from non-animal approaches may be used as supporting data for grouping and read-across adaptation or as elements in a weight-of-evidence adaptation.

ECHA keeps on its website updated guidance[52] on how to avoid unnessesary testing on animals and use alternatives to animal testing to fulfil REACH registration requirements.

Integrated approaches to testing and assessment

The use of integrated approaches to testing and assessment (IATA) falls in most cases under weight-of-evidence adaptation, unless the components of the IATA strictly correspond to the information requirement. An IATA can nevertheless to be used to structure a weight-of-

[50] https://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2017_en.pdf/075c690d-054c-693a-c921-f8cd8acbe9c3
[51] https://echa.europa.eu/documents/10162/22931011/non_animal_approcches_en.pdf/
[52] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals

evidence adaptation[53].

In a defined approach to testing and assessment, data generated by non-animal and animal methods are evaluated by means of a fixed data interpretation procedure. The data interpretation procedure is rule-based in the sense that it is based, for example, on a formula or an algorithm (e.g. decision criteria, rule or set of rules) that do not involve weight-of-evidence determination using expert judgment. The OECD guidance[54] on the reporting of defined approaches to testing and assessment provides templates to enable a structured approach of documentation.

Several examples of IATAs or defined approaches have been published in 2017 or are under discussion by the OECD for skin corrosion or irritation, serious eye damage or eye irritation and skin sensitisation, and other IATAs are being developed for non-genotoxic carcinogenicity. A specific strategy for skin sensitisation assessment under REACH has been developed based on the above OECD guidance documents (see section R.7.3 of ECHA Guidance on Information requirements and chemical safety assessment – Chapter R.7a)[55].

While no defined approaches has been formally approved yet, in April 2017 the OECD approved a project which analyses the predictivity of several preliminary defined approaches for skin sensitisation. If found acceptable, these defined approaches can be used under REACH.

Other scientific work on the non-animal approaches

ECHA is collaborating internationally to develop screening approaches for (de)prioritisation of substances and exploring how non-animal approaches could support regulatory assessments.

Together, *in vitro*, *in chemico*, *in silico*, *-omics* and other techniques and non-animal approaches are also called new approach methodologies (NAMs). Data may be collected also using high-throughput screening (HTS) methods or high-content methods. These methods are analytical techniques that enhance toxicity tests *in vivo* or *in vitro* by adding e.g. new endpoints or parameters, pattern recognition or high-throughput. These methods may be used in screening and (de)prioritisation, suggesting a mode of action (MoA), in identifying endpoints that can be used in developing adverse outcome pathway approaches, as supportive information for grouping and read-across, in integrated approaches such as IATAs, and as elements within weight-of-evidence adaptations.

In 2017, ECHA followed up the international work on NAMs and hosted the second workshop in October 2017 after the workshops on 2016 (in ECHA)[56] and a previous one organised by the United States Environmental Protection Agency (EPA). ECHA's NAM project started a process between the chemical regulatory agencies worldwide to reinforce the principles of cooperation between the OECD member countries, and enhance the use of non-animal approaches for screening and (de)prioritisation, chemical hazard and risk assessment, and for harmonised classification and labelling.

At OECD level, there are currently ongoing discussions on how to integrate the fish embryo acute toxicity (FET) test into the OECD Guidance Document 126 on the threshold approach for

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[53] http://www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm#guidancedocument

[54] ENV/JM/MONO(2016)28: https://www.bior.lv/sites/default/files/inline-files/env-jm-mono%282016%2928%5B1%5D.pdf.

[55] https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f

[56] https://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-new-approach-methodologies-in-regulatory-science

acute fish toxicity. The regulatory use of the FET test has been discussed in ECHA, hosted at the expert workshop co-organised by ECHA and German Environment Agency (May 2017, Helsinki), where research needs and areas for further developments to improve usability of FET for regulatory purposes were identified. Nevertheless, based on current knowledge, ECHA considers that the OECD Test Guideline 236 has a potential for use as part of a weight-of-evidence adaptation, in combination with other information, for the registrant to make a scientific justification to predict acute fish toxicity. Registrants are invited to include available FET data in the weight-of-evidence adaptations in their registrations to gain experience and to build the case studies that might be used as best practice examples. The report from the FET Workshop is available on ECHA's website[57].

4.2 Expert working groups

The expert group on (very) persistent, (very) bioaccumulative and toxic substances

The PBT Expert Group provides informal scientific advice on questions related to the identification of PBT and very persistent, very bioaccumulative (vPvB) properties of chemicals.

During the year, the expert group supported evaluation by providing informal scientific advice for the majority of substances placed on the CoRAP for 2017 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 reviewed the data provided in response to substance evaluation decisions for seven substances listed on the CoRAP for 2012-2014.

The expert group on endocrine disruptors

During 2017, the Endocrine Disruptor Expert Group provided advice regarding eight substance cases, all of them on CoRAP. This year was the first time that substance evaluation cases that are in the follow-up evaluation stage were discussed in the expert group. Five out of the six substances in the CoRAP 2017 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.

The expert group on nanomaterials

The Nanomaterials Expert Group[58] supports the implementation of ECHA's Workplan for Nanomaterials 2016-2018, and provides informal advice on scientific and technical issues regarding the implementation of the REACH, CLP and Biocidal Products regulations in relation to nanomaterials.

In 2017, the group discussed several topics. Some of discussions focused on technical aspects involved in the development and adaptation of OECD test guidelines and guidance documents; these discussions are now framed by the so-called Malta project, an initiative of several EU Member States started in Q3/2017 to intensify the effort to develop or update OECD test guidelines and guidance documents.

4.3 Good laboratory practice

According to Article 13(4) of REACH, 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

[57] https://echa.europa.eu/documents/10162/13630/fet_workshop_proceedings_en.pdf/a987ccab-5d4a-a226-2a73-994be484ca8d
[58] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group/

monitoring programme and whether the test facility is GLP-certified for the area of expertise relevant for the particular test. In 2017, ECHA continued random verifications of the GLP compliance of ecotoxicological and toxicological tests for which results were provided in the registration dossiers. In particular, ECHA requested 10 random study audits of different types of studies conducted in test facilities of EU member states. Additionally, ECHA requested one targeted study audit based on the identified concern. So far, three studies were found to be in compliance with the principles of GLP by the GLP monitoring authorities. The remaining study audit reports are pending. ECHA will inform the Member State competent authorities upon receiving the audit reports if necessary.

