ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH

Progress Report 2012

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

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
SEv	Substance evaluation
SID	Substance identity
tpa	Tonnes per annum(year)
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 of the Executive Director: Improve dossier quality and achieve compliance

It is with great pleasure that I bring ECHA's fourth full report on evaluation to your attention. It details our experience of evaluating dossiers over the last year and provides robust recommendations to registrants who have already registered or are still preparing registration dossiers for the next deadline on 30 May 2013.

This report represents a great deal of work – by registrants in the first place, but also by the scientists working in the Member States and here in ECHA. I pay tribute to all involved. I particularly congratulate my colleagues for meeting their challenging legal deadline of 1 December 2012, to examine all the proposals to undertake testing submitted as part of the registrations for the first deadline.

It reflects our efforts towards our first strategic aim: to maximise the availability of high quality data to enable the safe manufacture and use of chemicals. It assists registrants preparing for the coming registration deadline by helping them to avoid common mistakes.

Our findings from the year are highlighted in the Executive Summary and detailed in the report itself. The main finding remains the same – the mixed quality of information provided in dossiers – notably the clarity with which a substance is identified in the dossier and the scientific rigour with which assumptions and assertions are substantiated.

The purpose of describing a substance clearly and addressing potential hazards and exposure with scientific rigour is to ensure that the risks are properly identified and controlled in order to protect workers and the public at large. Registrants need to be clear that the safe use of chemical substances is not demonstrated where it is based on inadequate or incomplete information and/or on alternative information that has no valid scientific justification. For example, an exposure assessment needs to reflect what happens during the entire lifecycle of a substance. If registrants use a tool to do this – like our own Chesar tool – they need to make sure that the results achieve the protection targets. High quality information of this kind is absolutely fundamental to achieving full compliance with REACH, not a luxury or an optional extra.

That said, in this report we do acknowledge changes for the better, in particular because most registrants receiving draft or adopted decisions from ECHA have taken them seriously and improved the descriptions of substance identity and read-across. The testing proposals now agreed with ECHA will generate much more data on substances, which registrants and scientists may be able to use in the future – thereby increasing the potential for developing alternatives to animal testing.

In the interest of transparency, I have also decided to publish non-confidential versions of all adopted evaluation decisions on the ECHA website. This will increasingly enable registrants and stakeholders to understand the rationale and content of ECHA's decisions.

The main objectives for the evaluation work in the coming year is the achievement of the target to complete compliance checks on 5% of the dossiers received for the 2010 deadline and to issue the first set of substance evaluation decisions prepared by Member States.

As registrants have digested this report and learnt from the mistakes and shortcomings highlighted, I look forward to being able to report on many more improvements in dossiers in the coming twelve months.
Thank you for taking the time to read the 2012 Evaluation Report.

EXECUTIVE SUMMARY

BACKGROUND

REACH places the responsibility for establishing the safe use of chemicals on companies manufacturing and importing chemicals in the EU, which they must document in registration dossiers. The safe use of chemical substances is only demonstrated by adequate or complete information or by alternative information with valid scientific justification. **High quality of hazard, use and exposure information is required** in registration dossiers in order to provide a scientifically sound basis for the assessment of chemical risks. This will result in appropriate operational conditions, risk management measures and thereby lead to the safe use of chemical substances.

This document reports the **evaluation activities** carried out by ECHA in 2012, highlights the most frequently observed shortcomings encountered in registration dossiers and provides recommendations to registrants. It is timely both for companies preparing dossiers for the 2013 deadline as well as for registrants who have already submitted dossiers, since the recommendations help registrants to correct potential mistakes in their dossiers. Therefore, all registrants are encouraged to take the recommendations provided in this annual evaluation report into account and to take the initiative to update and improve their dossiers where needed.

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. Annexes VII to X of REACH lay down the **information requirements** for each endpoint based on a standard testing regime per tonnage band. When testing, the registrant must follow test protocols, which are in line with Article 13(3). These test protocols define the elements to be reported and thus the information that is required under REACH. Use of the many possibilities offered by REACH to adapt the standard testing regime in order to avoid animal testing is subject to conditions laid down by REACH. ECHA checks whether the registrant's adaptations fulfil these conditions. If they do not, ECHA will request to use the standard tests to generate the missing information.

ACTIVITIES

Testing Proposal Examination: ECHA examined all 557 dossiers with testing proposals for phase-in substances in accordance with the deadline of 1 December 2012 as set in REACH. This covers all such cases which had an adequate description of the substance identity. In 2012, 364 decisions were drafted and 171 decisions were taken on testing proposals. The most significant challenge for meeting the target was to resolve unclear or inadequate information on the identity of the substance (128 cases where additional information on substance identity was requested in a compliance check decision) or read across in registration dossiers, which also contained testing proposals. In some cases, a registrant had duly clarified the substance identity and ECHA was able to continue with the testing proposal examination and notified the registrant of the outcome by draft decision. In other cases, resolution of the substance identity issues and testing proposal examination was run in parallel. There were also cases where the testing proposal examination was suspended until substance identity information was clarified by a registrant. In parallel, ECHA processed 43 testing proposals for non phase-in chemicals.

Compliance Checks: In collaboration with Member States, ECHA developed a new approach for compliance checks. The approach uses advanced data analysis tools to select registration dossiers that potentially contain typical shortcomings for a critical endpoint in order to select the most suitable candidate dossiers for a targeted compliance check. This approach increases the efficiency of the process and the chances of finding pertinent information gaps in registration dossiers. Targeted compliance checks on substance identity were triggered by findings in testing proposal examinations. In 2012, ECHA initiated 295 targeted compliance checks and subsequently drafted 183 decisions. Additionally, ECHA concluded on 198 full compliance checks. The cumulative number of compliance checks concluded by ECHA since 2008 is 636 cases.

Follow-up: As mentioned before, ECHA focused its follow-up work on decisions seeking to clarify the identity of substances subject to proposed testing. In 59 cases, registrants had clarified the identity of the substance. However in 36 cases, ECHA needed to clarify the substance identity further in a second compliance check at the same time that it sent the draft decision on the proposed testing. Additionally to that, ECHA and the Member States developed a procedure for the follow-up process. Following this new work flow, ECHA concluded the first follow-up cases of decisions and informed the respective Member State of the continuing non-compliance when decisions had not adequately been implemented.

