ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH

Progress Report 2011

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ABBREVIATIONS

CAS	Chemical abstracts service
CCH	Compliance Check
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic or toxic for reproduction
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DNEL	Derived no effect level
EA	Exposure Assessment
EC	European Commission
ECHA	European Chemicals Agency
ECVAM	European Centre for the Validation of Alternative Methods
EINECS	European Inventory of Existing Commercial Chemical Substances
EOGRTS	Extended One-Generation Reproductive Toxicity test (OECD TG 443)
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ESIS	European chemical Substances Information System
EU	European Union
GLP	Good laboratory practice
HH	Human health
(Q)SAR	(Quantitative) Structure Activity Relationship
IUCLID	International Uniform Chemical Information Database
ITS	Integrated Testing Strategy
MSC	Member State Committee
MSCA	Member State Competent Authority
OC	Operational conditions
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bio-accumulative, and Toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
QOBL	Quality observation letter
RAAF	Read-Across Assessment Framework
RCR	Risk Characterisation Ratio
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
SAR	Structure Activity Relationship
SE	Substance Evaluation
SID	Substance Identity
SMILES	Simplified molecular input line entry specification
TCC	Technical completeness check
TG	Test Guideline
TPE	Testing Proposal Examination
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
vPvB	Very Persistent and very Bio-accumulative

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FOREWORD

Welcome to this report, ECHA's third on our experience of evaluating registration dossiers submitted under REACH. With growing experience, we are more robust in recommending improvements in the quality. I trust that all readers with a keen interest in the safe use of chemicals find the report useful to better understand the progress we and our partners have made in the last year in that direction.

This report is essential reading for potential registrants preparing to submit dossiers for the 2013 REACH registration deadline, but also for companies who have already registered. I make this point because I am aware of the temptation for you to step back and relax after having submitted a dossier; however, the law is clear that the dossier remains your responsibility and you need to keep it up to date. For instance, when new information becomes available, you identify mistakes in your dossiers or you learn about the shortcomings of your dossier from this report. I hope that you feel inspired by the recommendations contained in this document to look again at your dossiers and improve them – ideally, before we open them for compliance checking.

Companies have rightly been congratulated for meeting the first REACH and CLP challenges – the number of registrations and C&L notifications made is impressive. However, "the devil is in the detail" and now we have a clearer view of where this makes a difference in dossier compliance and quality of disseminated data. Remember, information is at the heart of REACH and it was the lack of data on tens of thousands of substances in use in Europe that led to REACH in the first place. Here, I want to highlight three key aspects for the safe use of registered chemicals.

The first issue is that of substance identity. We have seen many cases where we were unable to determine accurately the identity of a substance because the information provided was ambiguous. My message is that you will prevent problems later on when you are precise in identifying your substance. Otherwise, we must question the relevance of the hazard data and consequently the information you provide on how to use your substance safely. A dossier with confusing substance identity is more likely to undergo a compliance check.

My second point is on the use of "read across", where you use data on similar substances to make judgements about the hazardousness of your own. Read across is an excellent way of making best use of existing data and avoiding unnecessary testing on vertebrate animals, but that only holds true when read across is thoroughly justified on sound science. Otherwise, the dossier cannot meet the data requirements of REACH. Furthermore, the risk assessment will be built on shaky grounds and be unreliable.

My third point is on chemical safety assessments. The quality of those so far evaluated has been mixed. The whole thrust of REACH is to improve the safe use of hazardous substances throughout the supply chain up to articles used by consumers including the waste disposal. The chemical safety assessment is central in documenting the safe use during the entire lifecycle of chemicals. I therefore urge you to improve your chemical safety assessments and ensure that appropriate safety advice is communicated to your customers through your safety data sheets and the annexed exposure scenarios. ECHA is supporting industry in developing good quality reports through the ECHA-Stakeholder Exchange Network on Exposure Scenarios and the publication of best practice reports.

Dear readers, in the year to come we will receive a growing number of dossier updates following ECHA decisions from previous years. We will verify the adequacy of the new information and ascertain that the decisions are correctly implemented. If needed, further action will follow in close cooperation with the Member States and the European Commission.

Thank you for taking the time to read this report. I hope it convinced you on the valuable contribution of our evaluation process in instilling confidence in the REACH system. As always, we welcome your feedback on the content or format of the report and your suggestions to improve the efficiency of our efforts.

Geert Dancet
ECHA Executive Director

EXECUTIVE SUMMARY

BACKGROUND

The aim of REACH is to protect human health and the environment while enabling the free movement of chemicals on the internal market. In addition, REACH promotes the use of alternatives to testing on animals for the assessment of hazards. It has shifted the responsibility for establishing the safe use of chemicals to companies manufacturing and importing chemicals as a substance on their own, in mixtures or in articles in the EU. Substances produced or imported at one tonne or more per annum must be registered and their safe use demonstrated in a registration dossier.

Evaluation (the 'E' in REACH) assists companies in achieving compliance with REACH. It verifies the adequacy of the information provided in registration dossiers and helps to identify potential substances requiring EU-wide risk management. As the chemical safety assessments rely on scientifically sound information, the evaluation process contributes to the safe use of chemicals.

This document reports on the evaluation activities carried out by ECHA in 2011 (in accordance with Article 54 of REACH). It also highlights the most frequently observed shortcomings in the dossiers and provides recommendations to improve the quality of existing and future registration dossiers.

This report is timely for companies preparing dossiers for the 2013 deadline (substances produced at a volume of 100-1000 tonnes per annum) as well as for companies who have already submitted, because they have the obligation to keep their dossiers always up to date. Therefore, all companies are encouraged to take a proactive approach and update their dossiers taking into account the recommendations provided in this and previous annual evaluation reports.

ACTIVITIES

Dossier evaluation work involves examining testing proposals and checking dossiers for compliance with REACH. During 2011, ECHA focused most of its efforts on the examination of proposals to test substances on vertebrate animals. This was necessary, because all testing proposals on phase-in substances from the first registration deadline of 1 December 2010 for Annex IX and X information requirements have to be examined by 1 December 2012.

In line with the planning for 2011, ECHA started the examination of 472 **testing proposals**; adopted 22 final decisions; issued another 165 draft decisions; and closed 58 cases where proposals were inadmissible (e.g. testing was proposed for Annex VII or VIII endpoints) or had been withdrawn by the registrant. In 18 of the final decisions, the tests were requested as proposed by the registrant while in four decisions at least one of the tests proposed by the registrant was modified.

In 2011, ECHA completed 146 **compliance checks**; another 52 were in the draft decision stage at year end; and the evaluation of 41 dossiers continues into 2012. Of the 146 completed dossiers, 105 resulted in an ECHA decision asking the registrant to provide further information; in 19 cases, recommendations were given to the registrants on how to improve their dossier quality in quality observation letters; 10 draft decisions were withdrawn after a dossier update; and in 12 cases, the dossiers were closed without regulatory action.

As an evaluation related activity, ECHA continued the screening of isolated intermediates. ECHA sent 40 letters to registrants according to Article 36 requesting further information in order to verify the intermediate status. After analysing the information received ECHA will consider the need for further action, where necessary in coordination with the enforcement authorities.

Substance Evaluation is a process that will formally start in 2012. This process clarifies open questions related to the safe use of substances; in particular those issues that cannot be addressed in Dossier Evaluation. Substance Evaluation can, for example, take into account cumulative amounts of an individual substance from several manufacturers when assessing a known risk or investigate suspected risks or hazards further by requesting information that goes beyond the standard REACH requirements. ECHA and the Member State Competent Authorities prepared the list of substances to be evaluated within the coming years. This list is known as the Community Rolling Action Plan or CoRAP as adopted on 29 February 2012.

RECOMMENDATIONS

Most of the testing proposals were adequately prepared and ECHA was able to accept them upon examination. In some cases however, ECHA needed to refine the approach; modify studies proposed; or clarify the identity of the substance registered by opening a targeted compliance check before the proposed test could be examined. Based on that experience and on observations in compliance checks, ECHA recommends the following:

Substance Identity

Define your substance precisely. Ambiguous identity of the substance weakens not only the connection between the registration dossier and the substance on the market, but also puts into question the relevance of the hazard data in the dossier for the registered substance and consequently the information on how to use it safely. This also applies to information yet to be generated in proposed tests. Dossiers are routinely filtered and when the substance is not clearly identified, the likelihood of the dossier being selected for compliance check is higher.

Testing Proposal

Provide justification in your registration dossier, when you have already started or conducted a study to meet an Annex IX or X information requirement, i.e. for other than REACH purposes. Indicate a target date when study results can be expected in an updated dossier, if they are not already present. The purpose of the requirement to submit a testing proposal before actually conducting the test is to avoid unnecessary animal testing and ensure that the test is tailored to the information needs. That is rendered meaningless, if the testing has already begun or been completed and thus testing proposal examinations for studies already ongoing will be terminated.

If you are responding to a third party consultation on testing proposals on vertebrate animals, please ensure that you only submit information that is scientifically valid and relevant for the case. For your information to be useful, do not make it or your address confidential. It is not enough that ECHA considers your information in its decision, but registrants need to know about and use the information in their registration dossiers in order to potentially achieve compliance. This means that registrants will need permission to refer to that information and will thus need to be able to contact you, the information providers, to obtain it.

Hazard Assessment

You need to provide robust scientific arguments in your dossier when using read across to meet the rules set in Annex XI for adaptation of the standard testing regime. When using read across, all aspects of the information requirement need to be addressed as they would with the standard test on the substance registered. Read across therefore needs a scientific reasoning supported by experimental evidence establishing that the properties under consideration can indeed be predicted with sufficient certainty from data obtained with analogues or category members.

When addressing prenatal developmental toxicity, remember that the requirements of the Annexes IX and X are cumulative and testing on two species might be necessary even for an Annex IX substance (100-1000t/a). Before you propose testing on a second species, consider the outcome of the test on the first species and other available information. Document your considerations in your dossier.

Scientific Progress

When you use data from or propose testing using non-EU test methods, provide your arguments explaining how your approach satisfies the information requirements of REACH. ECHA can accept new and non-EU test methods for use under REACH on a case-by-case basis, if the information generated can be considered adequate for addressing the respective REACH Annex IX and X endpoints.

When testing is necessary to address the Annex IX or X 8.7.3. "two-generation reproductive toxicity study" information requirement, you may choose to propose either a two-generation reproductive toxicity study (test method: EU TM B.35/OECD TG 416) or an extended one-generation reproductive toxicity study (OECD TG 443). However, ECHA's current position is that for the latter test to meet the REACH information requirements, it will need to include an extension of Cohort 1B to mate the F1 animals to produce the F2 generation, which are kept until weaning.

Chemical Safety Assessment

Be thorough in completing your chemical safety assessment and document it in your chemical safety report. Across dossiers, deficiencies have been observed in all parts of the chemical safety reports and registrants are advised to pay specific attention to this part of their registration dossiers. For instance, ensure classification and labelling of your substance according to Regulation (EC) No 1272/2008 and especially consistency with the harmonised classification and labelling. Take account of existing assessments of the European Union and other international bodies and justify deviations there from. When using non-default assessment factors, provide a substance specific justification. Describe in detail your emission minimisation efforts for substances meeting the PBT or vPvB criteria in your chemical safety report. Address all hazards identified in your exposure assessment, develop adequate substance specific exposure scenarios, precisely describe your operational conditions and give the details of your implemented risk management measures so that you provide appropriate advice on the safe use of your substance. The chemical safety report is your tool for ensuring and demonstrating the safe use for your substance. The information given in the chemical safety report is the basis for advising users of the substance on its safe use in the derived extended safety data sheets and product labels. Missing elements in the chemical safety report automatically lead to gaps in the advice and consequently affect the safe use.

1 INTRODUCTION

1.1 BACKGROUND

The REACH Regulation[1] aims to improve the protection of human health and the environment. In this context companies manufacturing or importing chemical substances are responsible for ensuring that these substances can be used safely. This is achieved by generating information on the properties of the substances, identifying the uses, assessing the risks involved, developing and recommending appropriate risk management measures. The REACH Regulation requires EU companies to document such information in registration dossiers for chemical substances manufactured or imported in quantities of one tonne per year or more. The European Chemicals Agency (ECHA) is the central body implementing REACH together with other actors.

The Evaluation process (the 'E' in REACH) facilitates compliance with the obligation to provide adequate information on registered substances, thereby - together with industry's own responsibility - instilling confidence within the EU citizens that industry meets the requirements for the safe use of their substances. Evaluation is also an important means of identifying substances of concern with the aim of replacing those with safer alternatives. ECHA's decisions are based on the legal requirements and sound science.

Through the process of evaluation, ECHA requests additional information or testing when essential data are missing in registration dossiers. In addition, ECHA provides recommendations for registrants to improve the quality of dossiers.

The Agency publishes an annual report on evaluation, as required by Article 54 of the REACH Regulation, by the end of February of each subsequent year. This report describes the progress made in evaluating registration dossiers and in substance evaluation during 2011.

This annual report also advises on the most frequent observations and shortcomings encountered in the processes of dossier evaluation. It provides recommendations to registrants in order to improve the quality of existing and future registration dossiers. Hence, this report is timely to help with the registrations due for the 2013 deadline for registration of substances produced at a volume of 100-1000 tonnes per annum. Existing registrants have an obligation to keep their dossiers up to date. Therefore, they are encouraged to take a proactive approach and already update their registered dossiers taking into account the recommendations provided in this and previous annual evaluation reports.

This document is intended for a targeted audience such as (potential) registrants, regulators, and other stakeholders with basic scientific and legal background knowledge of the REACH Regulation.

1.2 THE THREE PROCESSES OF EVALUATION

The adequacy of the registered data and the quality of dossiers is evaluated in three ways:

Compliance Check: The compliance check determines whether or not the information submitted is in compliance with the law. At least 5% of the dossiers received by ECHA per tonnage band need to be checked for compliance.

Testing Proposal Examination: When testing is needed to fulfil Annex IX and X standard information requirements, the registrants are obliged to submit a proposal as part of the registration, describing the test

1 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

planned. All such testing proposals have to be evaluated by ECHA prior to testing. The aim is to ensure that tests are tailored to the information needs and unnecessary testing, especially testing that involves the use of vertebrate animals, is avoided.

Substance Evaluation: The process of substance evaluation aims to clarify possible risks of the (collective) use of a substance.

Dossier Evaluation combines Compliance Check and Testing Proposal Examination and is mainly carried out by the ECHA Secretariat, whereas Member State Competent Authorities are in charge of Substance Evaluation. The decision-making process is the same for both processes.

A more detailed description of the evaluation processes is provided in Annex 1.