4.4 Test guideline developments

In vitro methods

ECHA's web pages on testing methods and alternatives were updated to reflect new test methods and testing strategies[59]. The updates concern skin and eye irritation/corrosion, skin sensitisation and genotoxicity.

A new method to cover eye irritation endpoint has been approved by OECD, and included in to the OECD test No. 492. An Integrated Approach on Testing and Assessment (IATA)[60] for the eye effects was approved by OECD. IATA provides advice how to combine *in vitro* and other data in a weight-of-evidence approach.

Also during the year, the OECD approved the new *in vitro* methods for skin sensitisation U-SENS and IL-8 Luc Assay, which are included in OECD test No. 442E. These methods can be used to meet the information requirement on the third key event according to REACH Annex VII, 8.3.1. In addition, OECD has started a project on how to combine specific *in vitro* methods and other data to conclude on skin sensitisation hazard and potency classification. Use of these defined approaches is anticipated to lead in many cases to full replacement of *in vivo* tests.

On 9 October 2017, the OECD released three test guidelines specifically updated to enable the testing of nanomaterials. The OECD test No. 318, Dispersion stability of nanomaterials in simulated environmental media, describes test procedure to gain information on dispersion stability of manufactured nanomaterials in simulated environmental media. The main purpose of this test guideline is to assess the ability of a nanomaterial to attain a colloidal dispersion and to conserve this dispersion under environmentally relevant conditions. The other two tests were revised to study the health effects of nanomaterials. The OECD test No. 412, on subacute inhalation toxicity (28-day study), has been designed to fully characterise test article toxicity by the inhalation route following repeated 28-day exposure time, and to provide data for quantitative inhalation risk assessments. Correspondingly, the OECD test No. 413, on sub-chronic inhalation toxicity (90-day study), characterises the test article toxicity by the inhalation route following repeated 90-day exposure time.

4.5 Extended one-generation reproductive toxicity study

Commission decisions on dossier evaluation cases

During 2017, the Commission processed the 216 draft evaluation decisions referred to it for decision making in years 2011-2014 regarding two-generation reproductive toxicity (information requirements 8.7.3 of REACH Annexes IX and X) on which ECHA's Member State

[59] https://echa.europa.eu/support/oecd-eu-test-guidelines

[60] Guidance Document on an Integrated Approach on Testing and Assessment (IATA) for Serious Eye Damage and Eye Irritation Series on Testing & Assessment No. 263: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2017)15&doclanguage=en.

Committee could not reach unanimous agreement[61]. In most cases, the Commission decisions requested the registrants to update their registration dossiers with a testing proposal for extended one-generation reproductive toxicity study (EOGRTS) or a valid adaptation within a deadline of 90 days. Registrants who had already submitted a valid testing proposal were not asked to update their dossier again.

The response rate to the Commission decisions was high. For the 98 individual substances, approximately 50 % of registration dossiers were updated with testing proposals for EOGRTS, approximately 40 % with an adaptation, and less than 10 % of the registration dossiers were not updated within the deadline. All read-across categories (a total of 115 registration dossiers bundled in 5 categories) were updated with testing proposals to reflect the new EOGRTS information requirement. ECHA has started to process these cases.

Extension to the assessment of second filial generation (F2) and testing of developmental neuro- and immunotoxicity (DNT and DIT)

For the cases processed under dossier evaluation in 2017, the DNT Cohorts 2A and 2B have been mainly requested based on effects seen in thyroid, central nervous system (brain and spinal cord) and functional observational batteries. Investigations on DIT were triggered by effects seen on thymus and cell counts (eosinophils, leucocytes, lymphocytes), for example. The extension of Cohort 1B to produce the F2 generation for substances with significant consumer and/or professional exposure was mainly requested based on endocrine disrupting mode(s) of action and potential for bioaccumulation.

In 59 % of adopted dossier evaluation decisions the request was for a basic study design, i.e. without any additional cohorts. The second generation was included in 22 % of requests. Furthermore, DNT and/or DIT cohorts were triggered in 25 % of cases. Under substance evaluation, two out of three study requests included all cohorts, whereas in one request only the DIT cohort was triggered.

4.6 Litigation and European Ombudsman cases

Under Article 94 of REACH, an action may be brought before the European Court of Justice against a decision taken by the Board of Appeal or in cases where no appeal lies before the Board.

On 31 December 2017, three evaluation cases were pending before the General Court, one on dossier evaluation, challenging a statement of non-compliance, and two on substance evaluation, addressing various issues, including proportionality and the scope of review by the Board of Appeal.

The Board of Appeal

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

During 2017, ten new appeals against ECHA evaluation decisions were announced by the Board of Appeal on its website. Of these cases, six concerned dossier evaluation decisions and four concerned substance evaluation decisions (two of which challenge the same substance evaluation decision).

In 2017, the Board of Appeal closed 11 appeal cases on evaluation. Of these, five concerned

[61] http://ec.europa.eu/environment/chemicals/reach/implementation_en.htm

dossier evaluation decisions and six concerned substance evaluation decisions[62].

Some of these cases concerned the conditions under which ECHA can request further information on nanomaterials under both dossier and substance evaluation, the question whether downstream users can appeal evaluation decisions, and the competence of ECHA to request further information to examine the persistency of a substance under substance evaluation.

At the end of 2017, five dossier evaluation appeals and six 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[63].

Recent learnings from the decisions of the Board of Appeal are summarised in the following sections.

Nanomaterials

Titanium dioxide case[64] *(dossier evaluation)*

The Board of Appeal found that ECHA did not have the competence to ask nanomaterial-specific information for the substance identification under Section 2 of Annex VI to REACH. It thus annulled the contested decision in so far as it requested this information.