Substance Evaluation: On 29 February 2012, ECHA published the first Community rolling action plan (CoRAP 2012). The evaluating Member States started the evaluation of 36 substances targeting the presentation of the evaluation outcome for early 2013. Additionally, ECHA prepared the draft CoRAP 2013 published in October 2012 with its anticipated adoption also in early 2013.

RECOMMENDATIONS FOR REGISTRANTS

Identify your substance. If it is impossible to establish which substance a registration dossier covers, the overall scope of the registration is unclear and a further examination of the dossier is hampered. If the persisting non-compliance is such that the substance concerned by the registration cannot be identified, the registration may be considered invalid. If the dossier clearly covers more than one substance on the market, the registrant will need a separate registration of any substance that is indirectly included in the dossier.

Identify the test material. Clear identity of the material to be or which has already been tested is needed for linking information from the study results to the registered substance. Without an unambiguous link between the material tested and the registered substance, the information requirement is not met resulting in a data gap and non-compliance.

Make full use of all relevant information. The use of alternative approaches comes with the extra challenge, because it is of paramount importance that the chosen approach addresses the hazard endpoint and delivers adequate and reliable information comparable to that from the standard test. If this is not the case, testing is required. Often registrants did not make full use of all existing information, that is existing information was not available in the dossier for supporting the adaptation to the standard testing regime. Categories or the use of read-across then failed, because registrants did not present sufficient valid scientific justification for adapting the standard information requirements. Furthermore, when registrants have information available leading to classification, they need to classify and label the substance for those hazard classes accordingly. If done with diligence, testing may be unnecessary.

Provide clear use and exposure information. IUCLID now supports the reporting of uses in a harmonised life cycle structure. ECHA advises registrants to provide self-explaining names, describe all actual uses and include standard use descriptors in a consistent manner. They should also make sure that the use descriptions and exposure assessment are realistic and transparent to the downstream users. Methodologically correct and adequate description of uses, exposure scenarios, operational conditions and risk management measures provide clarity for downstream users thereby facilitating communication in the supply chain.

Make use of ECHA support. An ECHA decision informs registrants of data gaps in their registration dossier and of the information to provide in order to bring the dossier into compliance. Additionally, ECHA dedicates substantial resources to communicate with registrants who receive draft decisions to help them understand the rationale of the (draft) decision. Furthermore, ECHA and the Member States offer a number of additional information channels such as workshops (e.g. on read-across), webinars, helpdesks, Guidance and practical guides as well as this and previous evaluation reports. ECHA started publishing non-confidential versions of its decisions (CCH and TPE) and intends to make new ones available on its website on a monthly basis. All this information is available on the ECHA website.

Introduction

The REACH Regulation[1] aims to improve the protection of human health and the environment by making companies manufacturing or importing chemical substances in the European Economic Area responsible for ensuring their safe use. To achieve this, companies have the obligation to provide information on the properties of the substances, identify the uses, assess the risks involved, develop appropriate risk management measures and communicate this information along the supply chain. 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.

The purpose of the evaluation process is to generate information to fill data gaps to ensure compliance or to address concerns. Evaluation also contributes to the identification of substances of concern, with the aim of replacing them with safer alternatives. Through the process of evaluation, ECHA requires additional information to be provided from registrants– eventually generated by testing–when essential data on substances are missing. In this way, ECHA assists registrants in improving the quality of their dossiers in order to achieve full compliance with REACH.

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 dossiers and substances during 2012. This annual report also advises on the most frequent observations and shortcomings encountered during the processes of dossier evaluation. It provides recommendations to registrants in order to improve the quality of existing and future registration dossiers to move them closer to full compliance. Hence, this report is timely in helping with the registrations due for the 2013 deadline, i.e. for substances produced or imported at a volume of 100-1 000 tonnes per annum.

Existing registrants have an obligation to keep their dossiers up-to-date. Not taking account of relevant information may lead to improper advice on how to handle the substance safely. Therefore, registrants are encouraged to take a proactive approach and already update their active registration dossiers by taking into account the recommendations provided in this and previous annual evaluation reports.

This document is useful reading not only for registrants, but also for regulators and other stakeholders with basic scientific and legal background knowledge of the REACH Regulation. The report has three main parts. After a short introduction of the evaluation processes in Part 1, Part 2 describes the progress made during 2012 on dossier and substance evaluation in more detail and provides key statistical data. Part 3 reports the frequently found shortcomings in a generic way and advises registrants on how to improve their registration dossiers.

1 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (http://echa.europa.eu/regulations/reach/legislation)

1 Evaluation under REACH

1.1 PROCESSES

ECHA and the Member States evaluate the adequacy of the information submitted and the quality of registration dossiers in three processes: testing proposal examination, compliance checks and substance evaluation. These processes use virtually the same procedures for decision-making leading to ECHA decisions requiring further information. "Follow-up" of this evaluation assesses whether the registrants provided the requested information and whether this new information should lead to further actions (e.g. request for further information, a proposal for substance evaluation, authorisation, or restriction of the substance).

Section 1.3.1 provides a more detailed description of dossier evaluation follow-up, since the number of decisions where the deadline has passed now increases. Previous annual evaluation reports and the evaluation web page provide detailed information on dossier evaluation[2]. The follow-up of an ECHA decision has a slightly different approach under substance evaluation compared to dossier evaluation. As no decisions on substance evaluation have yet been produced, the chapter below (section 1.3) will focus on the follow-up of dossier evaluation decisions.

Dossier evaluation combines compliance checks and testing proposal examinations including the follow-up stage of these processes. The ECHA Secretariat is in charge of both processes, with the support of Member State competent authorities, the Member State Committee, and the national enforcement authorities.

Member State competent authorities are the main drivers of **substance evaluation.** ECHA coordinates the process, and drafts the annual update of the Community rolling action plan, which the Member State Committee adopts. The Member State competent authorities perform the evaluation of substances.