1.3 STRUCTURE OF THE REPORT

The report is structured in three main parts. After the short introduction (Part 1), Part 2 describes in detail the progress during 2011 on Dossier and Substance Evaluation providing also key statistical data. Part 3 reports frequently found shortcomings in a generic way and gives advice to registrants on how to improve their registration dossiers. The annexes contain an overview description of the Evaluation Processes and cumulative numbers for Compliance Check and Testing Proposal Examination.

2 PROGRESS IN 2011

2.1 DOSSIER EVALUATION

2.1.1 DOSSIERS SUBMITTED

More than 3 700 new registrations were completed under REACH in 2011, resulting in over 25 300 registrations completed by the end of 2011 and since the entry into operation. This figure excludes registrations of on-site isolated intermediates that are not subject to the evaluation process. These registrations are new registrations for jointly registered phase-in substances or for non phase-in substances. A breakdown of registrations per tonnage band and their status is presented in Table 1 below.

In order to understand the significance of the numbers and the link with the evaluation processes, the following should be considered:

- The total number of registration dossiers represents the number of successful registrations by 31 December 2011, i.e. submissions for which a registration number had been issued by that date.

- Registrations are counted only once regardless of the number of submitted updates, and the tonnage information and status provided below is based on the latest successful submission (which can either be an initial submission, a requested update or a spontaneous update).

- When a substance in a dossier is registered both as a standard registration (non-intermediate) and as a transported intermediate, it is only counted as one registration (non-intermediate) and assigned to the tonnage band of the registration.

The numbers in Table 1 cover all registration dossiers including those containing testing proposals:

TABLE 1: NUMBER OF COMPLETE REGISTRATION DOSSIERS BY THE END OF 2011

Tonnage per year	Registrations (non-intermediates)		Transported intermediates		Total
	Phase-in	Non-phase-in	Phase-in*	Non phase-in*	
1 - 10	953	932	1 022	688	6 811
10 - 100	922	306			
100 - 1000	1 804	184			
> 1000	16 116	151	2 279	21	18 567
TOTAL by status (phase-in/non phase-in)	**19 795**	**1 573**	**3 301**	**709**	**25 378**

* Phase-in substances = substances subject to transitional arrangements in REACH

** Non phase-in substances = new substance to the EU-market

2.1.2 PRIORITIES FOR TESTING PROPOSAL EXAMINATION

At the beginning of 2011, the ECHA database contained 565 dossiers with testing proposals. Article 43(2)(a) of the REACH Regulation specifies that *"the Agency shall prepare draft decisions … by 1 December 2012 for*

all registrations received by 1 December 2010 containing testing proposals …." To meet this legal target for the dossiers concerned, ECHA prioritised the processing of testing proposals during 2011. For non phase-in substances, Article 43 (1) of the REACH Regulation specifies a deadline of 180 days from receipt of the registration. Dossiers meeting this condition are processed upon arrival. The target for 2011 on concluding dossier evaluations (i.e. processing to the draft decision, quality observation letter (QOBL) or conclusion of no action) was set at 250 testing proposal examinations and 100 compliance checks.

Selection of dossiers containing testing proposals is done automatically, using the in-house IT-tool known as CASPER. It searches for the testing proposals (flagged with "experimental study planned") in the structured information as it is captured in the IUCLID study records.

CASPER was also used to help in prioritising the work to examine the testing proposals. In addition to the criteria specified in Article 40(1) of the REACH Regulation, the testing proposal evaluation was prioritised according to a combination of several other criteria: a) ambiguity in substance identity that prevents a meaningful examination of the testing proposal; b) structural similarity of different substances with testing proposals detected from a clustering analysis with the aim of facilitating the third party consultation and subsequent evaluation; c) substances that are part of a chemical category with related testing proposals; and d) testing proposals for vertebrate animal studies. In particular, this approach ensured that dossiers with clearly inadequate substance identity could undergo a targeted compliance check for substance identity and hence avoid an undue delay in subsequent examination of the testing proposal.

2.1.3 PRIORITIES FOR COMPLIANCE CHECK

The priority setting for compliance check has been described in the Guidance on dossier and substance evaluation and in the Guidance on priority setting for evaluation.
In line with the approaches described in these guidance documents, ECHA is currently selecting dossiers for evaluation using four sets of criteria:

a. random selection;
b. criteria set out in the REACH Regulation;
c. other concern-driven criteria; and
d. testing proposals with unclear identity of the substance registered.

The application of these criteria may evolve on the basis of the type of dossiers received, the effectiveness indicated by the evaluation outcomes, and discussions with Member State Competent Authorities, the Member State Committee and stakeholders. The average ratio of concern driven versus random checks is five to two.

Random selection is anticipated to gradually build a good overall picture of the compliance status of dossiers. It also avoids bias in the selection of dossiers and helps in refining the prioritisation criteria based on frequently encountered causes of non-compliance. The complementary approach of concern-driven selection prioritises dossiers that are most likely to contain shortcomings relevant to the safe use of the substance, and hence this optimises the use of ECHA's resources to have a maximum impact in terms of protection of human health and the environment.

2.1.4 TESTING PROPOSAL EXAMINATION

2.1.4.1 Testing proposals submitted and progress made

In 2011, significant progress was made on the examination of testing proposals. The annual target was to conclude the examination (i.e. send the draft decision to the registrants for comments or in some cases terminate

the process) on 250 dossiers with testing proposals. This target was not fully met (216) due to two main reasons: Firstly, in 67 cases, ECHA performed a targeted compliance check on substance identity prior to testing proposal examination as it is not possible to conclude on a testing proposal without knowing precisely the substance concerned. Secondly, ECHA stopped sending new draft decisions to registrants in early December to ensure that the 30 days commenting period did not overlap with the end of the year holiday period.

By the end of 2011, the total number of dossiers containing testing proposals had arrived at 566 (vs. 565 on 1 January). This value had fluctuated throughout the year as testing proposals were added or withdrawn by registrants. These changes are caused by new registrations and spontaneous updates of existing registration dossiers. Dossier updates may also happen during ongoing testing proposal examination and, if for a given dossier all testing proposals are withdrawn, the case is included in the number of closed cases (Table 3).

In additional to 115 cases carried over from 2010, ECHA initiated 472 testing proposal examinations in 2011, processing 587 testing proposal examinations in parallel (Table 2).

TABLE 2: TESTING PROPOSAL EXAMINATIONS IN PROGRESS DURING 2011

	Phase-in	Non-phase-in
No. of testing proposal examination initiated in 2011	448	24
No. of testing proposal examination carried over from 2010	94	21
Total number of dossiers subject to testing proposal examination in 2011	587	

By the end of 2011, 80 testing proposal examinations (14% of the cases opened) were completed; another 144 were in the decision making phase and the evaluation of the further 363 dossiers continues in 2012. Out of the 80 completed examinations, 22 were concluded with a final decision requesting the registrant to carry out tests; 58 examinations were closed (Figure 1).

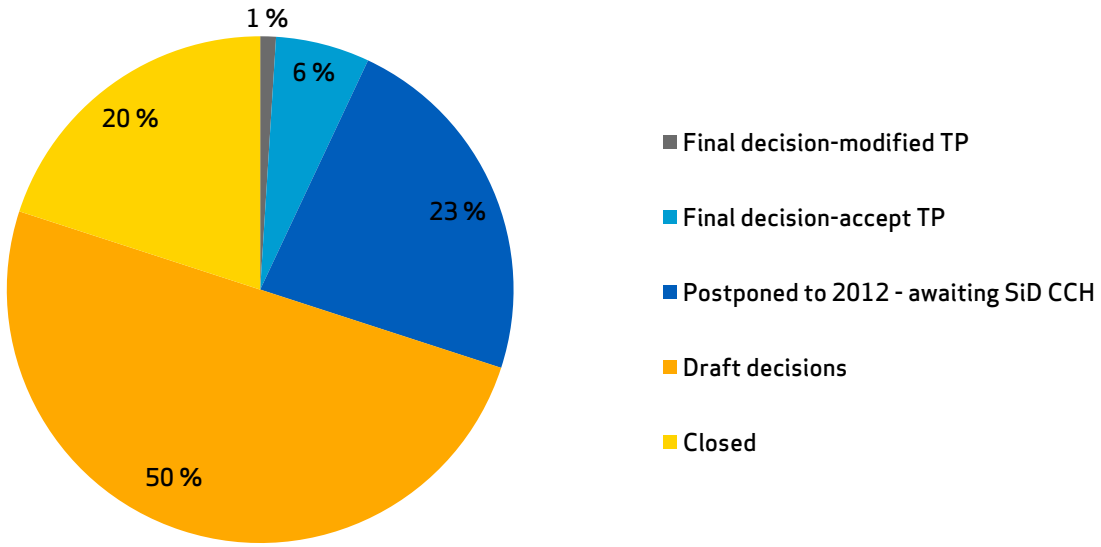

Figure 1: Concluded testing proposal examinations in 2011 by main outcome in percent

There are several reasons for closing a testing proposal examination. These include cease of manufacture or import by the registrant, withdrawal of the testing proposals (e.g. subsequent to downgrading of the

tonnage band), and inadmissibility. Inadmissible testing proposals are those that address Annex VII and VIII endpoints, those where the registrant indicated in the dossier that the Annex IX or X testing was already ongoing or even completed and those where, instead of testing results, a testing proposal was submitted to address a previous decision of a Member State Competent Authority according to Article 16(1) or (2) of Directive 67/548/EEC (see also Article 135 of the REACH Regulation).

When examining testing proposals, ECHA noted that in a number of cases the description of the substance identity was so ambiguous that clarification was needed to allow a meaningful testing proposal examination. Such cases were prioritised for compliance check in order to have sufficient time for subsequent processing of the testing proposal by the 1 December 2012 deadline. A number of such dossiers were to be updated with substance identity information in December 2011 and the follow-up process has been started.

For testing proposal examinations completed in 2011, the legal deadlines were respected (e.g. a draft decision was sent within 180 days of receipt of a non phase-in substance) except for one case. In this case, the legal deadline was missed by one day due to a clerical error (180 days versus six months).

The status of the testing proposal evaluations in 2011 is summarised in Table 3.

TABLE 3: NUMBERS OF TESTING PROPOSAL EXAMINATIONS AND STATUS OF THE PROCESSES IN 2011 (PERCENTAGES IN PARENTHESES)

Type	Total	Third party consultation	Draft decision	Final decision	Closed	Continue in 2012
Phase-in	542(92%)	422(72%)	129(22%)	9(2%)	48(8%)	356(61%)
Non-phase-in	45(8%)	30(5%)	15(3%)	13(2%)	10(2%)	7(1%)
TOTAL	587(100%)	452(77%)	144(25%)	22(4%)	58(10%)	363(62%)

2.1.4.2 Third party consultation

Before ECHA concludes upon a proposal for testing of a substance using vertebrate animals, the substance's name and the endpoint addressed are published on ECHA's website to invite third parties to submit scientifically valid and relevant information on the endpoint and substance in question. Any such information is subsequently taken into account in the testing proposal examination. The registrant is informed about the information provided (unless it is claimed confidential) and the conclusion drawn from this information by ECHA in the draft decision.

In this way, the information is shared with the registrants, who can consider any proposed alternative approaches and document them in their registration dossiers if they wish to include them in their testing strategy. To increase transparency in decision-making ECHA started in 2011 to provide summaries of responses to the third party comments on the ECHA website.

ECHA had to conduct more public consultations than there were dossiers with testing proposals at the end of the year for two reasons: a) registrants withdrew testing proposals after the public consultation had taken place, and b) registrants updated the dossier with a new testing proposal covering an additional endpoint and a second public consultation was necessary for the same dossier. Table 4 details the number of vertebrate

testing proposals and the status of the related third party consultation processes.

TABLE 4: TESTING PROPOSALS SUBJECT TO THIRD PARTY CONSULTATION*

No. of tests proposed		Phase-in	Non phase-in	Total
No. of registered dossiers*	containing testing proposals for vertebrate animals	398	33	**431**
No. of endpoints	covered by registered testing proposals for vertebrate animals	660	55	**715**
No. of third party consultations	consultations closed	354	27	**381**
	ongoing on 31st of December 2011	8	2	**10**
	in preparation	75	2	**77**

* Number of third party consultations is larger than the number of dossiers as registrants are withdrawing testing proposals during the process or adding new ones multiplying the number of third party consultations for their dossier

** Successfully registered (accepted and fee paid)

In 2011, ECHA received 481 comments on testing proposals published on the ECHA website from non-governmental organisations, companies, industry or trade organisations, and individuals. Non-governmental organisations provided the greatest number of comments (293), which mainly contained information intended to support the use of alternative testing strategies, the suggestion to use the extended one-generation reproductive toxicity study (OECD TG 443) instead of the two-generation reproductive toxicity study (EU B.35; OECD TG 416) and proposals for fulfilling the information requirement by use of read across to analogous substances with references to available information (e.g. publicly available OECD SID documents) rather than new testing. Companies provided 99 comments of which 46 concerned the details of a non-linear QSAR prediction and either contact details, model description and/or the results were claimed to be confidential. Registrants, industry and trade organisations provided information in 53 cases that generally supported the information already provided in the respective registration dossier (e.g. further explaining a read across approach). In the case of the 24 comments from individuals, these were more varied and no general pattern of responses was established. For example, one referred to the availability of an occupational exposure study whilst others referred to the availability of related test results.

ECHA assesses the comments received from third parties and informs the registrant of its consideration of any information that has been provided in the draft decision sent to the registrant. Registrants may then consider if this information is relevant to their information needs and use the information, including ECHA's considerations, to modify their approach. For example, the information may provide an adequate basis to adapt the information requirements rather than propose the conduct of a new study. It is not transparent to ECHA, i.e. reported in the dossier, whether a given withdrawal of a testing proposal was triggered by third party information or by other considerations of the registrant. So far, none of the third party information received has given grounds for ECHA to reject a testing proposal.

2.1.4.3 Final decisions

In 18 final decisions, the tests proposed by the registrants were accepted while in four cases at least one of the tests proposed had been modified.

The most common endpoints addressed in final decisions were prenatal developmental toxicity (10) and sub-chronic repeated dose toxicity (8), followed by viscosity (5). The information requested by final decision from the registrants is summarised in Table 5.