The Board ruled that when defining a substance broadly, registrants must provide toxicological and ecotoxicological information covering both the bulk form and the nanoforms of the substance. It thus considered that rather than requesting more information under Section 2 of Annex VI, ECHA could have performed a compliance check to verify whether the dossier included toxicological and ecotoxicological information addressing all possible forms of the substance as defined by the registrants. Alternatively, the substance evaluation process could have been used in case of a need to clarify a potential concern.

The Board held that neither ECHA nor it are in a position to interpret REACH in such a way as to amend or extend it. If the legislature sees a need for further information on the nanoforms, it would need to amend the REACH Annexes accordingly.

Silicon dioxide/synthetic amorphous silica (SAS)[65] (substance evaluation)

The Board of Appeal considered that being a nanomaterial is on its own insufficient to establish a concern under substance evaluation.

As a follow-up of the Board decisions regarding nanomaterials, ECHA reviewed its strategy[66] for addressing nanomaterials under evaluation processes awaiting for an update of the REACH Annexes which could eventually strengthen the regulatory tools.

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[62] There were, in fact, two appeal cases relating to the same substance evaluation decision, i.e. Cases A-014-2015 and A-015-2015 concerning the substance evaluation of silicon dioxide, also referred to as synthetic amorphous silica (SAS).
[63] http://echa.europa.eu/about-us/who-we-are/board-of-appeal
[64] Decision of 2 March 2017 in Case A-011-2014, Hunstman P&A Ltd and others.
[65] Decisions of 30 June 2017 in Case A-014-2015, Grace GmbH & Co. KG and Advanced Refining Technologies GmbH, and in Case A-015-2015, Evonik Degussa GmbH and others.
[66] https://echa.europa.eu/documents/10162/2792271/mb_57_2017_echa_strategy_nanoforms_en.pdf/

Persistency concern

BENPAT case[67] *(substance evaluation)*

The Board of Appeal upheld the contested decision in so far as the existing data did not demonstrate that the substance would not be persistent in the environment. In that respect, ECHA was also objectively justified in treating substances 7PPD and 77PD differently from the substance in question. However, the Board found that the OECD 309 study would not be suitable to identify the metabolites of the substance and it therefore annulled this aspect of the study request. Such annulment rendered the next study request, namely the OECD 308 sediment simulation study as regards the identity and properties of NER[68], not justified since the two studies together were to assess the possible persistency of the metabolites.

On a procedural aspect, the Board found that the Agency was not required to reach a firm conclusion on the bioaccumulative properties of the substance in order to request further information on persistence. Therefore, it requested that the statement related to bioaccumulative properties to be removed from the contested decision. This case is currently under appeal.

Interface between dossier and substance evaluation

TPBP case[69] *(substance evaluation)*

The Board of Appeal upheld ECHA's decision regarding both requests for a comet assay and for a pre-natal developmental toxicity study in a second species (second species PNDT). Regarding the second species PNDT, the Appellant claimed that ECHA should have requested the test under dossier evaluation. The Board considered that ECHA was entitled to use the substance evaluation procedure to ask for the study since it had demonstrated a potential risk (developmental toxicity) and all the registrants of the substance were at the same tonnage band and therefore treated equally.

On a procedural aspect, the Board confirmed that ECHA is competent to submit proposals for amendment on substance evaluation draft decisions.

Duty to state reasons

In December 2017, the Board of Appeal held that ECHA's dossier evaluation decision requiring vertebrate testing for the substance used exclusively in cosmetics should have explained the Agency's interpretation of the relationship between the REACH Regulation and the Cosmetics Regulation. ECHA should have in the decision referred to the joint ECHA/Commission public statement on this issue and explained how the interpretation set out therein applied to the present case, in order to justify why the requested vertebrate test was warranted[70].

Procedural aspects:

i. locus standi of downstream users

DCBS case[71] *(substance evaluation)*

[67] Decision of 8 September 2017 in Case A-026-2015, Envigo Consulting and DJChem Chemicals.
[68] Non extractable residues
[69] Decision of 13 December 2017 in Case A-023-2015, S.A. Akzo Nobel Chemicals NV and others.
[70] Decision of 12 December 2017 in Case A-013-2016, BASF Personal Care and Nutrition GmbH.
[71] Decision of 30 May 2017 in Case A-022-2015, Manufacture Française des Pneumatiques Michelin.

This appeal was lodged by a downstream user against an evaluation decision on a substance that it incorporates in tyres. The Board of Appeal considered the appeal as inadmissible because the Contested Decision did not impose any direct obligation on downstream users that did not prepare a CSR nor submit a downstream user report to ECHA, nor to a substance information exchange forum's (SIEF) member, member of a SIEF agreement, new consortium member or again to a registrant registering after the adoption of the substance evaluation decision. The Board used this opportunity to clarify the involvement of downstream users under substance evaluation. At the same time, the Board observed that substance evaluation does not extend to downstream users in general, but a request for information (under substance evaluation) may do so in certain cases, for example, confirmed in the case where a downstream user submitted a downstream user report related to a use targeted by the substance evaluation. This suggests that a downstream user might have a standing for challenging a substance evaluation decisions in these limited cases, meaning that a substance evaluation may be targeted towards him.

ii. Admissibility of expert review during appeal proceedings

Silicon dioxide/synthetic amorphous silica (SAS) case[72] *(substance evaluation)*

An expert review, not submitted during the decision-making but at the stage of the appeal proceedings, was found to constitute admissible evidence. The Board of Appeal noted that the Appellants had already announced at the Member States Committee meeting that they were preparing this study, that it was reasonable for the Appellants to commission this study and that the delay in producing this study was justified.

iii. Competence of the Board of Appeal on Community Rolling Action Plan

Silicon dioxide/synthetic amorphous silica (SAS)[73] *(substance evaluation)*

The Board of Appeal confirmed that it has no competence to decide on an appeal against inclusion into the CoRAP.

The European Ombudsman

On 21 July 2017 the European Ombudsman issued her decision[74] in response to a complaint filed by an animal welfare non-governmental organisation concerning a joint statement by the European Commission and ECHA clarifying their understanding of the relationship between the Cosmetics Regulation, which bans animal testing, and REACH, which allows animal testing of chemicals in certain limited circumstances to assess risks to human health and to the environment.