The subsequent **decision-making process** is similar for compliance checks, testing proposal examinations and substance evaluations, and involves all Member State competent authorities simultaneously.

1.1.1 Compliance check

The compliance check determines whether the information submitted is compliant with the requirements of REACH. ECHA needs to check for compliance in at least 5 % of the dossiers received per tonnage band.

1.1.2 Testing proposal examination

When fulfilling standard information requirements in Annexes IX and X requires testing to be performed, the registrants are obliged to submit a proposal as part of the registration, describing the test planned. All such testing proposals have to be evaluated by ECHA prior to testing. The aim is to ensure that the tests address the actual information needed and avoid unnecessary testing, especially when testing involves the use of vertebrate animals.

1.1.3 Substance evaluation

The process of substance evaluation aims to clarify possible risks of the (collective) use of a substance. The selection of substances is risk-based. Only registered substances included in the Community rolling action plan are subject to substance evaluation. The evaluating Member State may propose, by means of a

2 http://echa.europa.eu/regulations/reach/evaluation

draft decision, to request further information in order to clarify any potential risks the substance may pose. Following the formal decision making process, ECHA will take the decision, and if need be, designate one of the registrants to perform the tests on behalf of himself and others.

1.2 ADOPTION OF A DECISION

1.2.1 Dossier evaluation

Based on the observations made during the scientific evaluation of a dossier, the **ECHA secretariat drafts a decision** and informs the registrant thereof. Registrants have 30 days to comment on a decision, starting from the day they receive the draft via REACH-IT. ECHA will consider any comments submitted and may modify the draft decision accordingly. ECHA will notify the Member State competent authorities of the draft decision so that they may review it. This step is the start of the decision-making phase of the three evaluation processes.

Once ECHA forwards the case for decision-making, i.e. informs the **Member State competent authorities** of the draft decision, ECHA can no longer change the text, i.e. take into account any updates of the registration dossier submitted by the registrant. The Agency can now only react to proposals for amendments made by a Member State competent authority and any related comments submitted by the registrant. This is because Article 51 of the REACH Regulation sets out deadlines for the following steps of decision-making for the Member State competent authorities' proposals for amendments, the **referral to the Member State Committee**, the comments from the registrant on the proposals for amendments and reaching a unanimous agreement on the draft decision by the Member State Committee.

ECHA takes a decision when either the Member State competent authorities agree to a decision as drafted (i.e. none of the Member States proposes an amendment to the draft decision), or the Member State Committee agrees unanimously on the draft decision after due consideration of any proposed amendment. For the remainder of this report, "decisions taken" are referred to as "ECHA decisions". Upon receipt of the ECHA decision, registrants then have three months to lodge an appeal. After the three months have passed, and if no appeal has been lodged, the ECHA decision becomes enforceable.

In this complex process involving **actors across the whole EU**, it is of key importance that the factual basis for the decision-making, i.e. the submission of the registration dossier subject to the regulatory action, does not change during the decision making process. Therefore, information in updated dossiers submitted after referral of the draft decision to the Member State competent authorities can only be considered in the follow-up process.

After the deadline given in the decision, under the **follow-up process**, ECHA will take into account any information relevant for the endpoints addressed in the decision which is available in the latest update of the registration dossier (Article 42 of the REACH Regulation).

1.2.2 Substance evaluation

The decision-making process for substance evaluation is essentially the same as for dossier evaluation. The main difference is that the evaluating Member State considers comments submitted by the registrants and proposals for amendments made by the fellow Member State competent authorities. In addition, the ECHA Secretariat now takes on the role of reviewer and may submit a proposal for amendments. All registrants involved, as case owners, have the right to comment on draft decisions and possible proposals for amendments from the authorities. However, for practical reasons, they are encouraged to provide a single set of consolidated comments when there are common elements among dossiers in joint submissions or categories of substances. Addressees of the same draft decision can nominate one representative to send comments on behalf of the whole group on the draft decision and any subsequent proposals for amendment.

1.3 FOLLOW-UP TO EVALUATION

1.3.1 Dossier evaluation

The REACH evaluation process is only successful when the registrant delivers the requested information (i.e. complies with the ECHA decision) by the given deadline. When an ECHA decision becomes effective, the addressee of this decision must comply with the decision and deliver the information requested within the stated deadline. In the follow-up part of the evaluation process, ECHA looks in the latest submission of the respective registration dossier for the requested information.

When the registrant has successfully updated the dossier meeting all the requests of the ECHA decision, ECHA notifies the Member State competent authorities and the Commission of both the information that was provided as well as of its conclusions made according to Article 42(2). The Member State competent authorities may use this new information for the purposes of other processes (i.e. substance evaluation, authorisation and restriction). In addition, the new information may serve as a basis for harmonised classification or lead to identification as a candidate for the CoRAP.

There may be the situation where the new information leads to further concerns. In such cases, ECHA may open a new process of dossier evaluation and issue a decision requesting further information (Article 42 (1)).

When registrants fail to provide some or all of the required information by the deadline set in the decision, they are in breach of the REACH Regulation. Non-compliance with ECHA's decision will lead to the consideration of enforcement actions by the national enforcement authorities of the Member States, as introduced by Article 126 of the REACH Regulation.

ECHA does not have the competence to carry out enforcement actions concerning the decision nor does ECHA have the competence to extend the deadline given in the decision. Furthermore, REACH does not provide for the postponement of the deadline of an ECHA decision. If for any reason registrants cannot provide the required information by the deadline given, they can indicate such reasons in the updated dossier. ECHA can then communicate such delays and the reasons thereof to the Member State.

The Member States alone have the authority to undertake enforcement actions, which they have delegated to the respective national enforcement authorities. The communication between ECHA, Member State competent authorities and national enforcement authorities requires good coordination. The coordinator of the Member States enforcement authorities, the Forum, organised a workshop on 9 October 2012 at ECHA's premises and agreed on a procedure along the lines described in the paragraph below.