TABLE 5: INFORMATION REQUESTED BY THE FINAL DECISIONS ON TESTING PROPOSALS

Type of testing required requested	No. of decisions*
A. IX - 7.15. Stability in org solvents and ID of degradation products	1
A. IX - 7.16. Dissociation constant	3
A. IX - 7.17. Viscosity	5
A. IX - 8.6.2. Sub-chronic toxicity study (90-day)	8
A. IX - 8.7.2. Pre-natal developmental toxicity study	10
A. IX - 8.7.3. Two-generation reproductive toxicity study	2
A. IX - 9.1.5. Long-term toxicity testing on invertebrates	2
A. IX - 9.2.1.3. Soil simulation testing	1
A. IX - 9.2.1.4. Sediment simulation testing	1
A. IX - 9.3.2. Bioaccumulation in aquatic species	1
A. IX - 9.3.3. Further information on adsorption/desorption	1
A. IX - 9.4.1. Short-term toxicity to invertebrates	3
A. IX - 9.4.2. Effects on soil micro-organisms	3
A. IX - 9.4.3. Short-term toxicity to plants	1
A. X - 8.7.2. Pre-natal developmental toxicity study	1
A. X - 8.7.3. Two-generation reproductive toxicity study	1
A. X - 9.4.4. Long-term toxicity testing on invertebrates	2
A. X - 9.4.6. Long-term toxicity testing on plants	1
A. X - 9.5.1. Long-term toxicity to sediment organisms	2

* In general, final decisions addressed more than one information item needed to bring the registration into compliance (~2.6 as an average).

The 22 final decisions were adopted as follows:

- Nine draft decisions were adopted by ECHA as final decisions without referral to the Member State Committee (i.e. Member State Competent Authorities did not propose amendments).

- 13 draft decisions received at least one proposal for amendment by a Member State Competent Authority. The Member State Committee considered these proposals for amendments and unanimously agreed on the (modified) draft decisions. ECHA accordingly adopted the final decisions.

In two cases, the Member State Committee was not able to find unanimous agreement on the study protocol to be used for addressing the information requirement of Annex IX and X 8.7.3. "Two-generation reproductive toxicity study". Some members were in favour of requesting the study to be performed according to the "Extended one-generation reproductive toxicity study (EOGRTS) test protocol (adopted as OECD TG 443

on 28 July 2011) whilst other members could not agree on imposing the use of the new guideline (also in the light of the existing EU method B.35) or could only accept its use with certain specifications.

As a result, one draft decision was referred to the Commission for decision in the REACH Committee in 2011.

In the second case, the Member State Committee agreed in its November meeting to split the draft decision into two parts: One part to contain the testing agreed as a final decision to be sent to the registrant and another part to be referred to the Commission for decision in the REACH Committee. This procedure was chosen to enable the registrant to address the agreed information requirements without undue delay. This case was not concluded in 2011 and is therefore counted in the present statistics as "draft decision".

2.1.5 COMPLIANCE CHECK OF REGISTRATION DOSSIERS

In 2011, the priority was given to the examination of the testing proposals and in line with the multi-annual plan on evaluation; the annual target was set to 100 concluded compliance checks. Due to the encountered problems in the substance identity of dossiers with testing proposals, ECHA had to open more dossiers for compliance check than expected.

In 2011, the Agency examined 239 dossiers under compliance check: 158 of these checks were initiated in 2011 and 81 were carried over from 2010. Table 6 presents the number of dossiers undergoing compliance check in 2011. An overview of compliance checks conducted by the Agency since the beginning of the evaluation processes is presented in Annex 3.

TABLE 6: COMPLIANCE CHECKS UNDERTAKEN IN 2011

	Total number
No. of compliance checks initiated in 2011	158
No. of compliance checks carried over from 2010	81
Total number of dossiers under compliance check in 2011	239

By the end of 2011, 146 compliance checks were completed; another 52 were in the decision making phase and the evaluation of a further 41 dossiers continues in 2012. The outcome of the compliance checks in 2011 is presented in Figure 2.

Out of the 146 completed dossiers, 105 dossiers were concluded with a final decision requesting the registrant to provide further information; in 19 cases, quality observation letters were sent in order to allow the registrant to improve the dossier but not constituting a formal decision; another 22 dossiers (10 of them after draft decision) were concluded with no further action. Of the 105 final decisions, 75 concerned dossiers →1000t, 11 dossiers 100-1000t, eight dossiers 10-100t, and 11 dossiers 1-10t (Table 7).

TABLE 7: COMPLETED COMPLIANCE CHECKS IN 2011 BY TONNAGE BAND					
Tonnage band	final decision	quality obs. letter	closed after Draft Decision	without action	TOTAL
>1000t	75	3	1	7	86
100-1000t	11	3	7	2	23
10-100t	8	2	0	0	10
1-10t	11	11	2	3	27
TOTAL	105	19	10	12	146

For all compliance checks completed in 2011, all legal deadlines were respected (e.g. the possible draft decision was issued within 12 months from the start of the compliance check).

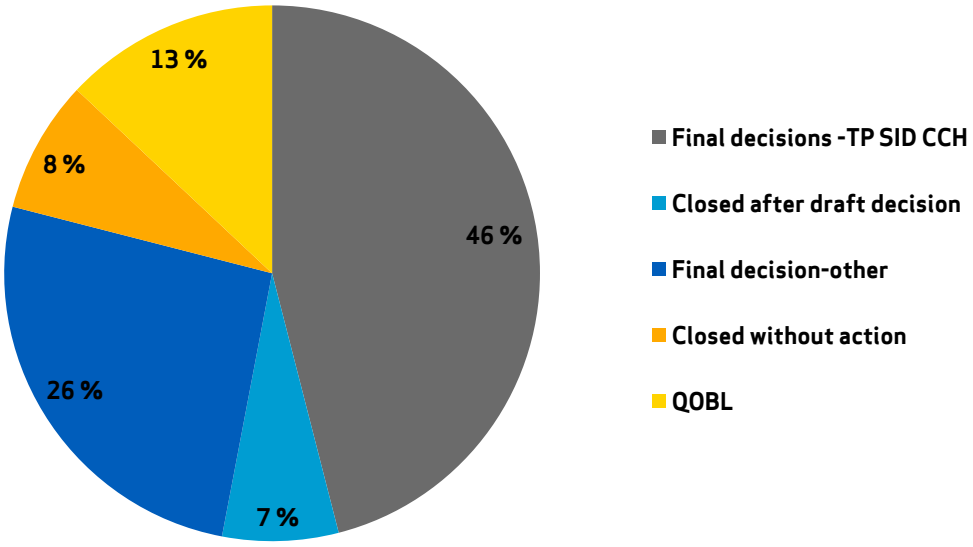

Figure 2: Completed compliance checks in 2011 by main outcome; QOBL= quality observation letter

The 105 final decisions were adopted as follows:

- 76 draft decisions were adopted as final decisions with no involvement of the Member State Committee since there were no proposals for amendments received from the Member State Competent Authorities. This predominantly applied to targeted compliance checks on substance identity (67 cases).

- 29 decisions received proposals for amendments by at least one Member State Competent Authority. These proposals for amendments were addressed in a written procedure or discussed in the meetings of the Member State Committee. The Committee reached unanimous agreement on all draft decisions and ECHA accordingly adopted the final decisions.

No draft decisions following a compliance check have been referred to the Commission so far.

The information requested by final decision from the registrants is summarised in Table 8.

TABLE 8: INFORMATION REQUESTED BY THE FINAL DECISIONS ON COMPLIANCE CHECK	
Type of information requested	No. of cases*
Exposure assessment and risk characterisation (Annex I)	1
Improved robust study summaries (Annex I, 1.1.4 and 3.1.5)	3
Derived no-effect levels as part of the human health hazard assessment (Annex I, 1.4.1)	5
Predicted no-effect concentration as part of the environmental hazard assessment (Annex I, 3.3.1)	8
Information regarding identification and verification of the composition of the substance (Annex VI, 2.)	10
Relative density (Annex VII, 7.7.4)	2
Boiling point (Annex VII, 7.3)	2
Vapour pressure (Annex VII, 7.5)	1
Surface tension (Annex VII, 7.6)	1
Water solubility (Annex VII, 7.7)	1
Explosive properties (Annex VII, 7.11)	1
Self-ignition temperature (Annex VII, 7.12)	3
Oxidising properties (Annex VII, 7.13)	3
Granulometry (Annex VII, 7.14.)	1
In vitro gene mutation study in bacteria (Annex VII, 8.4.1)	1
Short term toxicity to invertebrates (Annex VII, 9.1.1)	3
Growth inhibition study aquatic plants (Annex VII, 9.1.2)	5
Skin irritation (Annex VIII, 8.1)	1
Eye irritation (Annex VIII, 8.2)	2
Skin sensitization (Annex VIII, 8.3)	1
In vitro cytogenicity study in mammalian cells (Annex VIII, 8.4.2)	2
In vitro gene mutation study in mammalian cells (Annex VIII, 8.4.3)	10
Screening for reproductive/developmental toxicity (Annex VIII, 8.7.1)	2
Toxicokinetic (Annex VIII, 8.8)	2
Activated sludge respiration inhibition testing (Annex VIII, 9.1.4)	1
Hydrolysis (Annex VIII, 9.2.2.1)	1
Screening for adsorption/desorption (Annex VIII, 9.3.1)	1
Dissociation constant (Annex IX, 7.1.6)	1
Viscosity (Annex IX, 7.17)	1
Mutagenicity, *in vivo* (Annex IX, 8.4)	1
Sub-chronic toxicity study 90-day (Annex IX, 8.6.2)	3
Prenatal developmental toxicity (Annex IX, 8.7.2)	8
Two-generation reproduction toxicity study (Annex IX and X, 8.7.3)	1
Long term toxicity to invertebrates (Annex IX, 9.1.5)	1
Long term toxicity to fish (Annex IX, 9.1.6)	1

Type of information requested	No. of cases*
Degradation (Annex IX, 9.2)	1
Bioaccumulation in aquatic species (Annex IX, 9.3.2)	2
Short term toxicity to invertebrates (Annex IX, 9.4.1)	2
Short term toxicity to plants (Annex IX, 9.4.3)	2
Miscellaneous study requested under Annex X, 8.6.4	1
Request for further justification for deviations from the guidance	1
PBT-assessment	2

* In general, final decisions addressed more than one information item needed to bring the registration into compliance.

In some cases, the Agency sends quality observation letters inviting registrants to revise their registration dossiers and address shortcomings not related to formal data gaps. The incentive of these letters is to inform registrants and Member State Competent Authorities on quality issues found in registration dossiers that raise concern. The types of concerns addressed through quality observation letters are summarised in Table 9.

TABLE 9: TYPE OF SHORTCOMINGS ADDRESSED THROUGH QUALITY OBSERVATION LETTERS (QOBL)

Shortcomings/inconsistencies addressed through QOBLs	Number of cases*
Substance Identity	15
CSR related e.g. PNEC or DNEL derivation, exposure assessment, missing description of the waste stage, PBT issues	11
Classification and labelling	23
Guidance on safe use, e.g. sufficient advice on the prevention of exposure	1
Insufficient level of detail/inconsistencies in robust study summaries	9
Identified uses, strictly controlled conditions, status as intermediate	4
Data sharing	1
Full study report	1
Consideration of further studies	7
Inconsistent info on tonnage band	1
Test performed without submitting a TP	1
Clarification on the GLP status of eco-tox tests	1
Manufacturing process	1
Justification for adaptations to standard information requirements	1

* In general, QOBLs addressed more than one inconsistency

With regard to the dossiers for which evaluation has been completed in 2011, the random selection applied to about 15% of selected dossiers (22 dossiers), while 39% (57 dossiers) were selected using concern-driven criteria. 46% (67 dossiers) were targeted on the identification of the substance (SID) triggered by testing proposal examination.

An overview of the compliance check outcome of both types of selected dossiers (concern-driven/randomly

selected) is presented in Table 10. The results show that, except for the SID-targeted compliance checks related to testing proposals, the proportion of dossiers that were closed without any administrative action was similar for the two remaining types.

For the randomly selected dossiers, the percentage of quality observation letters and final decisions was lower (9% and 41% respectively) than that for the concern-driven selection (31% and 52%), whereas in all cases for dossiers targeted on SID triggered by TPE a decision (67) was sent (100%).

The outcome of compliance checks completed in 2011 suggests that the quality of the evaluated dossiers may be further improved (72% of the checks were concluded with a final decision and another 13% with a QOBL). However, it is important to realise that the observed quality of these dossiers cannot be generalised for all dossiers that have been registered by 1 December 2010. Due to the limited number of normal compliance checks concluded after subtracting the number of targeted compliance checks on substance identity upon testing proposal examination representative statistics remain unavailable at this moment.

TABLE 10: QUALITY OF DOSSIERS FOR WHICH COMPLIANCE CHECKS HAVE BEEN COMPLETED (FINAL DECISION OR NO ACTION) IN 2011

Shortcomings/inconsistencies addressed through QOBLs	Outcome type				Total
Reason for selection	Final Decision	Only QOBL	Closed after Draft Decision*)	Closed without action	
Concern			4	5	52
Random	9	2	6	5	22
CCH targeted to SID	1				1
CCH targeted to SID and HH	1				1
CCH triggered by TPE and targeted to SID	67				67
CCH triggered by TPE and concern		1		2	3
Total	105	19	10	12	146

* Cases closed after draft decision was sent to the registrant and the dossier been updated with the information required

It is expected that due to an initial learning curve in dossier preparation the dossiers will improve over time. Registrants are advised to make use of the possibility to update their dossier and improve the quality using their own initiative at any time.

2.1.6 FOLLOW UP OF DOSSIER EVALUATION

Article 42 of the REACH Regulation foresees that ECHA shall examine any information submitted as a consequence of a decision requesting new information. Once the dossier evaluation is completed, ECHA shall notify the Commission and the Member State Competent Authorities of the information obtained and any conclusions reached.

This new information (as well as already existing information) can trigger further action by ECHA or the Member State Competent Authorities. Those actions may include prioritisation of the substance for substance evaluation (Article 45(5)), preparing an Annex XV dossier for the identification of substances of very high concern to be included in Annex XIV (Article 59(3)) or preparing a restriction proposal (Article 69(4)).

By the end of the year, 42 updates of dossiers subject to targeted substance identity check decisions had been received and the follow-up procedure was initiated. The conclusions of these cases are expected to be available in the first quarter of 2012. No further follow-up cases were concluded as in 2011, the examination of testing proposals had been prioritised.

2.1.7 DIRECTIVE 67/548/EEC, ARTICLE 16(2) DECISIONS

A second group of decisions requiring follow-up work is represented by the decisions taken by the Member State Competent Authorities under the previous chemicals legislation Directive 67/548/EEC requesting notifiers to provide further information according to Article 16(2) thereof. After the entry into force of REACH, those decisions became ECHA decisions according to Article 135(1) of the REACH Regulation. The compliance of the information submitted by the registrant upon such decision shall be evaluated by the Agency according to Article 42 of REACH (Dossier Evaluation follow-up).