In her decision, the Ombudsman concluded that there was no maladministration by the Commission and ECHA in issuing the joint statement and that the Commission and ECHA were entitled to explain how animal testing data should be used to fulfil the requirements under REACH.

[72] Decision of 30 June 2017 in Case A-015-2015, Evonik Degussa GmbH and others.
[73] Decision of 30 June 2017 in Case A-015-2015, Evonik Degussa GmbH and others.
[74] Decision of 21 July 2017 in Case 1130/2016.

5. RECOMMENDATIONS TO REGISTRANTS

This chapter contains advice to all existing and future registrants under REACH.

The recommendations are based on the most frequent shortcomings observed during dossier and substance evaluation, or their follow-up, and includes also information on the guidance and tools made available to the registrants during the year.

5.1 Report the identity of your substance and representative test material correctly

Report clearly what you have registered

Check that your reported legal entity composition information is within the boundaries of the substance identity profile compositional information as reported in the boundary composition record in the lead registrant dossier. More information can be found in "*Guidance for identification and naming of substances under REACH and CLP*" [75].

Make full use of the available IUCLID reporting fields

Proactively update the lead registrant dossier to make use of the new reporting functionalities for the joint compositional profile and the test material records.

ECHA encourages you to take action to correct substance identification mistakes not only during dossier evaluation but also on your own initiative. More information on how to prepare a registration can be found in the manual "*How to prepare registration and PPORD dossiers*" [76].

Ensure that you can demonstrate you are in the correct joint registration

Check that your compositional information is within the boundaries agreed by your co-registrants and that the jointly reported REACH Annex VII-XI information is relevant for your composition.

A broadly defined substance identity means broad Annex VII-XI reporting

If you and your co-registrants have defined your substance identity broadly, ensure that you also clearly report in your registration file how you have fulfilled your REACH Annex VII-XI information requirements for all that is registered and covered by the registration.

Ensure you can demonstrate the relevance of your test materials

Report the constituent identities and concentration values of each test material and study used to generate your reported REACH Annex VII-XI data in the fields available in the Test Material Record.

Registering nanomaterials? Consult ECHA's Guidance

Consult the available ECHA Guidance on how to address the specific properties of the nanomaterials you register when generating or collecting REACH Annex VII-XI information for your registration file. Make use of the IUCLID 6 reporting fields available in the composition records to document what you have registered and what your REACH Annex VII-XI data refers to[77].

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[75] https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d

[76] https://echa.europa.eu/manuals

[77] https://echa.europa.eu/documents/10162/13643/appendix_r14_05-2012_en.pdf/7b2ee1ff-3dc7-4eab-bdc8-6afd8ddf5c8d

5.2 Provide information on GLP compliance of the whole study

When you report results of a toxicocological or ecotoxicological study, identify unambiguously the test facility in which the study was conducted by providing the complete name and address of the facility so that a good laboratory practise (GLP) compliance claim can be verifified.
If parts of a GLP study were not conducted in line with GLP principles, indicate which parts of the study were affected in the remarks field of the GLP compliance section in the IUCLID.

5.3 Make sure your registration dossier is complete

The experience gained so far with the manual verifications on incoming dossiers has enabled ECHA to identify several recommendations for registrants to successfully prepare and submit a registration dossier. ECHA has published an information document on the manual verification that describes the different areas of the manual verification checks and provides useful instructions on how to prepare a complete registration dossier[78]. You should take into account the information document and the following recommendations when preparing a registration dossier.

- Before you submit the dossier to ECHA, use the IUCLID Validation assistant tool.
- If the Validation assistant does not indicate any failures, it is not an automatic confirmation of that the dossier is complete, since the manual verifications are not displayed in the Validation assistant report. Ensure that you have included all the required data for the areas that are described in the information document on manual verification.
- When preparing your dossier, consider that the registration dossier should not only be prepared to pass the completeness check – it should contain all the information on the substance as specified by REACH and should aim to demonstrate that the substance is used in a safe manner.
- Each registrant is responsible for ensuring that they register the substance as part of the correct joint submission, and that they provide the correct substance identification information in their registration dossier. Registrants should not rely on company-specific substance identification information provided by the lead registrant (such as analytical or compositional information).
- Use the available templates that exist to support registrants with the reporting of certain information requirements. For example, IUCLID has integrated templates for the manufacturing process description that is required for UVCB substances and for the considerations of alternative methods that need to be reported with testing proposals on vertebrate animals.
- When certain information is requested in a specific IUCLID field, this information must be included in the appropriate field. Reference to other parts of the IUCLID dossier is not considered complete.

5.4 Use the support available for REACH 2018 registrants

Follow the Directors' Contact Group

The Directors' Contact Group[79] restarted their activity in 2017. Their objectives are to monitor the overall preparedness of companies and to identify and resolve the priority issues of concern in meeting obligations relevant to the registration of chemical substances. They have decided to reopen four solutions designed already for the 2010 and 2013 deadlines for

[78] The document is published on ECHA's website:
https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf
[79] https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

companies in exceptional circumstances (solutions 10, 15, 20 and 21)[80] from 31 January 2018.

Consult the REACH 2018 web pages

The REACH 2018 website[81] remains the main information point for the registrants falling under the 31 May 2018 registration deadline. "*Practical guide for SME managers and REACH coordinators*"[82], published already in 2016, includes many tips on how to fulfil information requirements at tonnages 1-10 and 10-100 tonnes per year, as does ECHA's web page "*What information you need*".[83]

Check our practical examples

A new support web page bringing together practical examples[84] was published on 31 May 2017. Among others, one example relevant for information requirements was published, namely "*Steps to gather information for low tonnage substances*"[85]. In early 2018, more practical examples related to hazard and risk assessment were published:

- How to gather information to register an inorganic mono-constituent substance (including the chemical safety assessment);
- How to gather information to register a multi-constituent or a UVCB substance - toxicological information;
- How to decide whether a substance is a polymer or not and how to proceed with the relevant registration.

In addition, links to the existing examples related to assessing hazards and risks of substances were gathered on the practical examples web page. Note that the examples with the OECD QSAR Toolbox were developed with an older version of the Toolbox, but the reasoning described in the document is still valid.