ECHA informs the REACH competent authority as well as the agreed focal points for enforcement issues of the responsible Member State about the breach (i.e. the non-compliance with an ECHA decision) and asks the national authorities for enforcement of the decision. A copy of the communication is sent to the registrant. The Member State focal points will inform ECHA, when an enforcement action is taken and by when the missing information will potentially arrive. ECHA will examine the dossier as soon as it receives the update of the dossier and proceeds as explained for the normal follow-up process.

Only after ECHA has carried out this step successfully and confirmed the compliance with the information request of the decision, is the process of dossier evaluation completed.

1.4 FURTHER INFORMATION

For a more detailed description of the evaluation processes please see the Evaluation Report 2011, Annex 1[3] and the ECHA website[4].

3 http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf
4 http://echa.europa.eu/regulations/reach/evaluation

2 Progress in 2012

2.1 DOSSIER EVALUATION

2.1.1 Dossiers submitted

ECHA received 2 528 new registrations and 102 tonnage upgrades of notified new substances under REACH in 2012, resulting in over 28 000 registrations since the entry into operation of REACH until the end of 2012[5]. This figure excludes registrations of onsite isolated intermediates that are not subject to the evaluation process. Table 1 below presents the status and breakdown of registrations per tonnage band.

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

- The total number of registration dossiers represents the number of successful registrations by 31 December 2012, i.e. submissions which received a registration number by that date;

- A registration is only counted once, regardless of the number of submitted updates, while the latest successful submission determines the tonnage information and status provided below;

- When a dossier indicates the use of the substance covered both as a non-intermediate and as a (transported) intermediate, for the purpose of this report it counts as one registration (non-intermediate) with the cumulative tonnage band of both uses.

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

TABLE 1: NUMBER OF ACTIVE REGISTRATION DOSSIERS BY THE END OF 2012

Tonnage per year	Registrations (non-intermediates)		Transported intermediates		Total
	Phase-in[1]	Non phase-in[2]	Phase-in[1]	Non phase-in[2]	
1 to 10	1 131	1 173			
10 to 100	1 111	459	1 420	830	8 896
100 to 1000	2 527	245			
→ 1000	16 569	225	2 288	31	19 113
Total	**21 338**	**2 102**	**3 708**	**861**	**28 009**

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

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

2.1.2 Priorities for testing proposal examination

At the beginning of 2012, the ECHA database contained 571 dossiers with testing proposals from the 2010 registration deadline and 38 dossiers with testing proposals for non phase-in substances. 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 …"

5 http://echa.europa.eu/information-on-chemicals/registration-statistics

To meet this legal target for the dossiers concerned, ECHA made the processing of testing proposals its priority during 2012. For non phase-in substances, Article 43(1) of the REACH Regulation specifies a deadline of 180 days from receipt of the registration. For dossiers meeting this condition, ECHA starts the processing upon arrival. The target for 2012 on concluding dossier evaluations (i.e. processing to the draft decision, quality observation letter (QOBL) or conclusion of no action needed) was set at 400 testing proposal examinations and 250 compliance checks.

An IT tool filters the IUCLID database and selects dossiers containing testing proposals. It searches for testing proposals (flagged with "experimental study planned") in the structured information of the endpoint study records. The tool also helps to prioritise the work to examine these testing proposals according to a combination of criteria, in addition to those specified in Article 40(1) of the REACH Regulation:

- ambiguity in substance identity that prevents a meaningful examination of the testing proposal;

- clusters of different substances with testing proposals based on structural similarity, the aim of which is to facilitate the third-party consultation and subsequent examination;

- substances that are part of a chemical category with related testing proposals;

- testing proposals for vertebrate animal studies.

In particular, this approach allowed dossiers with clearly inadequate substance identity to 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 Guidance on dossier and substance evaluation and the Guidance on priority setting for evaluation describe the priority setting of dossiers for compliance check.

In line with the approaches and criteria described in these guidance documents, ECHA is currently selecting dossiers for evaluation using four sets of criteria: random selection; criteria set out in the REACH Regulation; other concern-driven criteria; and testing proposals with unclear identity of the substance registered. Based on the targets set in the Multi-Annual Work Programme, ECHA prioritised dossiers in the two highest tonnage bands, with the intention to meet the 5 % target for the 2010 registrations by the end of 2013.

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 (86 %) versus random checks (14 %) was approximately six to one.

2.1.3.1 Random selection

ECHA anticipates random selection to gradually build a good overall picture of the compliance status of dossiers. It also avoids bias in the selection of dossiers and helps to refine 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 for maximum impact on the protection of human health and the environment.

In a (randomly selected) full compliance check, ECHA addresses the full dossier content in a single evaluation exercise. This means that ECHA performs a systematic evaluation of all information requirements in

the technical dossier (e.g. physicochemical, environmental and human health endpoints), including the corresponding elements and conclusions provided in the chemical safety report (i.e. hazard assessment, PBT/vPvB assessment, classification and labelling, exposure assessment and risk characterisation). This normally results in one draft decision per registration dossier.

It also results in the identification of typical shortcomings in registration dossiers. Paragraph 2.1.15 on page 21 contains details and statistics from these findings.

2.1.3.2 Enhancing efficiency of dossier evaluation

In 2012, ECHA has invested significant resources in developing intelligent methodologies for searching and analysing the information included in the technical dossiers and chemical safety reports to facilitate dossier evaluation. This computer-assisted filtering of the whole database enables handling the registrations in a systematic manner and substantially increases the chances for ECHA to select poor quality dossiers for compliance check.

The computer-algorithm filter selects dossiers with obviously incompliant essential elements for compliance check. By feeding back the learning from past dossier evaluations into the development of selection criteria, the reliability of IT-algorithms in detecting actual non-compliance issues is constantly improving. This new dossier selection strategy for compliance checks is expected to increase efficiency as it considers all registration dossiers almost simultaneously and allows addressing similar non-compliance issues in batch processes rather than one at a time.