The registration dossiers for which the deadline to provide the requested data as set out in the respective decisions has passed are not in compliance with the legal requirements and may be subject to enforcement actions by the national authorities. Currently, ECHA is interacting with Member State Competent Authorities to coordinate its response to registrants. As a first step, reminders were sent to 97 registrants about the pending requests.

This concerns in total 144 decisions for which the status is as follows:

- Dossier updates received (by 31 December 2011): 67
- Follow-up completed by ECHA: 4

More information on the process is provided in the document *"Questions and Answers for the registrants of previously notified substances" available on the ECHA website*[2].

2.1.8 APPEALS

In 2011, one of the final decisions upon compliance check has resulted in an appeal with ECHA's Board of Appeal in accordance with Article 91. At the date of the editorial deadline of this report, this case was still pending.

Cases brought to the Board of Appeal are published on the respective section of the ECHA website[3].

2.2 SUBSTANCE EVALUATION

2.2.1 BACKGROUND

According to REACH, the Substance Evaluation process is to start in 2012, after the establishment of the first Community Rolling Action Plan (CoRAP). In 2011, ECHA and the Member State Competent Authorities launched important activities to prepare for the successful launch.

2.2.2 WORKSHOP ON SUBSTANCE EVALUATION

ECHA hosted a workshop on substance evaluation from 23 to 24 May 2011. It was prepared for Member State Competent Authorities, the Member State Committee and the Commission. The objective of the workshop was to build a consensus view and as far as possible to agree on the most efficient process for

2 http://echa.europa.eu/documents/10162/17238/prev_not_sub_registrants_qa_en.pdf
3 http://echa.europa.eu/web/guest/about-us/who-we-are/board-of-appeal

substance evaluation. The workshop discussed the criteria for the selection of substances for substance evaluation and informed the Member States of the activities with regard to the development of the draft CoRAP along with discussions concerning the substance evaluation process itself, procedural aspects and templates for outcome documents in particular.

The MSC stakeholders were afterwards invited to provide comments on the substance evaluation process described in the draft proceedings. The final proceedings of the workshop are available on the ECHA website[4].

2.2.3 PREPARATION OF THE COMMUNITY ROLLING ACTION PLAN (CoRAP)

The Agency submitted the first proposal for the Community rolling action plan (CoRAP) to the Member States and ECHA Member State Committee on 20 October 2011, well before the legal deadline of 1 December 2011. The ECHA Secretariat had pre-filtered the IUCLID database and externally available sources using internally developed IT-tools called CASPER and PRO.S.P for candidate substances. The retrieved list had further been filtered by a manual screening of the respective registration dossiers, after which a shortlist of 50 substances had been suggested based on the criteria agreed in the workshop. A further 50 substances had been identified by the Member States.

The final draft plan contained 91 substances divided tentatively over the years 2012, 2013 and 2014, starting with 36 substances in 2012. For the practical preparation of the first draft CoRAP, ECHA asked the Member States for their capacity to conduct substance evaluations in the first coming years. According to the survey, the Member States are currently planning to evaluate 35 to 50 substances per year. In the coming years, the plan will develop further.

The Member State Committee adopted an opinion on the substances to be included in the CoRAP during its meeting from 6 to 10 February 2012. Based on this opinion, the Agency is adopting the final CoRAP for 2012–2014 on 29 February 2012[5] . In the future, the plan will be updated annually by the end of February.

2.2.4 DIRECTIVE 67/548/EEC, ARTICLE 16(1) DECISIONS

A group of decisions requiring follow-up work is represented by the decisions taken by the Member State Competent Authorities under the previous chemicals legislation Directive 67/548/EEC requesting notifiers to provide further information according to Article 16(1) thereof. After the entry into force of REACH, those decisions became ECHA decisions according to Article 135(2) of the REACH Regulation. The information submitted by the registrant shall be evaluated and conclusions shall be made by the respective Member State Competent Authority according to Articles 46 and 48 of REACH (Substance Evaluation follow-up).

The registration dossiers for which the deadline to provide the requested data as set out in the respective decisions has passed are not in compliance with the legal requirements and may be subject to enforcement actions by the national authorities. Currently, ECHA is interacting with Member State Competent Authorities to coordinate its response to registrants. As a first step, reminders were sent to 67 registrants about the pending requests.

This concerns 97 decisions for which the status is as follows (by 31 December 2011):

- Dossier updates received: 42
- Follow-up completed: 12

4 http://echa.europa.eu/documents/10162/17221/ws_on_substance_evaluation_may_2011_summary_proceedings_en.pdf
5 http://echa.europa.eu/web/guest/regulations/reach/evaluation/substance-evaluation

More information on the process is provided in the document *"Questions and Answers for the registrants of previously notified substances" available on the ECHA website*[6].

2.2.5 FACT SHEET ON SUBSTANCE EVALUATION

To promote transparency and better understanding of the process leading to the establishment of the first CoRAP for Substance Evaluation, ECHA published a fact sheet on Substance Evaluation in April 2011[7]. It provides an overview of the stages in the preparation of CoRAP, the role of ECHA and the Member States, the decision-making process and what it means for the registrants if their substance is included in the CoRAP.

2.3 EVALUATION RELATED ACTIVITIES

2.3.1 INTERMEDIATES

On-site isolated intermediates (REACH Article 17) and transported isolated intermediates (REACH Article 18) can be registered using reduced information requirements provided they are used under strictly controlled conditions. The determination of the applicable data requirements (reduced or standard) therefore depends on the fulfilment of these conditions. These prerequisites are separate from the data requirements set out by Articles 17 and 18 and, thus, do not fall within the scope of compliance check.

In order to verify the status of isolated intermediates according to REACH, Article 36 of REACH gives competence to ECHA and the Member State Competent Authorities to request information from registrants that they rely upon to decide whether their products fulfil the definition of intermediate and the conditions imposed by Articles 17 and 18, without checking under Article 41 whether the dossier actually complies with the reduced data requirements.

Under the above legal basis, ECHA has started a new process in 2011 called verification of intermediate status (as defined by REACH), to ensure the appropriate registration and safe use of the substances. It should be noted that this verification of the prerequisites for registration as an isolated intermediate does not address the compliance of the dossier with applicable information requirements. A manual screening of approximately 400 selected dossiers identified several cases where the information contained within the dossier is insufficient to confirm the isolated intermediate status. For those, ECHA has sent registrants letters requesting further *"information the registrant requires to carry out his duties under this Regulation"* (Article 36(1)). These letters are targeted to confirm the conditions for registration as intermediates. Firstly, Article 36 letters were sent out at the beginning of September 2011. Altogether, 40 Article 36 letters on intermediates have been sent by the end of 2011. More specifically, these requests related to 17 substances where screening of the lead registrant dossier revealed concerns on the intermediate status and strictly controlled conditions. Article 36 requests have also been addressed to member registrants of these substances in three cases (respectively, six, eight and six member registrants). In addition, registrants of three substances of very high concern have been addressed by Article 36 letters. A follow up on the responses to Article 36 letters is ongoing and may lead to the opening of compliance checks in 2012 for such dossiers, for which the status as intermediate according to REACH cannot be confirmed. Another potential follow-up action is the on-site verification of the intermediate status by national enforcement authorities of the Member States.

2.3.2 DOSSIER EVALUATION RELATED SCIENTIFIC DEVELOPMENT

An international test method may be recognised by the Commission or ECHA as being appropriate for use in registration dossiers based on Article 13(3) of the REACH Regulation. The European Commission can include a new method in the EU Test Method Regulation (EC) No 440/2008.

6 http://echa.europa.eu/documents/10162/17238/prev_not_sub_registrants_qa_en.pdf
7 http://echa.europa.eu/documents/10162/17236/substance_evaluation_fact_sheet_en.pdf

ECHA has in certain cases accepted non-EU test methods for studies required as an outcome of dossier evaluation for endpoints that have official test guidelines of the Organisation of Economic Collaboration and Development (OECD TG) or International standardisation Organisation (ISO) but no method in the EU Test Method Regulation. In these cases, the Member State Competent Authorities and the Member State Committee have agreed with using such non-EU Test Methods on a case-by-case basis. ECHA requested conducting the OECD TG 114 Viscosity, OECD TG 112 Dissociation Constant in Water, ISO 22030 Chronic Toxicity to Higher Plants, and OECD TG 488 Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays to fulfil the respective requirements indicated for Annex IX and X.

2.3.3 SUPPORT TO REGISTRANTS

2.3.3.1 Website section on evaluation

In January 2011, ECHA launched a dedicated section on evaluation on its website[8]. The new pages provide an overview of the three independent evaluation processes under REACH: compliance check, evaluation of the testing proposals and substance evaluation. A graph on the dossier evaluation process helps users to understand the different steps in the process and the role of all the actors involved. The new evaluation section also provides easy access to all guidance documents, practical guides and other information on evaluation published by ECHA.

2.3.3.2 Informal interaction with the registrants

The REACH Regulation provides the right for registrants to formally comment on a draft decision within a period of 30 days of receipt. Such formal comments have to be submitted in writing using a form provided on the ECHA website. In this way, registrants are given the right to be heard on the proposed requests for further information and may use this as an option to bring the dossier into compliance by submitting an updated dossier with available additional information already at this stage.

ECHA provided upon request further scientific and legal background information for registrants in order to better understand the information requests in the draft decision and the decision-making process in form of an oral discussion. The new approach had started in autumn 2010 as a pilot and was established permanently in 2011. In practice, ECHA offers in the notification letter of the draft decision offers the possibility to informally discuss the scientific and legal rationale behind the draft decision as well as providing details on the formal commenting period and commenting format for the registrant. (More details of this approach can be found in the Evaluation Progress Report of 2010.) As the interaction had in many cases improved the understanding between ECHA and the registrants, ECHA decided to implement the new approach in 2011 on a routine basis. In about 41% of the cases handled by ECHA in 2011, informal interaction took place and the majority of those interactions were perceived by ECHA staff as very useful, while most of the involved registrants expressed their satisfaction at the end of the interaction.

Where following the interaction the registrant intends to achieve compliance for his registration dossier this can only be done by updating the registration dossier. Oral information or documentation that is not included in the registration dossier will not be sufficient to allow ECHA a solid assessment. If the dossier is properly updated, this may result in a modified draft decision or even a complete withdrawal of a draft decision, if the dossier is then found to meet the legal requirements. Depending on the outcome of the interaction between ECHA and the registrant, ECHA may agree to wait for an updated registration dossier before referring its draft decision to the Member State Competent Authorities. Once a file has been referred to Member State Competent Authorities for proposing amendments in accordance with the decision making procedure, no updates are expected with regard to the information requirements contained in the draft decision. This is

8 http://echa.europa.eu/web/guest/regulations/reach/evaluation

without prejudice to Article 22, i.e. the obligation to spontaneously update the dossier if new data becomes available.

2.3.3.3 Access of registrants and stakeholder observers to decision-making process

ECHA is committed to transparency in its processes. To this end regular stakeholder observers of the Member State Committee are able to follow the discussions taking place when a case that has been referred to the Committee is introduced and initially discussed in the Committee meeting, unless confidential aspects of the registration dossiers are addressed. However, no documents related to the decisions or the proposals for amendment made by the Competent Authorities are provided to these observers.

A representative of the registrant (case owner) is also invited to attend the meetings during the initial discussion of their own case by the Member State Committee. Since the update of the working procedures of the Member State Committee on dossier evaluation in early 2011, the regular stakeholder observers of the Committee and case owners (registrants) have been able to follow the Member State Competent Committee discussions on dossier evaluation during the initial discussion of the dossier evaluation cases (both compliance check and testing proposal draft decisions). During 2011, fifteen case owners used this opportunity and participated in the Committee's discussions in the meetings (44% of the 34 cases addressed).

2.3.3.4 Stakeholders' Day

Evaluation featured high on the agenda of ECHA's Sixth Stakeholders' Day, which took place on 18 May 2011. The event gathered 500 participants from 30 countries. A further 500 watched the event via web streaming[9].

One of the three main sessions of the event was dedicated to evaluation and dissemination. ECHA provided an overview of the ongoing dossier evaluation process and recommendations to registrants for improving the quality of the information in their dossiers. Opportunities to reduce animal testing were highlighted in a presentation of an animal welfare organisation.

Individual discussions on evaluation issues took place in the one-to-one sessions, which provided the opportunity for participants to meet ECHA experts and discuss in detail the problems they were facing. Interest in this new form of interaction, introduced during the Fifth Stakeholders' Day is growing with more than 150 individual sessions held – an increase of one third, and a high level of satisfaction regarding the overall effectiveness of the discussions – "very high" for 21% of those that took part in them, and "high" – for 55%.

In conjunction with the Sixth Stakeholders' Day, ECHA organised an in-depth training session on 17 May, which focused entirely on the chemical safety assessment and Reporting tool (Chesar). It provided an overview of the functionalities for carrying out a chemical safety assessment for a "simple case" and a demonstration on how the information is then reported in the chemical safety report.

2.3.3.5 Update of REACH Guidance relevant to Evaluation

Following the first registration deadline and the end of the moratorium on the publication of guidance documents (30 November 2010), ECHA continued with finalising the guidance updates in 2011 in order to gradually close important guidance work initiated in 2010.
The guidance on identification and naming of substances under REACH has been updated to reflect changes in the REACH Regulation and to align it with the CLP Regulation. The revised Guidance on Intermediates was published in December 2010[10].

9 http://echa.europa.eu/news/events/6th_stakeholders_day_en.asp
10 These updates have not yet been mentioned in the Evaluation Report

The guidance on information requirements and chemical safety assessment has been updated stepwise in order to address the priority needs of industry and to keep it in line with the developments related to ECHA's chemical safety assessment reporting tool, Chesar. The updates of the chapters on the adaptation of information requirements, on exposure scenario building and environmental release estimation, and on the use of human data for derived no effect levels (DNEL) and derived minimum effect levels (DMEL) derivation were published on 16 December 2010[16]. In September 2011, a new chapter (chapter B.8 *"Scope of exposure assessment"*) was added to Part B "Hazard Assessment"[11] of the "Guidance on information requirements and chemical safety assessment" creating Version 2 of this part and the "Guidance on the compilation of safety data sheets"[12] was published. Both documents were subject of further updates in December 2011.

Furthermore, in 2011 the accessibility of the guidance was further improved by publishing "lighter" versions of the guidance documents and explanatory documents (e.g. guidance in a nutshell, practical guides, fact sheets) in multiple languages.

The registrants are invited to take note of these new documents and update the relevant parts of their dossiers accordingly. The new approaches described in the guidance (i.e. scope of exposure assessment) will be taken into account during ongoing and future dossier evaluation processes.

2.3.3.6 Practical Guide on Dossier Evaluation

In 2011, ECHA published a new Practical Guide 12 *"How to Communicate with ECHA in Dossier Evaluation"*[13]. It explains to industry and third parties what dossier evaluation is and how dossiers selected for evaluation are processed. It also gives advice on how and when registrants should react to communications sent by ECHA related to the evaluation of their registration dossier.