If you are a SME, consider using ECHA Cloud Services

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications in a cloud environment. By using the services, you can work together in a more transparent and interactive way. The service allows SMEs and their consultants to work online with the latest version of IUCLID without having to install IUCLID on computers or company servers. It has a simple interface focusing on the REACH 2018 registration deadline tasks, and also offers a guided approach to help inexperienced SME registrants through the process of entering their IUCLID data. The service provides the user with up to 1 GB of data storage, fully managed backups and dedicated helpdesk support. More information on IUCLID Cloud is available on-line [86,87,88].

[80] https://echa.europa.eu/documents/10162/23556156/171219_dcg_four_solutions_en.pdf/9451fa44-266c-74d5-40d9-8beebd0e5c8b
[81] https://echa.europa.eu/reach-2018
[82] https://echa.europa.eu/practical-guides
[83] https://echa.europa.eu/support/registration/what-information-you-need
[84] https://echa.europa.eu/support/registration/practical-examples
[85] https://echa.europa.eu/documents/10162/23221373/example_low_info_reqs_en.pdf/3db4c47b-4ebf-1768-6350-e87b530a8f7e
[86] https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services
[87] https://www.linkedin.com/groups/12043483
[88] https://www.youtube.com/playlist?list=PLOPGDACSd6qyDkdXwPua1Fjb5bJksY75k

5.5 Avoid unnecessary testing on animals

Share data and use non-animal approaches where possible

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

If new data for skin corrosion/irritation, serious eye damage/eye irritation and/or for skin sensitisation needs to be generated, you will have to perform the *in vitro* studies first, irrespective of the annual tonnage of the substance. Unjustified *in vivo* testing when non-animal alternatives are available may lead to compliance check or direct enforcement action.

For substances expected to not be acutely toxic based on non-animal approaches (e.g. *in vitro* and QSAR data), consider conducting a sub-acute repeated-dose toxicity study (28-day study) first. The results from that study may be used within a weight-of-evidence approach to conclude on oral acute toxicity without conducting an acute oral toxicity study.

Information from non-animal approaches may also be used as supporting data for grouping and read-across adaptation. Results from several individual non-animal approaches (e.g. *in silico*, *in vitro*) may allow to adapt information requirements and avoid an animal test under weight-of-evidence adaptation.

Provide your considerations on non-animal approaches with your testing proposals

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. Apart from information requirements listed in Annexes IX and X, some testing proposals may need to be submitted already at Annex VII or at Annex VIII level[89]. For example, the Annex VIII, Column 2 requires the registrant to consider appropriate mutagenicity *in vivo* studies in cases where positive results in *in vitro* genotoxicity studies have been obtained. It should be noted that where this involves tests mentioned in Annexes IX or X, such as *in vivo* somatic cell genotoxicity studies, testing proposals must be submitted by the registrant and accepted by ECHA in a formal decision before testing can be initiated.

When your testing proposal involves testing on vertebrate animals, you have to include your considerations on non-animal approaches for that information requirement in the dossier documentation.

Justify and document your weight-of-evidence approach

If you propose an adaptation based on weight of evidence, the individual lines of evidence and the justification should provide a sufficient confidence level when compared to information expected with the default test. Documentation of the weight-of-evidence adaptation should be transparent and conclusions justified.

You need to document the quality and relevance of the pieces of evidence, as well as their consistency and completeness, in relation to the standard information requirements. You should also address the associated uncertainties and their impact in a way that allows ECHA to assess and verify all the pieces of evidence provided in the technical dossier.

Provide robust grouping and read-across arguments

Use ECHA's Read-Across Assessment Framework (RAAF[90]) to check the robustness of your

[89] https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f

[90] ECHA Read-Across Assessment Framework (RAAF): https://echa.europa.eu/documents/10162/13628/raaf_en.pdf.

read-across adaptation. The RAAF describes the aspects of grouping and read-across justifications that ECHA considers to be crucial for both human health and environmental endpoints. A technical document[91] on the key issues for assessing the complexity of grouping and read-across for multi-constituent and UVCB substances was published on ECHA's website in March 2017. This document describes the additional key issues proposed to be considered when predictions based on grouping and read-across cases involving multi-constituent substances and/or UVCBs are used to adapt standard information requirements.

Justify the grouping and read-across by showing how structural similarity and dissimilarity are connected to the prediction and create a data matrix, allowing side-by-side comparison of properties of the sources and target substances.

5.6 Your chemical safety report should reflect the actual uses and risks

Derive DNELs according to ECHA's Guidance

Derivation of DNEL (derived no-effect level) is a key element for the risk characterisation of a chemical substance. The DNEL is set by REACH as the threshold above which humans should not be exposed. Therefore, it is important that your DNEL is derived appropriately to make sure that your substance is manufactured and used in such a way that they do not adversely affect human health. A DNEL has to be derived based on the dose descriptor giving rise to the highest concern per route of exposure and type of effect. Usually it is the study with the lowest NOAEL/LOAEL (no/lowest observed adverse effect level).

A set of assessment factors should be applied to convert the dose descriptor into a DNEL. For an explanation on the background to these assessment factors, consult REACH Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health (version 2.1, November 2012)[92].

You need to justify and document any deviation from these default assessment factors with scientific arguments that are specific to your registered substance.

If it is not possible to derive a DNEL for a particular hazard, for example skin/eye irritation/corrosion, skin sensitisation, mutagenicity, you should carry out and report a qualitative assessment.

Use the DNEL and PNEC calculators in IUCLID 6

DNEL and PNEC calculators[93] are new features in IUCLID 6 (versions 1.2.0. and 1.3.0.).

The DNEL calculator was developed in collaboration with the State Secretariat for Economic Affairs (SECO) from the Swiss Confederation in order to support the derivation of worker and general population derived no-effect levels (DNELs) for long-term systemic effects for oral, dermal and inhalation routes based on ECHA's Guidance.

The PNEC calculator was developed to support the derivation of predicted no-effect concentrations (PNECs) for the aquatic, sediment and terrestrial environmental protection targets based on ECHA's Guidance.