Building on the experience gained from compliance checks and testing proposal examinations carried out to date, ECHA and the Member State competent authorities have gained considerable insight into common dossier compliance issues that potentially compromise the safe use of the related substances. ECHA published many of these deficiencies in previous annual evaluation reports or presented them in webinars and workshops together with information in order to help registrants to understand how to bring their registration dossiers into compliance with REACH. Frequent data gaps or study deficiencies that remain unresolved despite communication to registrants via the aforementioned channels will be subject to this approach.

2.1.3.3 Concern-driven targeted compliance checks

Rather than evaluating individual dossiers fully, ECHA also targets compliance checks on selected endpoints (e.g. related to "persistent, bio-accumulative and toxic", carcinogenic, mutagenic, toxic to reproduction or sensitising properties) in a systematic and cumulative manner for all registered dossiers in its database. ECHA continually discusses and refines these concern-driven dossier selection criteria in collaboration with Member State competent authorities to ensure maximum impact on the protection of human health and the environment, as well as a streamlined decision-making process. The consequence of this approach is that for dossiers containing several instances of non-compliance, registrants may receive more than one draft decision per registration dossier at different moments in time. ECHA therefore invites all registrants to consider re-assessing the overall quality of their registration dossiers, especially for typical shortcomings as highlighted in this and previous reports, to avoid multiple draft decisions as a result of these targeted compliance checks.

However, when applying the intelligent selection tools, ECHA detected a number of dossiers which had a large number of data gaps. Some of these (20) had been individually registered despite existing joint submissions of the same substance. As a result, the individual dossiers did not contain all available information for the substance registered. ECHA notified the registrants by draft decision of specific data gaps and reminded the registrants of the obligation to obtain the already existing information from the existing joint registrations.

2.1.3.4 Compliance checks on substance identity

The processes of testing proposal examinations triggered a number of compliance checks targeted on substance identity.

The description of the identity of the substance determines the scope of the registration. When the registrant describes the identity of a substance inaccurately, the information provided becomes ambiguous. This can lead to a situation where the description of the substance becomes so broad that the registration dossier appears to cover more than one substance. As a result, the registration no longer links to a substance on the market (Remember: Article 6(1) of REACH defines that "a substance" needs "a registration"). It puts further into question the relevance of the hazard data provided in the dossier for the substance actually manufactured or imported by the registrant (whichever that may be) and the deduced information on its safe use.

The consideration above also applies to information yet to be generated by proposed tests. During the process of a testing proposal examination, ECHA publishes information on the substance registered, the proposed test material, and the hazard endpoint to be addressed. If the identity of the substance registered is unclear, neither can ECHA examine whether the proposed testing was necessary nor is any interested third party able to determine precisely the kind of information needed.

In such situations, ECHA needs to clarify the identity of the substance registered before it can proceed with the examination of the testing proposal or the compliance check.

2.1.3.5 Conclusion

ECHA encourages registrants preparing for the new registration deadline, as well as registrants who have already successfully completed their registration, to keep their knowledge of the information which is frequently required by ECHA following compliance checks up-to-date. Section 3 of this and previous annual evaluation reports contains details of commonly missing and required information. It is recommended that registrants consider whether the issues raised by ECHA apply to their own registration and whether or not they need to update their dossiers.

2.1.4 Testing proposal examination

2.1.4.1 Prior clarification of the identity of the substance

When preparing the examination of testing proposals, ECHA noted a number of cases where the description of the substance identity was ambiguous thereby broadening the scope of the registration in such a way that a meaningful testing proposal examination was not possible. Such cases were of the highest priority for compliance checks, in order to clarify the identity of the substance registered and still have sufficient time for subsequent processing of the testing proposal before the 1 December 2012 target date.

In this context, ECHA had to request additional information on the identity of the substance registered by issuing a formal evaluation decision for 128 cases, with the following results.

In 59 cases, the registrants clarified the identity of the substance in a timely manner after receipt of a decision and in such cases ECHA could continue and conclude the testing proposal examination with the draft of a decision sent to the registrant according to Article 40.

In 19 cases, ECHA did not receive clarifications on the substance identify before the end of 2012. In 36 cases, the situation was such that the new information submitted on the substance identity raised further ambiguity, which had not been visible before and ECHA requested clarification in a second compliance check decision. In those cases (55 altogether), ECHA sent the draft decisions containing the conclusions on the testing proposed at the same time as compliance check draft decisions on the substance identity and invited the registrants to resolve the issues in parallel.

In 14 cases, ECHA suspended the examination of the proposed tests due to the persisting ambiguity of the description of the substance identity. As a consequence of the identified non-compliance, the deadline of 1 December 2012 for examining the testing proposals was no longer applicable. If a registrant duly clarifies the substance identity, ECHA will further examine the testing proposal and notify the registrant of the assessment by draft decision within 180 days.

In some cases, the substance identity remained enigmatic even after submission of further information by the registrants in consequence of a targeted compliance check decision. The non-compliance with ECHA's decision and the REACH Regulation may be subject to enforcement actions by the national authorities of the Member States as introduced by Article 126 of the REACH Regulation. Member States have been informed about the relevant cases and ECHA expects further communication on the non-compliance with ECHA's decision to take place between the registrant and the respective Member State authorities until the case is resolved.

If, due to persisting ambiguity of the substance description, the substance concerned by the registration cannot be identified, rendering the evaluation of information on the hazards and risks necessary to ensure a high protection of human health and the environment unachievable, the registration may be considered invalid.

In nine cases, the registrant ceased manufacture after receiving a draft decision from ECHA. According to Article 50(3) of REACH this situation results in a permanent invalidation of the respective registration and ECHA closed the evaluation.

2.1.4.2 Third-party consultation

The use of a public consultation is one of the measures to ensure avoiding unnecessary tests on animals. Before ECHA decides on a proposal for testing using vertebrate animals, it publishes the substance's name and the endpoint addressed on its website and invites third parties to submit scientifically valid and relevant information on the endpoint and substance in question. The examination of a testing proposal by ECHA takes into consideration any such information received from third parties in its conclusion. In its draft decision on the testing proposal, ECHA provides the information that is available from third parties and also includes a consideration of its relevance to the testing proposed and the conclusion drawn. Registrants may then consider whether 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 such that the proposal to conduct a new study would be obsolete. It is not normally transparent to ECHA whether it was the third-party information that triggered a withdrawal of a testing proposal by a registrant.
Table 2 details the number of vertebrate testing proposals and the status of the related third-party consultation processes.