As in the case of other practical guides published on a regular basis by the Agency, the need for this publication was triggered by ECHA's observations on the needs of stakeholders and analysis of the questions addressed to the Agency. It communicates these observations to a wider audience. However, it is not a formal guidance that is established under the formal guidance consultation process involving stakeholders. It is produced under the sole responsibility of the Agency with the aim to support stakeholders in their interaction with ECHA.

2.3.3.7 Examples of Exposure Scenarios and CSR

Practical examples of exposure scenarios covering industrial, professional and consumer end uses with the aim of establishing a common understanding between industry and authorities of the information that an exposure scenario should contain have been published on the ECHA website.

ECHA has also been preparing for the publication of an "Illustrative Example" of a full chemical safety report with the objective to illustrate: i) the nature and content of the information required in a chemical safety report, in accordance with the chemical safety report format (Annex I, Section 7 of REACH); ii) how to improve the quality and consistency of chemical safety reports and to resolve common shortcomings identified by ECHA through dossier evaluation; iii) the format of the report generated when using ECHA's chemical safety assessment and reporting tool, Chesar[14].

2.3.3.8 Chesar

Chesar is a tool developed by ECHA that aims to help companies carry out their chemical safety assessments

11 http://echa.europa.eu/documents/10162/17235/information_requirements_part_b_en.pdf
12 http://echanet/Request/Lists/Requests/Attachments/3202/SDS_Guidance_v1.1_12-2011.pdf
13 http://echa.europa.eu/documents/10162/17235/pg_12_how_to_comm_with_echa_in_dossier_evaluation_en.pdf
14 http://guidance.echa.europa.eu/other_en.htm

and prepare their chemical safety reports. Chesar provides the structured workflow for carrying out a standard safety assessment for the different uses of a substance. At the same time, the tool is flexible enough to also accommodate assessments in more specific situations. The tool also helps to structure the information needed for the exposure assessment and risk characterisation that will facilitate the generation and updating of a transparent chemical safety assessment. The Chesar tool and supporting documentation (user manuals) can be downloaded from the ECHA website[15].

2.3.3.9 ECHA-Stakeholder Exchange Network on Exposure Scenarios

In 2011, ECHA and accredited stakeholders set up a joint network (ENES) to better understand and address the challenges that industry faces with developing and communicating exposure scenarios in the supply chain. The network aims to reach a wide range of industry sector registrants – for example, manufacturers, formulators and downstream users all engaged in preparing and using exposure scenarios - in the expectation that developments in one sector can facilitate improvement and consistency in approach in others and thereby enhance the safe use of chemicals through the supply chain.

The first ENES meeting, which took place in Brussels from 24 to 25 November, was organised jointly with the European Chemical Industry Council (Cefic), European Association of Metals (Eurometaux), the oil companies' European association for environment, health and safety in refining and distribution (CONCAWE), European Association of Chemical Distributors (Fecc) and the international Association for Soaps, Detergents and Maintenance Products (A.I.S.E.). 100 delegates from industry associations, individual companies and Member State Competent Authorities took part in the meeting discussions on the needs/ challenges of generating and implementing the exposure scenario and setting the priorities for the future in order to raise further awareness and understanding of the importance of exposure scenarios[16].

15 http://echa.europa.eu/documents/10162/17221/evaluation_under_reach_progress_report_2010_en.pdf
16 http://echa.europa.eu/en/web/guest/view-article/-/journal_content/a1755ca4-ec8c-458c-bca8-101ac8ab7bce

3 RECOMMENDATIONS TO REGISTRANTS

3.1 GENERAL OBSERVATIONS

Dossier evaluation processes undertaken in 2011 reveal that, in general, registrants strive to fulfil their obligations under REACH regarding information requirements. However, it has been identified that further improvement is possible and certain aspects highlighted hereunder deserve the attention of all registrants.

This section reports on the most frequent observations and shortcomings encountered in the processes of dossier evaluation and provides recommendations to registrants in order to improve the quality of registration dossiers. These recommendations contain technical and scientific terminology in order to make them most useful for registrants when preparing (updates of) the technical dossier and the chemical safety report. This part of the document is therefore intended for a targeted audience with sufficient scientific and legal background knowledge of the REACH Regulation.

The most frequently found shortcomings in registration dossiers addressed by an ECHA decision were related to substance identity (72%), *in vitro* mutagenicity studies (16%), exposure assessment and risk characterisation (9%), prenatal developmental toxicity (8%) and robust study summaries (8%). Except for the robust study summaries, which have already been addressed by last year's report (page 34)[17], these frequently encountered issues are detailed together with some other more general issues in the sections below.

The registrants are encouraged to take a proactive approach and update their dossiers taking into account the recommendations provided below.

3.2 SUBSTANCE IDENTITY

A registration under REACH is based on the identity of the registered substance. Substance identification therefore constitutes an essential element for the purpose of REACH including the evaluation processes and needs to be unambiguous and accurate.

The importance of ensuring a clear substance identity is linked to the principle for which one registration shall cover one substance under REACH. This aspect is fundamental for deciding if two substances should be part of the same joint registration. Advice on how to identify the substance registered has already been given in the Progress Report 2010 on Evaluation under REACH (pages 24-25[18]). However, given the key role of the proper identification of the substance registered and therewith defining the scope of the registration dossier, the most important aspects are summarised below.

Each registrant is responsible for ensuring the correctness and preciseness of the information included in a registration dossier. The information on the identity and composition shall be specific to the substance that is actually manufactured or imported.

Particular attention should be given to the information provided on the name and composition included in registration dossiers of substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

It should be noted that in general, the naming of a UVCB substance consists of two parts: the chemical name

17 http://echa.europa.eu/documents/10162/17221/evaluation_under_reach_progress_report_2010_en.pdf
18 http://echa.europa.eu/documents/10162/17221/evaluation_under_reach_progress_report_2010_en.pdf

and the more detailed description of the manufacturing process. Such description shall include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical processes involved, the corresponding process parameters and further purification steps, if appropriate.

Significant differences in the source used or in the manufacturing process would be likely to result in different substances. The specificity of the information provided is therefore essential for unambiguously determining the identity of these substances.

Registrants shall note that special information requirements on the composition of UVCB substances have been defined and should be provided. It should be noted that, among such requirements, information on specific constituents/groups of constituents present in the substance shall be provided.

The identity and composition specified in the registration dossier needs to be supported by appropriate analytical information. Qualitative and quantitative analytical data generated on the substance as manufactured are required in order to confirm this information.

Clear substance identification is a pre-requisite for the examination of testing proposals. When ECHA is not able to conclude on the identity of a registered substance due to inconsistency or ambiguity, a substance identity targeted compliance check is initiated.

3.3 *IN VITRO* MUTAGENICITY

The data in Table 8 identifies *in vitro* mutagenicity as the second most frequent type of shortcomings addressed in final decisions on compliance check, in particular *in vitro* gene mutation study in mammalian cells (10%) and *in vitro* gene mutation study in bacteria (6%). In that respect, the following points are brought to the attention of the registrants:

In case of negative findings in both lower tier mutagenicity tests (i.e. *in vitro* gene mutation study in bacteria and *in vitro* cytogenicity study in mammalian cells), the study summary of the *in vitro* gene mutation test in mammalian cells (OECD 476) must be provided in the dossier as well.

As already detailed in the Evaluation under REACH Progress Report of 2010 in chapter 3.1.3.1 - Use of existing data, ECHA considers that data on four bacterial strains does not fulfil the information requirement for that endpoint. Consequently, when only data from an *in vitro* gene mutation study in four bacterial strains is available, registrants shall provide data for the fifth strain specified in the current EU B.13/14 test method.

If the registrant considers that other available relevant data (e.g. higher tier mutagenicity tests) can cover the data provided by the fifth strain, the absence of data on the fifth strain shall be clearly justified in the dossier.

3.4 RELEVANCE OF THE TEST AND THE TEST MATERIAL FOR THE SUBSTANCE REGISTERED

Concerning testing proposals, the registrants are advised to consider the rational for the proposal carefully. For example submission of testing proposals for viscosity testing for a solid substance or dissociation constant testing for a substance without ionisable groups are not appropriate as such testing is technically not possible.

Another problem is ambiguity in the identity of the test material, especially where the composition of the registered substance has a large variation of the relative amounts of constituents and the relevance of the material proposed or used for testing is not obvious. Registrants are advised to identify the test material carefully and ensure that the material is also representative for all member registrations in a joint submission.

3.5 IDENTIFICATION OF TESTS PROPOSED

It is important to note that if testing proposals are made only in the CSR, i.e. the registration does not contain the required indicators in the technical IUCLID-dossier; they are not detected in the automated search. Consequently, the registrant will not receive any decision regarding the testing proposal. Registrants who submitted testing proposals in such an improper manner are invited to update their dossier urgently and correct it by including the testing proposals under the relevant IUCLID entries/endpoints in the section "study result type" by selecting from the drop-down menu experimental study planned.

3.6 USE OF THIRD PARTY INFORMATION

In order to prevent unnecessary animal testing, there is a third party consultation of testing proposals for studies using vertebrate animals. In this process, interested parties have 45 days to submit scientifically valid information and studies addressing the endpoint and substance in question.

ECHA takes into account all scientifically valid information and studies received in preparing its decision. However, as in accordance to Article 1(3), registrants are responsible for the safe use of the substances they place on the EU internal market, it is also for the registrants to consider this information and document this in their registration dossiers. The registrants are therefore advised to take into account relevant third party information.

The submitter may claim confidentiality for the information. In this case, the information cannot be disclosed to other parties including the registrants. Information providers are asked to submit such information that can be passed on to the registrant, including contact details, so the registrant can decide whether the additional information is sufficient for addressing the information need and contact the information provider where necessary. It is further recommended to the third party to include sufficient information, so as to give the registrant the opportunity of judging whether the information is relevant or not.

If the access to information provided by the third party is subject to compensation, ECHA cannot impose on the registrant to acquire such data.

Some comments have been submitted by third parties that are not relevant for the testing proposal examination. Examples of such comments are given here:

- Proposal for integrated testing strategy or tiered testing. Such a proposal is not new information and hence is not a sufficient basis to fulfil the data/information requirements.

- *in vitro* methods and QSAR models for chronic and developmental toxicity. It should be noted that the data currently produced from such methods and models are not able to act as a one-to-one replacement for the long term repeated dose, carcinogenicity, mutagenicity, and reproductive toxicity studies, but might be useful as a part of a weight of evidence approach.

- Information from other regulatory assessments and from other (similar) substances. The validity of such information is considered on a case-by-case basis and cannot be used without an accompanying scientific justification.

3.7 TESTING WITHOUT PRIOR SUBMISSION OF A TESTING PROPOSAL

In the ECHA report on The Use of *Alternatives to Testing on Animals for the REACH Regulation* (published 30 June 2011)[19], a statistical analysis of registration dossiers submitted under REACH showed there to be

19 http://echa.europa.eu/documents/10162/17231/alternatives_test_animals_2011_en.pdf

107 higher tier studies on vertebrate animals which appeared to be or have been conducted in the absence of testing proposals. ECHA strongly recommends that registrants justify in their dossier the conduct of such tests without a testing proposal and ECHA decision.

There can be reasons why this statistical approximation may over-estimate the number of such studies. For example, the statistical analysis used the year 2009 or later as a reference date. As this normally refers to the reporting date, most of the studies may have been started before the requirement in REACH entered into force. It is also possible that studies may have been conducted to fulfil other non-EU regulatory purposes and were submitted because they were available.

Subsequent analysis further showed that these 107 tests were submitted in 91 registration dossiers. Eighteen of these registration dossiers were originally submitted under the previous chemicals legislation (Directive 67/548/EEC) and testing proposals were not required in those cases.

For the remaining dossiers (73), it is only possible to further assess this matter through individual examination of the registration dossiers and this is undertaken if the dossier is subjected to a compliance check. Ten of the dossiers identified in the statistical analysis are already undergoing a compliance check and the remainder may be subject to compliance checks conducted in the future. In the case of a (suspected) non-compliance with the REACH requirement of submission of a testing proposal before conducting a higher tier test involving vertebrate animals, ECHA informs the Member State Competent Authorities, who in turn have the possibility to inform the relevant national enforcement authorities.

Registrants are advised to update their dossier in the relevant IUCLID endpoint study record with the reason (e.g. for a purpose other than REACH) for conducting a new higher tier study without a testing proposal to fulfil an Annex IX or X information requirement if they omitted to do this in their original dossier. If the test results are not available yet, a commitment on the date when this information will be available in the dossier should be included as well.

3.8 SEQUENTIAL TESTING

Testing for reproductive toxicity, e.g. developmental toxicity or two-generation reproductive toxicity, does not need to be conducted under certain conditions of column 2 of the respective Annex based on results from other toxicity studies. As the outcome of the sub-chronic toxicity study (90-day repeated dose toxicity) may inform upon the need of conducting one or more reproductive toxicity studies, ECHA gives registrants sufficient time to allow for sequential testing, e.g. first sub-chronic toxicity and then reproductive toxicity.

3.9 PRENATAL DEVELOPMENTAL TOXICITY ON A SECOND SPECIES

ECHA considers that data from a second prenatal developmental toxicity study in another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation subject to the Annex IX, 8.7.2. column 2 requirements. So specifically, a prenatal developmental toxicity study in a first species is required according to Annex IX, 8.7.2, and a second prenatal developmental toxicity study in another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation, subject to the Annex IX/X, 8.7.2. column 2 requirements.

Annex IX, 8.7.2 provides that the prenatal developmental toxicity study shall initially be performed on one species, and that the decision to proceed with a study in a second species shall be based on the outcome of the first test and all other available data. In interpreting this, ECHA notes the column 2 provision that if a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary.

Thus if the results of the prenatal developmental toxicity study in the first species provide grounds for classification at Category 1B, then no further testing for prenatal developmental toxicity is required (unless there is a need for data to support a robust risk assessment). However, if there is classification at category 2, or no classification, then the ECHA guidance is opposite: at Annex X, a study in a second species will normally be required when the first study is negative, unless a weight of evidence assessment or specific data e.g. toxicokinetic data provide scientific justification not to conduct the study in a second species.

Registrants are advised to pay specific attention to the potential need of a pre-natal developmental toxicity study when updating dossiers with information requirements according to Annex X.