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[91] Read-Across Assessment Framework (RAAF) - Considerations on multi-constituent substances and UVCBs: https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316.

[92] REACH Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health: https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/.

[93] https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf

Both DNEL and PNEC calculators use the information already provided in the endpoint study summaries of the IUCLID dossier and populate automatically the summary records in sections 6 (Ecotoxicological information) and 7 (Toxicological information) of IUCLID.

Your exposure assessment needs to cover all identified hazards

According to Section 5.0 of Annex I to REACH, when the exposure assessment is triggered, i.e. criteria given in Article 14(4) are met, it "shall consider all stages of the life-cycle of the substance" and "cover any exposures that may relate to the hazards identified". ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment (version 2.1, December 2011) clarifies that there are three types of identified hazards requiring exposure assessment:

1. hazards leading to classification;
2. classifiable hazards where the severity of the effects is lower than the criteria for classification and so the substance is not classified;
3. hazards for which currently no classification criteria exist.

The three points above entail that exposure assessment is not limited to the classifiable hazards or adverse effects observed at doses or concentrations where classification is triggered, but should cover all hazards identified. It should be noted that hazard is considered as identified when adverse effects have been observed in studies at the highest recommended concentration or doses tested. The DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect, or protection target would be needed. For instance, when adverse effects have been observed in studies conducted at the highest practicable and biologically relevant concentration on environmental aquatic toxicity according to OECD and EU test guidelines (e.g. 100 mg/l as a limit test for acute aquatic toxicity in the OECD guideline), taking into account the properties of the substance determining the environmental fate, it would indicate that quantitative exposure assessment, i.e. derivation of predicted environmental concentrations (PECs), is mandatory for the water, sediment and soil environmental compartments.

Use correct exposure scenarios and exposure estimations

The reliability of the exposure assessment highly depends on the reliability of the exposure scenarios and input parameters used in the exposure estimation. One of the main parameters affecting the outcome of the environmental exposure assessment are the release factors to the environment. ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation[94] suggests generic worst-case release factors for each environmental release category (ERC) that registrants can use without further justification. If non-default ERC release factors (site-specific or sector-proposed specific environmental release categories (SpERCs)) are available and used for exposure estimation, this should always be justified. This justification should be detailed enough, the source referenced (and retrievable) and linked to the related operational conditions or risk management measures, so ECHA can understand whether it covers the relevant scenarios for possible releases from substance processing according to the relevant exposure scenario. For example, SpERC developers and users should ensure that the description provided in the SpERC factsheet is detailed in a clear and accurate manner with sufficient justification, and covers all relevant activities or processes, operational conditions, and risk management measures claimed. In general, SpERCs include a definition of scope (applicability domain), information on conditions of use leading to a certain expected release factor, expected release factors, and an explanation of how the release factors were derived. If the SpERC factsheet does not contain sufficient background information on the release factor proposed, the registrant's CSR may not be convincing in demonstrating the control of risk.

[94] https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af

The exposure assessment requires the estimation of the level of the substance to which humans and the environment may be exposed. It is another key element in assessing whether the risks are adequately controlled throughout the lifecycle of a substance. It consists of two clear steps: identifying exposure scenarios (as discussed above) and estimating the exposure in each scenario.

The exposure estimates give the level of exposure that is expected when manufacturing and using a chemical substance and they are compared with the derived DNELs to ensure that human health is not adversely affected. For estimating the level of exposure, an adequate or representative set of measured data can be used. In the absence of workplace exposure data, the exposures should be carefully estimated by using the exposure models that are appropriate for the physico-chemical properties of the substance and the route of exposure. When using a model to obtain exposure estimates, you should understand how it works and its limitations, so that it is fit for purpose and you can enter the parameters correctly. In other words, you should use the model within its domain of applicability, and you should not deviate from the underlying assumptions in the model. For exposure tools integrated into Chesar, users receive warnings when using the tool in a way that may conflict with the applicability domain.

Justify your exposure based adaptions

When you use Annex XI, section 3, substance-tailored exposure-driven testing by claiming implementation of strictly controlled conditions throughout the life-cycle of the substance, for confirmation of applied conditions during the whole lifecycle of the substance, you should also provide a description of the specific activities performed at each lifecycle stage and on each relevant site concerning the handling and use of the substance in the registration dossier. For each specific activity it should contain a brief description of the system and/or equipment that demonstrates how the substance is rigorously contained by technical means during its whole lifecycle and how other requirements of Article 18(4)(a) to (f) of REACH are implemented.

More information on what information and documentation is relevant and necessary to be submitted in the registration dossier to support a claim of strictly controlled conditions is given in ECHA's Practical Guide 16, "*How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID*"[95], and ECHA's Guidance on intermediates[96].

Improve use descriptions

The basis for prioritising substances for evaluation and regulatory risk management are their hazard properties and exposure potential. In order to assess the exposure potential of a substance, there needs to be sufficient information on how it is used. For example, the work on the plastic additives has demonstrated that insufficient information on uses has been provided in REACH registrations to allow (de)prioritisation of substances used as additives in plastics based on their exposure potential. The lack of such information means adequate safety assessments for substances in plastic articles cannot be performed. In order to be able to prioritise and deprioritise plastic additives, registrations should be updated so that they provide a clear picture on the use patterns of these substances and conditions of safe use.

Use maps are a tool which aim to improve the quality of information on use and conditions of

[95] https://echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf/291b6e50-5598-42d3-8a2b-d63d50a68104
[96] https://echa.europa.eu/documents/10162/23036412/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641

use communicated up the supply chain and the efficiency of this communication process. Use maps are now available on ECHA's website for plastic compounding and conversion, which we recommend the registrants use. These use maps will be extended to cover article service life.

5.7 Familiarise yourself with new guidance on PBT/vPvB assessment

Take note that Chapter R.11 of the Guidance on Information Requirements and Chemical Safety Assessment[97] which covers PBT/vPvB assessment was updated in 2017. The integrated testing strategies for persistence and bioaccumulation were updated and there is further explanation on applying a weight-of-evidence approach, as required by REACH Annex XIII.