TABLE 2: TESTING PROPOSALS (CUMULATIVE) SUBJECT TO THIRD-PARTY CONSULTATION*

No. of tests proposed		Phase-in	Non phase-in	Total
No. of dossiers**	containing testing proposals for vertebrate animals	395	39	**434**
No. of endpoints	covered by registered testing proposals for vertebrate animals	652	63	**715**
No. of third-party consultations	closed	466	49	**515**
	Ongoing on 31 December 2012	1	1	**2**
	in preparation	6	0	**6**

* number of third-party consultations is larger than the number of dossiers as registrants were withdrawing testing proposals during the process or adding new ones multiplying the number of third-party consultations for their dossiers
** Successfully registered (accepted and fee paid)

As reported in 2011, many of the third party comments received had been generic in nature and concentrated on alternative testing strategies, which registrants may or may not have considered already; typically speaking, the supporting studies or information lacked adequate justification and/or details. In 2012, there were some occasions when the provided third-party comments were more case-specific e.g. by identifying a potential use of read-across, weight of evidence, or combinations of both of these approaches.

There are a limited number of examples where registrants appear to have revised their approach to be in line with that suggested in third-party comments. To illustrate, in one case a third party provided information that the registered substance hydrolyses rapidly and that data for the hydrolysis product could potentially fulfil the information requirement. Following receipt of these comments, the registrant was able to identify and acquire the additional data, which was needed to meet the information requirements and updated the dossier. In this case, the registrant withdrew the testing proposal and considered that the information requirement could be met by read-across. In another case, a third party proposed that the information requirement for an inorganic salt could be met by using read-across to a similar inorganic salt sharing the same toxicologically relevant species. The registrant updated the dossier following the suggestion during the decision making process. The decision taken could not consider the late update of the dossier. However, ECHA will assess the information provided including the validity of the read-across in the follow-up part of the process.

So far, none of the third-party information received has given grounds for ECHA itself to reject a testing proposal directly. It is the registrant who, after obtaining the relevant information, determines if the suggested approach can be scientifically justified and whether the information requirements can be met by such an approach.

To increase transparency in decision-making, ECHA started publishing non-confidential versions of its decisions (CCH and TP) by the end of 2012, and intends to make new ones available on its website on a monthly basis. These documents include ECHA's reflections on third-party comments[6] and replace the separately published ECHA responses on this question.

6 http://echa.europa.eu/information-on-chemicals/testing-proposals/current

2.1.4.3 Meeting the legal deadlines

According to Article 43, the legal deadlines for testing proposal examinations are for ECHA to prepare a draft decision within 180 days of receipt of a non phase-in substance or by 1 December 2012 for phase-in substances registered before 1 December 2010. Additionally, a 180-day deadline applies for phase-in substances of registrations motivated by the 2010 registration deadline, if the registrant updated the registration dossier after 3 June 2012 with a new Annex IX or X testing proposal.

Despite significant challenges, ECHA met all legal deadlines of this reporting year. Table 3 gives an overview of concluded cases with different deadlines.

TABLE 3: TESTING PROPOSAL SUBMITTED BY DEADLINE (DRAFT DECISION STAGE)

	Submitted	Concluded*
No. of cases motivated by the 2010 registration deadline with deadline for sending draft decision of 1 December 2012: Article 43(2)(a)	571	557**
Phase-in cases with deadline for sending draft decision 180 days after successful submission of the updated dossier (after 3 June 2012)	2	1***
Non phase-in cases with deadline for sending draft decision 180 days after successful submission of the dossier: Article 43(1)	91	83
No. of cases motivated by the 2013 registration deadline with deadline for sending draft decision of 1 June 2016: Article 43 (2)(b)	17	8
No. of cases motivated by the 2018 registration deadline with deadline for sending draft decision of 1 June 2022: Article 43 (2)(c)	0	0

* draft decision sent to the registrant or closed as the proposal was inadmissible or withdrawn
** cases with incompliant and ambiguous substance identity despite ECHA decision (14)
*** the minimum time for examining a testing proposal is 180 days from the submission

2.1.4.4 Processing of testing proposals

Excluding the 144 dossiers already in the decision-making phase (i.e. a draft decision sent to the registrant), but counting 363 cases carried over from 2011 and adding 79 testing proposal examinations that ECHA initiated results in 442 dossiers with testing proposals that were processed in parallel in 2012.

In 2012, the examination of testing proposals made significant progress. The first annual target was to conclude the examination and send a draft decision to the registrants for all remaining testing proposals in dossiers submitted by the 2010 deadline (400). The second annual target, given the same priority, was to conclude the examination of all testing proposals in non phase-in registration dossiers and send the draft decision to the registrants within 180 days of the dossier's receipt. The status of the testing proposal evaluations at the end of 2012 is summarised in **Table 4**. Note that the difference of numbers between **Table 3** and **Table 4** is caused by withdrawals of testing proposals by the registrants.

TABLE 4: NUMBERS AND STATUS OF TESTING PROPOSAL EXAMINATIONS ON 31.12.2012

Type	Total	Decision drafted	Decision taken	Closed	Continue in 2013
Phase-in	529	282	151	76	20
Non phase-in	57	23	20	8	6
Total	**586**	**305**	**171**	**84**	**26**

By the end of 2012, ECHA had concluded 560 testing proposal examinations by either making a decision (171), draft decision (305) or closing the case (84). The evaluation of a further 26 dossiers continues in 2013 (Figure 1). This number includes the 14 cases where the identity of the substances needs to be clarified with the help of enforcement authorities.