3.10 TWO-GENERATION REPRODUCTIVE TOXICITY

The Extended One-Generation Toxicity Study (EOGRTS) OECD Test Guideline No. 443 can be suitable under certain conditions for a higher-tier study on a registered substance to fulfil the current information requirement in Annexes IX and X, 8.7.3. of REACH for a "two-generation reproductive toxicity study". The recent adoption of the OECD Test Guideline 443 will give registrants a choice between test methods when addressing the standard information requirement 8.7.3.:

- A two-generation reproductive toxicity study (test method: EU TM B.35/OECD TG 416);

or

- An extended one-generation reproductive toxicity study (OECD TG 443) including the extension of Cohort 1B to mate the F1 animals to produce the F2 generation which shall be kept until weaning. The conduct of the study should allow generation of data equivalent to the current EU TM B.35 in line with REACH provisions.

There may be cases where registrants have specific information on properties of a substance justifying that it is not necessary to include the second filial generation in the EOGRTS in order to investigate adequately the reproductive toxicity of the substance. Such arguments might be used in a weight of evidence approach according to Annex XI, 1.2. of REACH to justify adapting the standard information requirements of Annex IX/X 8.7.3 for the two-generation reproductive toxicity study. It remains the responsibility of the registrant to present such arguments in their testing proposal, and they can update their registration dossier if necessary to present such justifications. These scientific arguments will be considered in the examination of the testing proposal and the subsequent decision making. Any justifications must be scientifically well established and documented in order to allow ECHA and Member States to understand and examine the approach taken.

When registrants comment on the draft decision for the testing proposal, ECHA expects that registrants express their preference on the method they want to use, so that their preference can be considered during the decision making procedure. It should be noted that when the Member State Competent Authorities propose amendments to ECHA's draft decision the case is referred to the ECHA Member State Committee for agreeing on a final decision. Registrants will receive any proposal for amendment made and can take position on those. In addition, registrants will be invited to the Member State Committee meeting that addresses the decision for their substance and will be heard there.

Registrants may change their existing testing proposals with regard to the test method they prefer to use for reproductive toxicity before they receive a draft decision by updating their registration dossier.

The approach described above is based on the ECHA Secretariats' understanding of the legally binding information requirements of the REACH Regulation concerning reproductive toxicity and how EOGRTS may be used to fulfil them. It is to be noted that, currently, there is no unanimity among Member States authorities on how to exactly implement OECD TG 443 to meet the REACH information requirements, and this is causing uncertainty for the decision making in the Member State Competent Authorities. Parallel

to this communication the European Commission is analysing the introduction of OECD TG 443 in the Test Method Regulation (EC) No 440/2008, and its implementation under REACH.[20]

3.11 ADAPTATION OF STANDARD INFORMATION REQUIREMENTS

3.11.1 (QUANTITATIVE) STRUCTURE-ACTIVITY RELATIONSHIPS

ECHA received information generated by computational tools such as (quantitative) structure-activity relationships. Besides the advice already given under chapter 3.1.5 ECHA would like to point out that the Joint Research Centre (JRC)/Institute for Health and Consumer Protection, is keeping an inventory of information on (quantitative) structure-activity relationship models. Developers and users of (quantitative) structure-activity relationship models can submit information on their (quantitative) structure-activity relationship models by using a standard (quantitative) structure-activity relationship model reporting format (QMRF)[21]. The JRC performs a basic quality control of the documentation and the summaries describing the (quantitative) structure-activity relationship models are included in the (quantitative) structure-activity relationship model database of the JRC. It is emphasised that inclusion of a model in the (quantitative) structure-activity relationship model database does not imply acceptance or endorsement by the JRC or the European Commission. The adequate documentation of the actual prediction by using the (quantitative) structure-activity relationship prediction reporting format (QPRF) is the responsibility of the registrant. In the QPRF, justification for why the substance fits in the applicability domain of the model must be provided. In this, more than one line of evidence should be considered. For example, the substance descriptors should be in the range of the descriptors, used in the model. This is a necessary but not a sufficient precondition for considering that the substance is in the applicability domain. Ideally, the applicability domain should express the structural, physicochemical, and response space of the model. It follows that the structure of the substance for which one or several properties are predicted must fall into this applicability domain. Any inclusion and exclusion rules that define the response variable should be recorded. These should include information on the mechanism or mode of action, if possible. It should be noted that normally (quantitative) structure-activity relationships should not be used alone, but rather within a weight of evidence approach.

Further guidance on the use of quantitative structure-activity relationships under REACH is available from ECHA's website[22] (Chapter R.6 of the REACH Guidance on Information requirements) and a practical guide how to report (quantitative) structure-activity relationships in IUCLID is also available there (Practical guide No 5)[23]. Good practices were formulated in the Evaluation 2010 Report.[24]

3.11.2 *IN VITRO* METHODS

One of the goals of REACH is the promotion of alternative methods for the assessment of hazard. *in vitro* methods qualify as one group of such methods. However, ECHA would like to remind registrants that, even if validated and by regulatory bodies accepted *in vitro* methods are available, for an endpoint where information from an *in vivo* study is a REACH requirement e.g. skin irritation/corrosion for substances above 10 tonnes per annum, the registrant should use Annex XI adaptations to justify the adequacy of the submitted information generated by the use of *in vitro* studies.

New *in vitro* methods are being constantly validated; hence, the ECHA Guidance documents may not contain the latest developments, therefore it is necessary to follow appropriate websites to investigate the current status of methods and their applicability. The "Tracking System for Alternative test methods Review, Validation and Approval in the Context of EU Regulation on Chemicals" (TSAR) reports regularly on the

20 http://echa.europa.eu/documents/10162/17911/echa_newsletter_2011_4_en.pdf
21 http://ihcp.jrc.ec.europa.eu/our_labs/computational_toxicology/qsar_tools/QRF
22 http://echa.europa.eu/documents/10162/17224/information_requirements_r6_en.pdf
23 http://echa.europa.eu/doc/publications/practical_guides/pg_report_qsars.pdf
24 http://echa.europa.eu/doc/evaluation_under_reach_progress_report_2010_en.pdf

current regulatory status and the use of alternative methods[25].

Care should be taken when using and selecting an appropriate *in vitro* method, since specific test guidelines may have certain limitations e.g. can only be used for certain types of chemical classes. This is especially relevant for *in vitro* tests assessing ocular effects, where the applicability domain of the test can be narrow. The information can be obtained from the tests guidelines and from the validation reports of the tests[26]. When using such methods the registrant will have to demonstrate that the registered substance falls within the applicability domain of the test.

ECHA published Practical Guide 1 (How to report *in vitro* data) and Practical Guide 10 (How to avoid unnecessary testing on animals) to assist registrants in avoiding unnecessary testing and submitting compliant information[27].

3.11.3 EXPOSURE BASED ADAPTATION

REACH allows for the omission of certain studies based on the exposure scenarios developed for the substance. According to Annex XI, 3, exposure based adaptation is possible for tests in section 8.6 and 8.7 of Annex VIII and tests in Annex IX and X. In order to qualify for exposure based adaptation, the registrant needs to develop exposure scenarios for the substance. In addition, the registrant needs to provide adequate justification and documentation for the adaptation, which shall be based on thorough and rigorous exposure assessment. However, ECHA noted cases where exposure based waiving was used without having these elements in place.

It should be noted that the conditions laid down in point 3.2. (a) (ii) of Annex XI stipulate that for repeated dose toxicity tests or reproductive toxicity tests, a no effect level derived from a lower tier test is not considered as an appropriate basis to omit the respective higher tier test. On the other hand, according to point 3.2. (b) of Annex XI exposure based adaptation may be used to omit such repeated dose toxicity studies when the registrant can demonstrate that strictly controlled conditions as described in Article 18(4)(a) to (f) apply to the substance.

3.11.4 GROUPING OF SUBSTANCES AND READ-ACROSS APPROACH

Read across is, under certain conditions, accepted under the REACH Regulation as a means to meet information requirements, and many registration dossiers contain read across cases. Category and analogue approaches are forms of identifying potential candidate substances for a read across by grouping of chemically similar substances.

The registrant is responsible for presenting the scientific arguments on which the read-across/category approach is based. These arguments have to establish that the properties under consideration can indeed be predicted with sufficient certainty from data obtained with analogues or category members. In other words, the registrant has to demonstrate that the non-standard information covers the information requirements, as would the standard test on the registered substance. If such adequate and reliable documentation is missing, ECHA cannot assess the validity of a presented or proposed read across and consequently the case cannot be accepted. The basic requirements are formulated in Annex XI (1.5) of the REACH Regulation.

The ability to utilise read across depends further on the identity and composition of the source substance and the target (e.g. registered) substance, as well as on the quantity and nature of impurities in either substance. It follows therefore that a read across case should address the issue of the detailed composition

25 http://tsar.jrc.ec.europa.eu/
26 http://ecvam.jrc.it and http://iccvam.niehs.nih.gov/
27 http://echa.europa.eu/documents/10162/17250/pg_report_in_vitro_data_en.pdf and http://echa.europa.eu/documents/10162/17250/pg_avoid_animal_testing_en.pdf

of source and target substance.

It should be noted that at the core of this approach there should be a read across hypothesis, which justifies why the properties of a substance can be read across to another substance. In the case of the category approach, this hypothesis may be concerned with trends among substances and/or mechanistic considerations. The validity of this hypothesis may need confirmation by experimental data. The way the data gap will be filled should be explained (e.g. if minimum, maximum, average value, or trend analysis is used). The trends might not always be linear and this should be kept in mind during the filling of data gaps. It is the responsibility of the registrant to justify scientifically the case for the read-across, for example in terms of a plausible trend and/or biological mechanism, with supporting evidence from the literature or testing if appropriate.

The OECD QSAR Toolbox[28] offers different ways of data gap filling, together with methods for profiling and grouping substances. The use of such a tool, however, does not replace scientific reasoning or supporting evidence.

ECHA carefully evaluates each case of read across in compliance checks and testing proposal examinations. Next to the requirements of Annex XI, this evaluation follows the extensive guidance that is made available to the registrants on the ECHA website[29] (Chapter R.6 of the REACH Guidance on Information requirements, Practical guide No. 6[30], and Good practices formulated in the Evaluation 2010 Report[31]).

3.12 CHEMICAL SAFETY ASSESSMENT

The Chemical Safety Assessment and Report are meant *"to assess and document that the risks arising from the substance … are adequately controlled".* (Annex I Section 0.1.). Article 14(1) requires a chemical safety report for substances manufactured or imported in quantities of 10 tonnes or more per year. Article 14(4) of REACH specifies that exposure assessment and subsequent risk characterisation be carried out for those substances where any of the following applies: a) the substance fulfils the CLP classification criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 or b) the substance is assessed to be persistent, bio accumulative, and toxic (PBT) or very persistent and very bio accumulative (vPvB).

In order to provide the best possible advice to registrants of how to improve the Chemical Safety Assessment for their substances, findings from other processes than evaluation are also compiled in this recommendation section.

3.12.1 HAZARD ASSESSMENT

Based on the hazards identified, the registrant is expected to determine, for which target population, routes and duration of exposure, types of effects and environmental protection targets exposure assessment is required. Furthermore, it needs to be made transparent where a quantitative risk characterisation is required and where a qualitative risk characterisation is needed. Frequently the outcome of the hazard assessment was not documented in a sufficiently transparent way to determine the required scope of the exposure assessment and the related risk characterisation.

One specific example with frequently observed complications was the use of assessment factors. A derived no-effect level for humans is in most cases derived from a dose applied in a toxicological experiment with animals. It can be the highest dose without adverse effects or the lowest dose with such effects.

28 www.qsartoolbox.org/
29 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08
30 http://echa.europa.eu/doc/publications/practical_guides/pg_report_readacross_categ.pdf
31 http://echa.europa.eu/doc/evaluation_under_reach_progress_report_2010_en.pdf

The experimental dose cannot be directly used as a no-effect level for humans because the experimental situation differs in many aspects from the situation of human exposure. Apart from the fact that humans may differ from animals in sensitivity to the effects of the chemical substance in question, exposure may differ in frequency and duration. These and other differences between experiment and the human situation have to be compensated for to prevent an underestimation of hazard. To this end, so-called assessment factors are applied. Two types of assessment factors can be distinguished. Default assessment factors, i.e., factors that do not depend on the chemical substance and factors that take relevant properties of the chemical substance into account, the so-called substance-specific assessment factors. The latter are to be preferred over the former.

However, in most cases knowledge about substance properties that allows the definition of substance-specific factors is absent. This means that most derived no-effect levels are the result of applying default assessment factors to a no observed adverse effect level or a lowest observed adverse effect level. Although the REACH guidance advocates the full use of the knowledge on substance properties when assessment factors are applied, it has defined default assessment factors, because these indicate the level of uncertainty that is accepted in the absence of the knowledge on substance properties. It is not expected that registrants deviate from the default assessment factors if the substance properties do not allow them to do so. In particular, the assessment factors suggested by ECETOC cannot be used as default assessment factors to replace the values agreed and specified in the ECHA guidance without substance specific justification.

3.12.2 PBT ASSESSMENT

It was noted in some dossiers, that the registrant did not take into account all available information and the PBT status of substances already included on the candidate list for substances of very high concern was not addressed in the chemical safety report. Moreover, for substances regarded as being PBT (or vPvB), the chemical safety report did not contain a demonstration that emission was minimised. The evaluation of the PBT status must reflect the assessment of existing EU and other international bodies. For recognised PBT-substances, an assessment containing a demonstration that emissions are minimised must be provided.

3.12.3 SCOPE OF EXPOSURE ASSESSMENT

Section 5.0 of Annex I of REACH lays down that the exposure assessment *"shall consider all stages of the life-cycle of the substance" and "cover any exposures that may relate to the hazards identified".*

However, there were cases noted where the exposure assessment only covered hazards leading to classification, and other hazards identified not leading to classification were not covered; moreover, hazards leading to classification (such as dermal/eye irritancy) were also not addressed in the exposure and risk assessment. As consequence, exposure estimation and subsequent risk characterisation were missing for one or more of the endpoints. ECHA also noted the cases where exposure of humanity via the environment was not assessed (nor the omission properly justified). The registrants are advised to carefully check for consistency of the hazards identified (e.g. derivation of no-effect level and no-effect concentration) and exposure assessment within their dossiers. New guidance on the scope of exposure assessment has been issued assisting registrants in doing so (Guidance on information requirements and chemical safety assessment Part B: Hazard assessment Chapter B.8 (pp51-63)).

ECHA noted further that assessments of the life cycle stages subsequent to one or more downstream uses were missing in a number of chemical safety assessments. More specifically, for substances included in an article for end-use, the article service life stage had neither been assessed from the perspective of consumer exposure nor for the potential impact on the environment. Information related to risks possibly arising from the waste life stage was also found to be missing. It is important for the safe use of substances that comprehensive information

on the fraction of substance released at the different life cycle stages and whether specific measures are required for controlling the risk is included in the registration dossiers and communicated to downstream users.