5.8 Identify and address information of the degradation products

The identification of the degradation products is a standard information requirement of Annex IX, Section 9.2.3. of REACH. Information on degradation products should be provided if you do not have valid evidence showing that your substance is readily biodegradable.

It is necessary for the PBT/vPvB assessment, as Annex XIII to REACH specifies that "the identification [of PBT and vPvB substances] shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products". Information on degradation products should also be taken into account for the exposure assessment (Annex I 5.2.4. of REACH), when applicable, and for the hazard assessment (e.g. Column 2 of Annex X 9.4 and Annex X 9.5.1 to REACH). Finally, this information is required for the preparation of section 12 of the safety data sheet (Annex II to REACH), when applicable.

Information on degradation products is generally obtained from simulation tests. For further information see ECHA's Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7.9.

5.9 Classify multi-constituent and UVCB substances correctly

The classification of a substance containing impurities, additives or multiple constituents (multi-constituent, UVCB) should, similar to mixtures, primarily be based on available relevant information (including test data) on the substance. However, when classifying for CMR properties or when evaluating the bioaccumulation and degradation properties within the hazardous to the aquatic environment hazard class, it is strongly recommended that the classification of the substance, similar to mixtures, should be based on information of the known individual constituent(s), as there is no toxicological difference between a mixture and a substance containing other constituent substances.

In exceptional cases, data on the substance itself might show more severe effects for classification for CMR or relevant effects on the bioaccumulation or degradation properties, which have not been identified from the information on the constituent substances. These data should then be used, if available. For non-CMR hazard classes, data on the constituents should be used for classification in accordance with the mixture rules where data on the substance is not available. The testing of a complex substance for classification purposes is strongly discouraged if there are data on the constituents.

[97] https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

5.10 Familiarise yourself with new documents on nanomaterials

ECHA invites you to familiarise yourself with the following five documents that provide advice to registrants preparing registration dossiers that cover nanoforms in 2017.

ECHA has published two completely new publications: the nano-specific Appendix R.6-1 to Chapter R.6: QSARs and grouping of chemicals of the Guidance on information requirements and chemical safety assessesment[98], and a document proposing best practices for registration of nanomaterials, "*How to prepare registration dossiers that cover nanoforms: best practices*"[99].

The best practices document provides recommendations for distinguishing between different nanoforms of a substance. Following the recommendations provided in the document will ensure consistent reporting of information on nanoforms in registration dossiers and facilitate registrants in clearly demonstrating that they fulfil their registration obligations for nanomaterials. Furthermore, Appendix R.6-1 provides an approach on how to justify the use of hazard data between nanoforms (and the non-nanoforms) and within groups of nanoforms of the same substance.

In addition, ECHA published updates to three of its existing guidance documents on nanomaterials: the Appendices[100] for nanomaterials to Chapters R.7a, R.7b and R.7c of the Guidance on information requirements and chemical safety assessesment (endpoint-specific guidances). These Appendices provide nano-specific guidance on how to meet the information requirements set out in Annexes VI-X to REACH.

5.11 Respond to ECHA's evaluation decisions

Respect the deadlines set in the decision

You are reminded to respect the deadline to update the registration dossier. Even in cases where the information may be late, it is in your own interest to communicate to ECHA in a dossier update with justifications and to provide all the requested information according to the expected timeline.

Report the new information correctly

You are requested to pay attention to detail when reporting the requested information in the technical dossier. ECHA must be able to assess the studies independently and form its opinion about the study validity and the significance of the results.

Information about the test material composition is crucial for ECHA to be able to conclude on the relevance of the study results to the registered substance.

You must also take all the new hazard information into account in the chemical safety assessment and reflect this in the CSR.

When updating your dossier, if you decide to adapt the information requirement (i.e. you do not perform the requested experimental test), any such adaptations must meet the conditions described in Column 2 of the respective REACH Annex, or you should follow the rules set out in

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[98] Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals: https://echa.europa.eu/documents/10162/23036412/appendix_r6_nanomaterials_en.pdf/.
[99] How to prepare registration dossiers that cover nanomaterials: best practices: https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/.
[100] https://echa.europa.eu/documents/10162/13632/appendix_r7a_nanomaterials_en.pdf/, https://echa.europa.eu/documents/10162/13632/appendix_r7b_nanomaterials_en.pdf/ and https://echa.europa.eu/documents/10162/13632/appendix_r7c_nanomaterials_en.pdf/.

Annex XI to REACH. Such adaptations must be fully justified and documented in order to allow ECHA to properly assess and verify the adaptation used.

5.12 Recommendations related to substance evaluation

When your registered substance is included in the CoRAP, review and update your dossier as early as possible

Perform a thorough check of your registration dossier and submit a dossier update, if needed, to facilitate the future evaluation process.

It is crucial to:

- Update your dossier in a timely manner before the start of the evaluation process;
- Ensure that the identitification of your registered substance is clear and appropriately documented;
- Make sure that your use and exposure scenarios are accurate and up-to-date, and that your exposure estimations are correct.

Ensure a good communication up and down the supply chain to gather the necessary information on the intended uses of your registered substance.

- Contact your downstream users as early as possible to have all the relevant information in place and also consider being in contact with specific downstream user organisations.
- Downstream users of a substance included in the CoRAP who own or have access to useful information should consider informing the lead registrant[101] or the evaluating MSCA[102].

Whenever possible, avoid submitting dossier updates once the substance evaluation has started, unless in agreement with the evaluating MSCA.

Use the opportunity to interact with the evaluating Member State competent authority

ECHA has published recommendations on best practice for informal interactions, as Member State competent authorities have agreed on a common approach on interaction with registrants during substance evaluation[103].

Discuss with your co-registrants and decide who could be nominated as a representative for interacting with the evaluating MSCA.

The evaluating MSCA may approach you in writing to request further clarifications before preparing a draft decision. Ensure your responses are timely and discuss with the evaluating MSCA on the need or timing of any update of the registration dossier.

Interact with ECHA where necessary

While the evaluating MSCA performs the evaluation, ECHA coordinates the overall substance evaluation process. You can contact ECHA for clarification on issues of more administrative nature using the ECHA contact form[104].