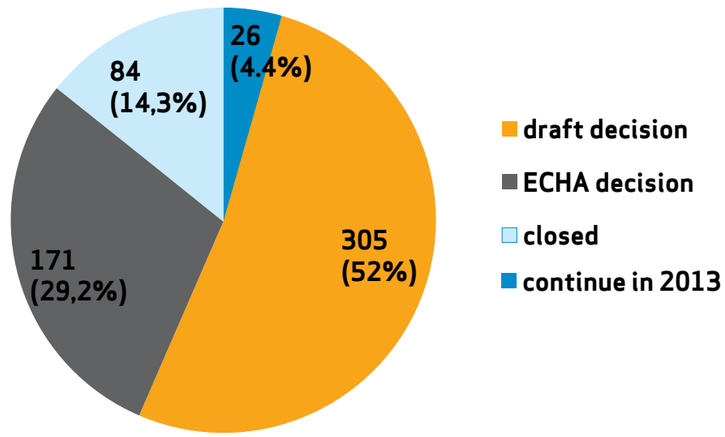

FIGURE 1: TESTING PROPOSAL EXAMINATIONS IN 2012 BY MAIN OUTCOME IN PER CENT

There are several reasons for closing a testing proposal examination before referral to the Member State competent authorities. These include the cessation of manufacture or import by the registrant, withdrawal of the testing proposals, and inadmissibility. Inadmissible testing proposals are those where REACH does not foresee a testing proposal examination. These cases are where:

1. the proposal is addressing Annex VII and VIII endpoints;

2. testing is already ongoing or completed;

3. a testing proposal instead of testing results 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).

2.1.4.5 ECHA Decisions

In 130 decisions (adopted and subsequently taken), ECHA accepted the tests proposed by the registrants, while in 40 cases the Agency modified at least one of the tests proposed. In one case, ECHA rejected the test proposed altogether. Of the 170 accepted or modified proposals, 24 cases also contained a proposal for a two-generation reproduction toxicity study. The decisions were split into a part containing such elements of the draft decision that found unanimous agreement of the Member State Committee and a part containing the proposal for a two-generation reproduction toxicity study. The Committee handled these latter proposals separately from other information requirements and ECHA referred the draft decisions to the Commission after the Committee had failed to unanimously agree on the draft decisions.

The most common endpoints addressed in ECHA decisions were prenatal developmental toxicity (67) and sub-chronic repeated dose toxicity (67), followed by the group of physicochemical properties (39) and long-term aquatic toxicity testing on invertebrates (34). The information required by ECHA decision from the registrants is summarised in Table 5.

TABLE 5: INFORMATION REQUIRED BY THE ECHA DECISIONS ON TESTING PROPOSALS

Type of testing required	No. of decisions*
Annex IX, 7. Physicochemical properties	39
Annex IX, 8.4. Mutagenicity	12
Annex IX, 8.6.2. Sub-chronic toxicity study, 90-day	67
Annex IX, 8.7.2. Prenatal developmental toxicity study	67
Annex IX, 9.1.5. Long-term aquatic toxicity testing on invertebrates	34
Annex IX, 9.1.6. Long-term aquatic toxicity testing on fish	17
Annex IX, 9.2.1. Biotic degradation	10
Annex IX, 9.3. Fate and behaviour in the environment	8
Annex IX, 9.4. Effect on terrestrial organisms	12
Annex X, 8.7.2. Prenatal developmental toxicity study	4
Annex X, 8.7.3. Two-generation reproductive toxicity study	0 (24)**
Annex X, 9.2.1. Biotic degradation	1
Annex X, 9.4. Effect on terrestrial organisms	8
Annex X, 9.5.1. Long-term toxicity to sediment organisms	6

* In general, ECHA decisions addressed more than one information item needed to bring the registration into compliance (~2.6 as an average).
** The Member State Committee did not find unanimous agreement and referred the respective decision to the Commission.

ECHA adopted the 171 decisions as follows:

- 45 draft decisions were taken by ECHA as decisions without referral to the Member State Committee (i.e. Member State competent authorities did not propose amendments);

- 126 draft decisions received at least one proposal for amendment by a Member State competent authority;

    - For 102 of these draft decisions, the Member State Committee considered the proposals for amendments, unanimously agreed on the actual wording and ECHA accordingly adopted these decisions;

    - The remaining 24 decisions were split into two separate draft decisions with one part being agreed unanimously by the Member State Committee and becoming ECHA decisions;

    - ECHA referred the second part of the split decisions (all 24) to the European Commission for further processing (referring to two-generation reproductive toxicity study).

In December 2012, ECHA started to publish decisions taken on its website[7]. After an introduction period, the list will be updated on a monthly basis.

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

2.1.5 Compliance checks

In 2012, ECHA processed 427 dossiers under compliance check in parallel: 93 of these checks were already ongoing (carry over from 2011) and 334 newly initiated in 2012. By the end of 2012, the status of 354 compliance checks were "concluded" and the evaluation of a further 73 dossiers will continue in 2013. From the 354 concluded cases, ECHA brought 66 cases through the decision making process resulting in an ECHA decision requesting the registrant to provide further information. In one case, ECHA decided to only send a quality observation letter in order to allow the registrant to improve the dossier, but not constituting a formal decision and completed another 131 compliance checks with "no further action required". In 156 cases, ECHA drafted a decision requesting more information, but the decision making process is still ongoing. Table 6 details the distribution of the cases across the tonnage bands of the registrations.

TABLE 6: IN 2012 CONCLUDED COMPLIANCE CHECKS BY TONNAGE BAND

Tonnage band	ECHA decision	Quality observation letter	Draft decision	Closed		Total
				after draft decision	without action	
→ 1000 t/a	48	1	156	13	106	168
100 to 1000 t/a	12	0	0	0	10	22
10 to 100 t/a	3	0	0	1	0	4
1 to 10 t/a	3	0	0	0	1	4
Total	**66**	**1**	**156**	**14**	**117**	**354**

ECHA opened 295 dossiers for a targeted compliance check and subsequently sent 183 draft decisions. In these draft decisions, ECHA requested further clarification of substance identity triggered by testing proposal examination (55), addressed specific data gaps and the obligation to jointly register same substances (23), information on the octanol-water partitioning coefficient (70) and on mutagenicity (18).