3.12.4 EXPOSURE ASSESSMENT, RISK ASSESSMENT AND RISK CHARACTERISATION

The objective of the exposure assessment is to *"estimate … the dose / concentration of the substance to which humans and the environment … may be exposed"* (Annex I Section 5.0). This estimate for the dose or the exposure concentration is then to be used for demonstrating the control of risks by comparison with the estimated no effect level or no effect concentration. The proper exposure assessment is therefore paramount to the safe use of a substance.

Generic exposure scenarios have often been used for the exposure assessment without adapting these generic scenarios to the identified uses and to the relevant substance properties to be assessed. As consequence, the reported conditions of use are not consistent with the nature/level of hazard and are practically irrelevant for the uses to be covered by the exposure scenario. If using generic exposure scenarios, it is important that these reflect realistic conditions of use and have been developed in a dialogue in the supply chain. Registrants should make sure that the risk management suggested in the exposure scenarios are sufficiently concrete and practically relevant to the operational conditions to be expected for the identified use.

Further, operational conditions and risk management measures driving releases to environment were not sufficiently described in the respective exposure scenario. Consequently, the link of release and exposure estimates to the exposure scenarios could not be established. If risk management measures and operational conditions are used to limit the otherwise too high release into the environment, it needs always be described in detail in the respective exposure scenarios and the deviation from the default release factor of the respective environmental release category should be clearly justified.

In fact, a lack of consistency and traceability between exposure scenarios and exposure estimates was observed where the A-B Tables from the old technical guidance document or specific environmental release category had been used to derive release estimates. In all those cases, the registrant is advised to carefully evaluate the use of those adaptations to the default settings of the first tier exposure models, explain in detail why these adaptations are justified and report relevant operational conditions and risk management measures in the exposure scenario.

In some cases, the assignment of use descriptors (i.e. environmental release category, process category, product category, article category) was not consistent with the description of the use (e.g. environmental release category 7 related to the use of fluids in closed system was used to describe the use of lubricants in open system, such as metalworking fluids). This affects the exposure estimation when using tier 1 models and can lead to an underestimation or an overestimation of the exposure. In either of the cases, inadequate risk management measures may be the consequence. The registrant is then advised to properly evaluate and assign the appropriate use descriptor while using tier 1 tools for assessment purposes.

Regional background exposure was not considered for the derivation of predicted exposure concentration in the local assessment in some cases. Consequently, the registrants deviated from the standard methodology suggested in Guidance R.16 without giving a scientific explanation justifying his approach. Registrants are advised in such cases to document the scientific reasons why they need to deviate from the default approach.

In order to demonstrate safe use, the exposure assessment must demonstrate that the estimated exposure level is lower than the respective estimated no effect levels (c.f. Annex I Section 5.1.1.). The quotient of exposure divided by the derived no effect level is called risk characterisation ratio. The use of a given

exposure scenario and the respective risk characterisation may lead to the conclusion that the risk posed by the use of the substance is not under control (e.g. risk characterisation ratio > 1). In these cases, the registrant is supposed to change operational conditions, use risk management measures or generate new information for refining the exposure and risk assessment. Nevertheless, in some cases no explanation was given although the reported risk characterisation ratios were above one and safe use of the substance was consequently not demonstrated. Registrants are advised to implement risk management measures and change operational conditions to bring risk characterisation ratios below one before using a substance and submitting a registration dossier.

3.12.5 CLASSIFICATION AND LABELLING

ECHA would like to remind registrants that by adoption of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation), substances are to be classified according to the new classification criteria provided in Annex I to that Regulation. The classification and labelling in accordance with the CLP Regulation and the underlying information related to the respective hazards needs to be reported in the registration dossier. This applies as from 1 December 2010.

A registered substance subject to harmonised classification and labelling according to the CLP Regulation needs to be classified accordingly. However, if the registrant has information on hazard classes or differentiations not addressed by the harmonised classification and labelling, the registrant also needs to classify the substance also for those hazard classes and differentiations (Article 4(3) of the CLP Regulation).

When the registrants have information leading to a higher hazard class than provided by the harmonised classification and labelling, the registrants need to send proposals according to Article 37 of the CLP

Regulation to the Competent Authority of the Member State where their business is located.

4 REFERENCES

INFORMATION ABOUT ECHA:

European Chemicals Agency
http://echa.europa.eu

ECHA News and Events
http://echa.europa.eu/news

ECHA Support
http://echa.europa.eu/support

ECHA Evaluation
http://echa.europa.eu/evaluation

Examination of testing proposals
http://echa.europa.eu/consultations/test_proposals_en.asp

Member State Committee work
http://echa.europa.eu/web/guest/about-us/who-we-are/member-state-committee

THE LEGISLATION:

Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
http://echa.europa.eu/web/guest/regulations/reach/legislation

Regulation (EC) 1272/2008 on Classification, Labelling and packaging (CLP Regulation)
http://echa.europa.eu/web/guest/regulations/clp/legislation

TEST METHODS:

ECVAM pre-validated test methods
http://ecvam.jrc.it/ and http://tsar.jrc.ec.europa.eu/

Regulation (EC) No 440/2008 on test methods
See Implementing Legislation under REACH or CLP (given above)

PRACTICAL GUIDES

Practical guide 1: How to report *in vitro* data
http://echa.europa.eu/documents/10162/17250/pg_report_in_vitro_data_en.pdf

Practical guide 2: How to report weight of evidence
http://echa.europa.eu/documents/10162/17250/pg_report_weight_of_evidence_en.pdf

Practical guide 3: How to report robust study summaries
http://echa.europa.eu/documents/10162/17235/pg_report_robust_study_summaries_en.pdf

Practical guide 4: How to report data waiving
http://echa.europa.eu/documents/10162/17250/pg_report_data_waiving_en.pdf

Practical guide 5: How to report (Q)SARs
http://echa.europa.eu/documents/10162/17250/pg_report_qsars_en.pdf

Practical guide 6: How to report read-across and categories
http://echa.europa.eu/documents/10162/17250/pg_report_readacross_en.pdf

Practical guide 10: How to avoid unnecessary testing on animals
http://echa.europa.eu/documents/10162/17250/pg_avoid_animal_testing_en.pdf

Practical guide 12: How to communicate with ECHA in dossier evaluation
http://echa.europa.eu/documents/10162/17235/pg_12_how_to_comm_with_echa_in_dossier_evaluation_en.pdf

GUIDANCE:

Guidance for identification and naming of substances under REACH
http://echa.europa.eu/documents/10162/17235/substance_id_en.pdf

Guidance in a nutshell on Registration data and dossier handling
http://echa.europa.eu/documents/10162/17224/nutshell_guidance_registration_en.pdf

Guidance on intermediates
http://echa.europa.eu/documents/10162/17224/intermediates_en.pdf

Guidance on Classification and Labelling notification
http://echa.europa.eu/documents/10162/17235/pg_7_clp_notif_en.pdf

Guidance on the preparation of dossiers for harmonised classification and labelling
http://echa.europa.eu/documents/10162/17218/clh_en.pdf

Guidance on data sharing
http://echa.europa.eu/documents/10162/17223/guidance_on_data_sharing_en.pdf

Questions and Answers for the registrants of previously notified substances
http://echa.europa.eu/documents/10162/17238/prev_not_sub_registrants_qa_en.pdf

OTHER REFERENCES

JRC computational toxicology website
http://ihcp.jrc.ec.europa.eu/our_labs/computational_toxicology

JRC computational toxicology: reporting QMRFs
http://ihcp.jrc.ec.europa.eu/our_databases/jrc-qsar-database

OECD Guidelines for the testing of chemicals
http://titania.sourceoecd.org/vl=3953176/cl=18/nw=1/rpsv/periodical/p15_about.htm?jnlissn=1607310x

European chemical Substances Information System (ESIS)
http://esis.jrc.ec.europa.eu

Updated risk assessments
http://echa.europa.eu/chem_data/transit_measures/info_reqs_en.asp

Annex 1: Evaluation processes under the REACH Regulation

After the submission of dossiers by registrants, ECHA carries out a technical completeness check (TCC) and verifies that the fee has been paid (financial completeness check), in order to issue a registration number. During the TCC, ECHA checks each submitted dossier to see whether the necessary information has been provided. However, these checks do not include any assessment as to the quality or adequacy of the data provided. Quality and adequacy of data is assessed during the evaluation process of REACH.

REACH foresees that processing of dossiers submitted may take up to three weeks or, for dossiers submitted shortly before the registration deadlines, it may take several months (due to the higher number of incoming dossiers). Subsequently there will always be a slight difference between the number of dossiers submitted and the number of registrations. Some of the dossiers submitted may not pass the financial and/or technical completeness check and hence they are not considered registered under REACH. Evaluation may be conducted only on registrations.

REACH provides for three different evaluation processes: compliance check, examination of testing proposals (these two are known as dossier evaluation) and substance evaluation.

- In a **compliance check** ECHA can either evaluate the quality of the information in the whole dossier including the chemical safety report or can target the evaluation to a certain part of the dossier e.g. to the human health information or specific parts of the chemical safety report.

- In the **examination of testing proposals** ECHA evaluates all submitted testing proposals with the aim of checking that adequate and reliable data is produced and to avoid unnecessary vertebrate animal testing.

- **Substance evaluation** is launched when there is concern that a substance constitutes a risk to human health or the environment. The Member States carry out the scientific assessment required for substance evaluation.

All evaluation decisions include consultation with the registrant and the Member States. The consultation ensures that a decision for requesting further information is made only after a thorough consideration of all the available information including the opinion of the registrant and consensus being reached among the Member States. Where no unanimity is reached between Member States the decision making is referred from ECHA to the Commission.

After the decision has been made and after having received the requested further information from the registrant, ECHA or the relevant Member State (in case of substance evaluation) examines the information and informs the European Commission, the other Member States and the registrant of the conclusions made (see Figure 1).

The outputs from dossier and substance evaluation aim to result in improved risk management of the chemicals concerned and promote their safe use. The obligation to control the risks and to provide the users of the substance with adequate information on risk management measures lies with the registrants. However, the Member States can impose national actions or initiate the adoption of EU-wide risk management measures (e.g. occupational exposure limits, EU-wide restriction, EU-harmonised classification and labelling).

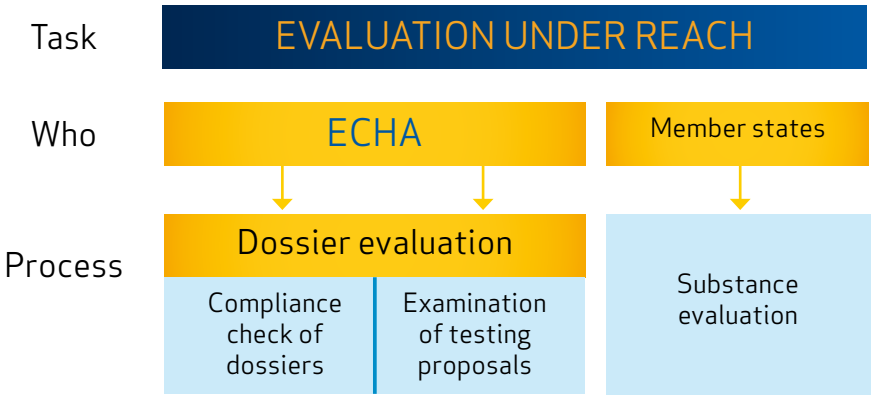

Figure 1: Evaluation processes under the REACH Regulation

A1.1. COMPLIANCE CHECK

The purpose of the compliance check is to examine whether registration dossiers comply with the requirements of the REACH Regulation. The Agency can decide which dossiers are checked for compliance and whether the examination should cover all or part of a dossier. The REACH Regulation requires that the Agency carries out compliance checks on at least 5% of the total number of registration dossiers received for each tonnage band. Since the number of registration dossiers submitted each year may vary significantly, the 5% target is not meant to be reached every year but rather over a period of several years. The Agency has established a timeframe for the 5% target in its Multi-Annual Work Programme and monitors its progress.

The outcome of a compliance check may be:

- **No further action** is necessary since the information provided in the registration dossier is considered sufficient to fulfil the REACH requirements.

- **A quality observation letter** (QOBL) is sent to the registrant: when evaluating the dossiers the Agency may identify shortcomings that are not necessarily related to the lack of information. For example, the risk management measures proposed by the registrant may be inadequate if the proposed classification and labelling does not reflect the reported study results. In such cases, the Agency informs the registrant through a quality observation letter and asks for a revision of the dossier and submission of an updated version. Furthermore, it informs the Member States, which may take action if the registrant does not clarify the issue.

- **A draft decision** is sent to the registrant when the Agency identifies that information required by REACH is missing. The draft decision lays down the missing data that is requested to be generated and submitted by a certain date. The decision-making process as described by the REACH Regulation is followed resulting in a legally binding decision.

A1.2. EXAMINATION OF TESTING PROPOSALS

Registrants submit testing proposals and seek permission from ECHA to undertake tests foreseen under Annexes IX and X of REACH (for substances at 100 – 1000 tonnes p.a. and 1000 tonnes p.a. or more), if they identify a data gap and cannot otherwise fulfil the REACH information requirements. ECHA evaluates all such testing proposals with the aim of checking that adequate and reliable data is produced and to avoid unnecessary (animal) testing.

The majority of tests examined in testing proposals concern testing for long-term effects (organ toxicity, reproductive toxicity). All proposals for tests involving vertebrate animals are published by ECHA on its

website and third parties are invited to provide scientifically valid information and studies. When examining the testing proposal the grounds for conducting the proposed test are assessed, taking into account the dossier information and all relevant scientifically valid information received from third parties during public consultation. ECHA evaluates all testing proposals and information submitted by third parties within set deadlines[32]. The outcome is always a decision, which may contain the acceptance or rejection of the testing proposal; it may define modified conditions for the test or suggest additional tests to be performed.

A1.3. DECISION-MAKING PROCESS

The decision-making process to reach a final ECHA decision is the same for compliance checks and examinations of testing proposals. Both dossier evaluation processes comprise tasks where the ECHA secretariat makes scientific and legal assessments. These assessments consider whether the information provided in the dossier meets the REACH requirements. If ECHA concludes that additional testing or other information is required, it prepares a draft decision that is then adopted through a decision-making process. First, the registrant has the opportunity to comment on the draft decision issued by the Agency. Secondly, the Agency sends the draft decision to the Member States Competent Authorities for their review. At this stage, Member States Competent Authorities may propose amendments.