- Ensure that your REACH-IT contact information is kept up to date.

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[101] ECHA publishes the name of the lead registrants if permitted by the companies. For more information, check the "Lead registrant list" at: https://echa.europa.eu/regulations/reach/registration/registration-statistics.

[102] In the CoRAP list, ECHA publishes the Member State and contact details of the respective competent authority responsible for the evaluation of each substance.

[103] https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf

[104] https://www.echa.europa.eu/contact/helpdesk-contact-form

When you receive a substance evaluation draft decision, review it and provide your coordinated comments

Upon receipt of the draft decision from ECHA via the REACH-IT tool, review its content to understand the requests (including the test methods and/or the testing strategy).

Whenever possible, coordinate responses and submit a single set of consolidated comments within 30 days. The deadline for comments as well as the link to the webform are specified in the notification letter.

- All relevant registration numbers are listed in an appendix to the draft decision.
- Alternatively, you can consult the Co-registrants page in REACH-IT, which displays the contact details and roles of the existing registrants of the substance.

Similarly to the comments on the draft decision, coordinate responses to the proposals for amendment (PfAs) and submit a single set of consolidated comments within 30 days.

- Only comments on the PfAs are accepted, whereas comments on the (amended) draft decision *per se* are not taken into consideration at this stage of the process.
- Also, at this stage it is not possible to extend the deadline to submit comments, due to the strict timelines of the decision-making process imposed by REACH.

Start discussing with testing laboratories to explore their capacity for new testing, so as to prepare a smooth start of activities once the final decision is received.

- This information can also be used to inform the evaluating MSCA on realistic deadlines to be included in the decision.
- No testing may be conducted until the decision-making process is completed, as there may be changes to the requests.

When you receive a substance evaluation decision, agree with your co-registrants who performs the study

After the agreement by Member State competent authorities or the Member State Committee members, ECHA adopts the decision and communicates it to the concerned registrants using REACH-IT.

Within 90 days of receipt of the decision, you need to inform ECHA of the agreed legal entity which is to perform the requested tests on behalf of the other registrants who are addressees of the decision and/or impacted by it.

- If ECHA is not informed of such agreement within 90 days, it has the obligation to designate one of the addressees of the decision to perform the tests on behalf of all concerned registrants.

Any issues regarding data and cost sharing among the registrants need to be solved within the SIEF or consortia. The substance evaluation decision is not setting rules on how to share data and costs among the registrants of the same substance. The data and cost sharing should happen in accordance with the data-sharing obligation set out in REACH and in the Commission Implementing Regulation 2016/9.

Inform ECHA and the evaluating MSCA once all information requested in the decision has been submitted

Once all the requested information has been provided by an updated registration dossier, inform ECHA about this using the webform indicated in the notification letter[105].

Inform the evaluating MSCA by e-mail.

- The evaluating MSCAs' contact information is provided in the CoRAP list published on ECHA's website[106].

If all requested information cannot be submitted according to the deadlines specified in the decision, complete the ECHA webform and include any relevant explanations and supporting evidence concerning the status of any pending information requirements.

- At the same time, inform the evaluating MSCA about the dossier update situation. This interaction should enable the evaluating MSCA to have a fully informed view for deciding whether to propose specific actions.

5.13 Take note of ECHA's Guidance updates

ECHA has continued to develop and update REACH Guidance in 2017. The following updated Guidance documents were published on ECHA's website during the year.

- Corrigendum to the Guidance on data sharing (version 3.1), published 13 January 2017.
- New and updated appendices on nanomaterials to Chapters R.6, R.7a, R.7b and R.7c of the Guidance on Information Requirements and Chemical Safety Assessment, published 24 May 2017.
- How to prepare registration dossiers that cover nanoforms: best practices (version 1.0), published 24 May 2017.
- Corrigendum to the Guidance for identification and naming of substances under REACH and CLP (version 2.1), published 1 June 2017 in all EU languages.
- Update to the Guidance on requirements for substances in articles (version 4.0), published 28 June 2017.
- Update to the Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.11, Part C and specific sections of Chapters R.7b and R.7c (related to PBT/vPvB assessment) (versions 3.0/4.0), published 28 June 2017.
- Update to the Guidance in a nutshell on registration (version 3.0), published 5 July 2017.
- Update to the Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.7a, Sections R.7.5 on Repeated dose toxicity (version 6.0), published 19 July 2017.
- Update to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (version 3.0), published 4 July 2017.
- Update to the Guidance on the application of the CLP criteria (version 5.0), published 4 July 2017.

ECHA invites you to take note of these new or updated resources[107] and to update the relevant parts of your dossiers, where appropriate. ECHA will consider the new approaches described in the Guidance in ongoing and future dossier evaluations.

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[105] https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx
[106] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
[107] ECHA's Guidance web pages https://echa.europa.eu/support/guidance

5.14 Consider the impact of the United Kingdom's withdrawal from the EU on your registration

As of September 2017, ECHA has been providing companies with advice to help them prepare for the expected impact of the UK's withdrawal from the EU. This is published in the Q&A section of ECHA's web pages on the matter[108]. ECHA is continually updating the information it provides on these pages as the withdrawal process develops.

ECHA recommends that you consult this information and its updates over the coming months and beyond, until the UK's withdrawal takes effect. The ongoing negotiation process underlines the importance of the recommendation to keep yourself up to date on ECHA's evolving advice on the probable impact of the United Kingdom's withdrawal from the EU.

[108] https://echa.europa.eu/uk-withdrawal-from-the-eu

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
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
NER	Non extractable residues
PBT	Persistent, bioaccumulative and toxic
PfA	Proposal for amendment
PEC	Predicted environmental concentration
PNEC	Predicted no-effect concentration
OECD	Organisation for Economic Co-operation and Development
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 ECHA to securely submit, process and manage data and dossiersSEV Substance evaluation
SID	Substance identity
SIP	Substance identity profile
SIEF	Substance information exchange forum
SONC	Statement of non-compliance following a dossier evaluation decision
SVHC	Substance of very high concern

TPE	Testing proposal examination
t/a	Tonnes per annum (year)
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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