In cases where the Agency receives proposals for amendments from the Member States, it will forward the draft decision to the Member State Committee (MSC). If the MSC reaches unanimous agreement, the Agency takes the decision accordingly. In cases where the Agency receives no proposals for amendment from the Member States, it takes the decision as notified without further involvement of the MSC. The need for unanimity underlines the intention of the legislator to avoid unnecessary (animal) testing and at the same time to check that adequate and reliable data is produced and that all available information has been considered. If unanimous agreement cannot be reached in the MSC, the European Commission prepares the draft decision to be taken in the Committee procedure referred to in Article 133(3) of REACH.

The decision contains the type of information to be provided by the registrant and a deadline by which this information has to be provided. ECHA will monitor such deadlines and will inform the Member States if the information has not been submitted in an updated dossier by the deadline. The Member States may then decide to take enforcement actions. If the information is received in an updated dossier, it will be assessed in relation to the original request; the Commission and the Member States are informed about any conclusions made (Figure 2).

Due to the complexity of the dossier evaluation processes, it may sometimes take around two years from the moment evaluation is initiated until the final conclusion is reached. This may happen for those dossiers where a draft decision has been issued which require consultation of all parties as described above.

32 For non-phase-in substances the examination takes place within 180 days of receipt of the dossier including a testing proposal. For phase-in substances there are three deadlines (01/12/2012, 01/06/2016 and 01/06/2022) depending on the registration deadlines, see Article 43 REACH.

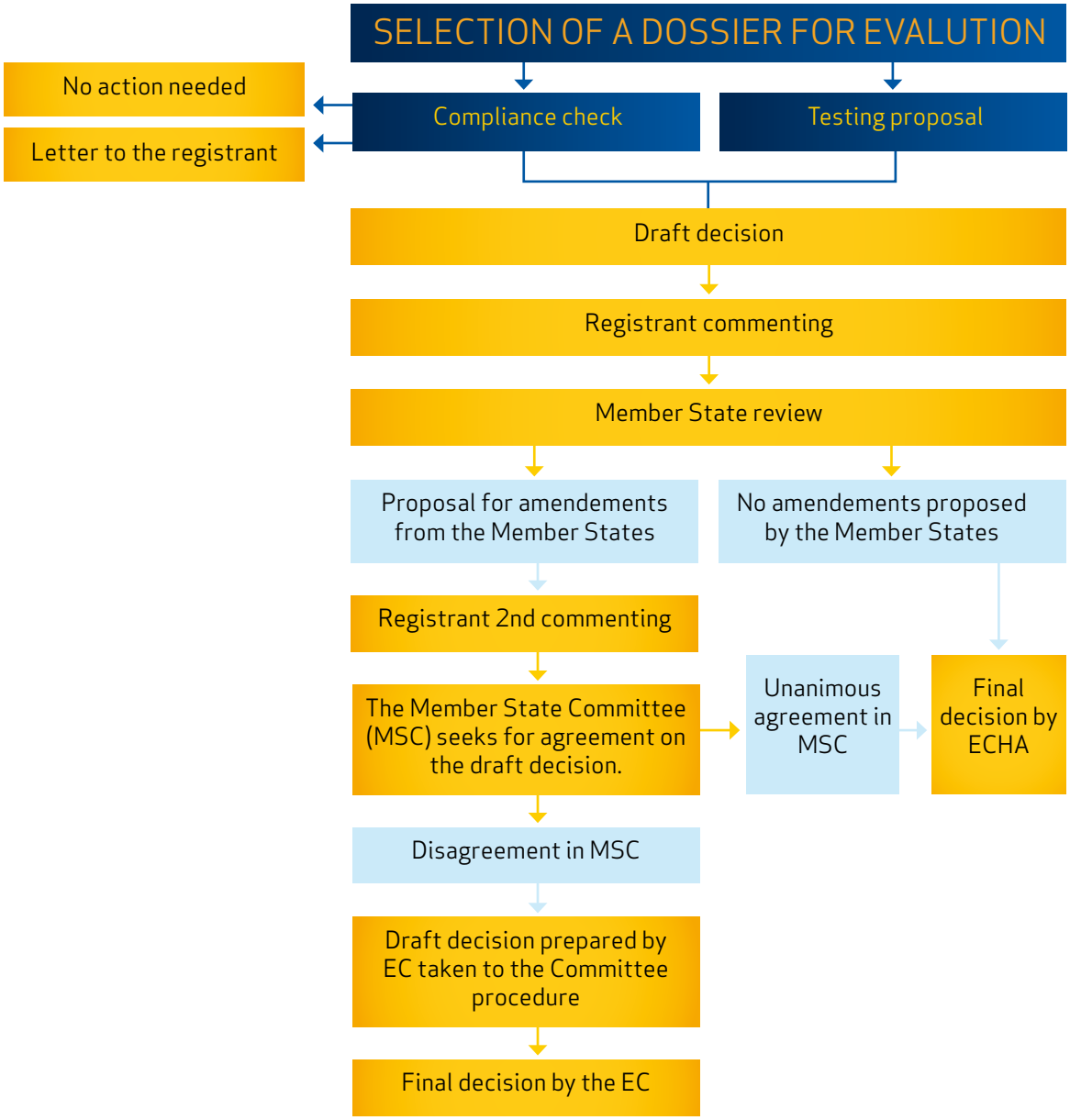

Figure 2: Dossier evaluation process; major steps;
MSC = Member State Committee; EC = European Commission

A1.4. SUBSTANCE EVALUATION

Dossier evaluation is meant to ensure that a submitted registration dossier contains the minimum information required by REACH and that potential risks arising from identified uses are documented and can be controlled. This type of evaluation is limited to the uses and the amounts of the substance covered by the individual registrations dossier. The standard information requirements of REACH neither cover all possible hazards a given substance may pose, nor does the dossier specific safety assessment cover accumulative tonnages from all uses of the same substance covered by joint registrations.

Substance evaluation is intended to close this gap and aims at verifying, through a decision requesting further information from the registrant, whether a substance constitutes a risk to human health or the

environment. Substance evaluation is not limited to the assessment of the information contained in a single dossier. It may also take into account information from other sources and account for cumulative tonnages of several dossiers. Information beyond the standard REACH information requirements can be requested from the registrants. Thus, decisions regarding the type of information necessary to clarify the concern and whether there are any alternative methods suitable for deriving that information are taken on a case-by-case basis.

If there are grounds for considering that a substance constitutes a risk to human health or the environment, the substance is first placed on a list of substances to be evaluated, the Community rolling action plan (CoRAP). This plan will be updated annually (by the end of February).

A1.4.1 CRITERIA FOR SELECTING AND PRIORITISING SUBSTANCES FOR SUBSTANCE EVALUATION

The REACH Regulation Article 44(1) provides the general criteria for substances to be selected for substance evaluation. The legal text defines that prioritisation shall be on a risk-based approach. According to Article 44(1):*"(...) the criteria shall consider:*

- *Hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;*

- *Exposure information;*

- *Tonnage, including aggregated tonnage from the registrations submitted by several registrants."*

The criteria have been refined in May 2011 by ECHA in cooperation with the Member States and are published on ECHA's website: Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria):

http://echa.europa.eu/doc/reach/evaluation/background_doc_criteria_ed_32_2011.pdf

These criteria were applied in the initial step of the identification of substances with potential concerns. A further ranking process takes into consideration whether the substances are already subject to regulatory measures and the effectiveness of the substance evaluation to clarify the concern by requesting further information on the substance. Thus, meeting the risk-based criteria alone does not automatically mean an inclusion of the substance in the CoRAP.

According to Article 45(5) of the REACH Regulation, a Member State may notify ECHA of a substance, whenever it is in possession of information suggesting that the substance is a priority for evaluation. Thus, the draft CoRAP contains also substances that have been proposed based on notifications from Member States.

Both hazard and exposure information (or a lack of it) is taken into consideration upon prioritising the substances. In the current first draft CoRAP with many substances, the initial concerns are generally related to potential PBT[33]-properties, suspected endocrine disruption, or carcinogenic, mutagenic and reprotoxic properties in combination with wide dispersive or consumer use(s) and/or high tonnages. In general, the uses of these substances cover various areas and do not focus on any particular industrial, professional or consumer uses.

33 Persistent, Bioaccumulative and Toxic

When the final CoRAP is published, it will also contain a general indication of the reasons why the substance was prioritised and selected for substance evaluation.

A1.4.2 PROCESS AFTER SUBSTANCE IS INCLUDED IN THE CORAP

From the publication of the final CoRAP, the respective Member States have one year to evaluate substances specified for 2012 and, where regarded as necessary, to prepare a draft decision for requesting further information to clarify the suspected risks. Such draft decisions are reviewed and agreed by the other Member States and ECHA. If proposals for amendments in the draft decision are made, the case will be referred to the Member State Committee before ECHA adopts the final decision. If no unanimous agreement is reached by the Member State Committee, the decision is taken by the European Commission.

The process for decision making is analogous to the process used for compliance checks and examinations of testing proposals. First decisions under substance evaluation may be expected in the end of 2013.

Once the registrant(s) submit the requested information, the responsible Member State has twelve months to assess this information and to decide whether a further request for information is necessary or whether the evaluation can be completed. In this latter case, the responsible Member State should consider whether and how to use the information obtained for the purposes of Community level risk management measures. The conclusion can also be that the risks are sufficiently under control with the measures already in place. ECHA informs the Commission, the registrant and the other Member States about the conclusions. As a further follow-up to the substance evaluation, Member States may decide to:

- Propose EU-wide risk management measures (e.g. EU wide restriction, EU-wide authorisation, EU-harmonised classification and labelling, occupational exposure limits, measures for the protection of the environment under the Water Framework Directive) or

- Impose national actions.

Any proposed Community-wide actions will be subject to a separate decision making process. For authorisation, restriction and/or harmonised classification under the REACH and the CLP Regulation, stakeholders are consulted at all relevant stages of the process and decisions are taken based on the opinions adopted by the ECHA Committees.

The decisions on data requests and evaluation reports will be made publicly available once finalised.

A1.5. MORE INFORMATION

Detailed information on the process of **Dossier Evaluation** can be found in the procedure on the ECHA website of the Integrated Management System of the Agency http://echa.europa.eu/about/quality_management_en.asp.

Annex 2: Information requirements for the registration of substances

REACH requires registrants to provide information on the intrinsic properties of a substance in the form of a registration dossier. The information required on intrinsic properties for each substance is dependant on the tonnage manufactured or imported[34]; the higher the tonnage, the more information needs to be submitted. For substances manufactured or imported in quantities of 10 tonnes per annum (tonnes p.a.) or above, the registration dossier must include a chemical safety report. For dangerous substances, i.e. substances which are classified or substances considered as persistent, bioaccumulative and toxic (PBT-substances), an exposure assessment must be included in the chemical safety report. The registrant has the responsibility to ensure that the identified uses are safe. All information must be submitted to the Agency in electronic format.

When fulfilling the information requirements, the registrant should first collect all relevant available information on the substance. This includes information on substance identity, physico-chemical properties, toxicity, ecotoxicity, environmental fate, exposure and instructions for appropriate risk management.

Where there is insufficient information on the intrinsic properties to meet REACH requirements, the registrant must generate new information[35] or, for tests at higher tonnage levels (100 tonnes p.a. or above), prepare a testing proposal[36]. The new information may be generated by using standard or alternative methods. The registrant may adapt the standard information requirements by using (Quantitative) Structure Activity Relationship ((Q)SAR) models, a weight-of-evidence approach, substance-grouping approaches (read-across) or *in vitro* methodology. REACH requires the use of alternative methods for generating information wherever possible, in order to avoid unnecessary animal testing. However, any adaptation to the standard information requirements shall be duly justified.

Further information on requirements for registration can be found in: Guidance in a nutshell on Registration data and dossier handling and in Practical Guides 1-6 and 10.

34 The tonnage ranges for data requirements (in tonnes per annum, tonnes p.a.): → 1 – 10 tonnes p.a., → 10 – 100 tonnes p.a., → 100 – 1000 tonnes p.a. and → 1000 tonnes p.a.
35 For endpoints mentioned in Annexes VII-VIII of the REACH Regulation
36 For endpoints mentioned in Annexes IX – X of the REACH Regulation

Annex 3: Compliance check overview (cumulative)

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check*	183	140	**323**
Draft Decisions sent to the registrant**	41	11	**52**
Final Decisions	80	37	**117**
Only Quality Observation Letter sent to the registrant***	13	46	**59**
Terminated at the decision making stage****	2	9	**11**
Terminated without administrative action	10	33	**43**
Sum of Conclusions	**146**	**136**	**282**

* Dossiers ever opened for compliance check notwithstanding their current status.

** Draft decisions which did not become final by 31 December 2011.

*** Some additional quality observation letters have been sent together with draft decisions, but are not counted here.

**** Terminated upon further information provided by the registrant.

Annex 4: Testing proposals in registration dossiers (cumulative)

	Tonnage per year	Number of registration dossiers with testing proposal	Number of registration dossiers containing vertebrate testing proposal	Number of endpoints covered by testing proposals	Number of endpoints covered by testing proposals for vertebrate animals
Phase-in	1-10	3	3	7	5
	10-100	8	4	12	5
	100-1000	75	57	191	98
	>1000	410	317	825	529
	Intermediates	23	17	30	23
	Total phase-in	**519**	**398**	**1 065**	**660**
Non phase-in	1-10	3	3	4	4
	10-100	10	5	16	7
	100-1000	21	14	52	28
	>1000	13	11	28	16
	Total non phase-in	**47**	**33**	**100**	**55**
Total		**566**	**431**	**1 165**	**715**

Annex 5: Testing proposals cumulative

		Phase-in	Non phase-in	Total
No of registered dossiers*	containing testing proposals	519	47	**566**
	containing testing proposals for vertebrate animals	398	33	**431**
No of endpoints	covered by registered testing proposals	1065	100	**1 165**
	covered by registered testing proposals for vertebrate animals	660	55	**715**
No of third party consultations	closed	354	27	**381**
	No of third party consultations	8	2	**10**
	planned	75	2	**77**
Dossiers with testing proposals opened for examination**		543	52***	**595**
Draft Decisions sent to the registrant ****		129	15	**144**
Final Decisions sent to the registrant		8	19	**27**
Terminated testing proposal examinations*****	at the decision making stage	4	5	**9**
	before a decision was issued	44	8	**52**
Sum of conclusions		185	47	**232**

* Successfully registered (accepted and fee paid). Note: this number changes over time as dossiers may be updated by the Registrant (e.g. test endpoints added and/or withdrawn).

** Dossiers ever opened for examination notwithstanding their current status.

*** same registration dossier was opened for examination more than once hence the difference vs. number of registered dossiers

**** Dossiers ever opened for examination notwithstanding their current status.

***** Terminated upon further information provided by the registrant (e.g. cease of manufacture, tonnage downgrade or withdrawal of a testing proposal).

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