Figure 2 presents the outcome of the compliance checks in 2012, also showing the number of cases triggered by testing proposal examination.

In 2012, ECHA completed all compliance checks within the legal deadline (e.g. issued the possible draft decision within 12 months from the start of the compliance check).

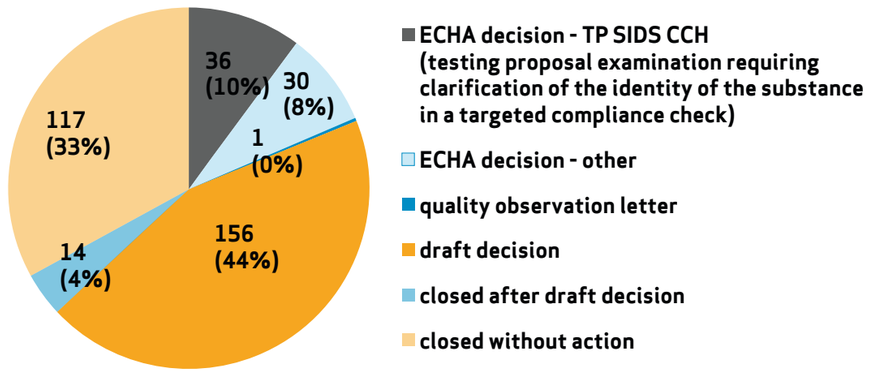

FIGURE 2: CONCLUDED COMPLIANCE CHECKS IN 2012 BY MAIN OUTCOME

ECHA adopted 66 ECHA decisions as follows:

- 47 draft decisions as ECHA decisions with no proposals for amendments from the Member State competent authorities. This predominantly applied to targeted compliance checks on substance identity and other areas of concern (36 cases).

- 19 after the Member State Committee reached unanimous agreement on proposals for amendments in a written procedure or by discussion in one of the meetings.

ECHA has not referred any draft decisions following a compliance check to the Commission in 2012. The information required by an ECHA decision from the registrants is summarised in **Table 7**.

TABLE 7: INFORMATION REQUIRED BY ECHA DECISIONS TAKEN UNDER COMPLIANCE CHECK (2012)

Type of information required	No. of cases*
Exposure assessment and risk characterisation (Annex I)	15
Robust study summaries, hazard and exposure assessments, risk characterisation(Annex I)	4
Information regarding identification and verification of the composition of the substance (Annex VI, 2.)	44
Waste from production and use (Annex VI, 3.6)	1
C&L according to CLP Regulation (Annex VI, 4.)	2
Physicochemical properties (Annex VII)	3
Toxicological information (Annex VIII)	5
… of which: Screening for reproductive/developmental toxicity (Annex VIII, 8.7.1)	4
… of which: Toxicokinetic (Annex VIII, 8.8)	1
Physicochemical properties (Annex IX)	1
Sub-chronic toxicity study, 90-day (Annex IX, 8.6.2)	12
Prenatal developmental toxicity (Annex IX, 8.7.2)	11
Two-generation reproduction toxicity study (Annex IX and X, 8.7.3)**	2
Effects on terrestrial organisms (Annex IX, 9.4)	2
Mutagenicity (Annex X, 8.4)	1
Developmental toxicity study in the rabbit via the oral route (Annex X, 8.7.2)	7
Carcinogenicity study (Annex X, 8.9.1)	1
Effects on terrestrial organisms (Annex X, 9.4)	1
Justification for use of read-across	1
PBT assessment	1

* In general, ECHA decisions addressed more than one information item needed to bring the registration into compliance.
** requiring data-sharing for existing test results

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 8.

TABLE 8: TYPE OF SHORTCOMINGS (CUMULATIVE) ADDRESSED THROUGH QUALITY OBSERVATION LETTERS

Shortcomings/inconsistencies addressed through QOBLs*	Number of cases**
Substance Identity	6
CSR related e.g. PNEC or DNEL derivation, exposure assessment, missing description of the waste stage, PBT issues	11
Classification and labelling	3
Insufficient level of detail/inconsistencies in robust study summaries	3
Full study report	1
Consideration of further studies	3
Test performed without submitting a TP	1
Data sharing rule (need for joint submission)	1
Justification for adaptations to standard information requirements	2

* QOBL = quality observation letter
** In general, QOBLs addressed more than one inconsistency

Table 9 presents an overview of the compliance check outcome of both types of selected dossiers (concern-driven/randomly selected). The results show that, except for the SID-targeted compliance checks related to testing proposals, the proportion of dossiers that ECHA closed without any administrative action was similar for the two remaining types. However, it needs to be stressed that a number of decisions are still pending (draft decision in the decision making phase), which are not accounted for in the table.

The outcome of compliance checks concluded in 2012 suggests that the quality of the evaluated dossiers may be further improved: In the majority (66%) of the cases following compliance check an ECHA decision was either drafted (48%) or taken (18%). However, it is important to realise that the observed quality of these dossiers cannot be generalised. Due to the limited number of concluded full compliance checks on randomly selected dossiers, representative statistics remain unavailable at this moment.

ECHA still expects that due to continuous learning, dossiers will improve over time. ECHA advises registrants to make use of the possibility to update and improve the quality of their dossiers at any time.

TABLE 9: QUALITY OF DOSSIERS: CASES CLOSED OR DECISION SENT TO THE REGISTRANT IN 2012

	Outcome type						Total
Reason for selection	Closed without action	Only QOBL	Closed after draft decision*	Decision taken without proposal of amendment: Article 51(3)	Decision taken after ECHA MSC agreement: Article 51(6)	Commission to take the decision: Article 51(7)	
Concern	11	1	0	7	14	0	33
Random	9	0	2	4	5	0	20
Intelligent selection tool	68	0	0	0	0	0	68
CCH targeted to SID	3	0	1	4	0	0	8
CCH targeted to SID, C&L and exposure	11	0	0	0	0	0	11
CCH triggered by Substance Evaluation Process	13	0	1	2	0	0	16
CCH triggered by TPE and targeted to SID	2	0	10	30	0	0	42
Total	117	1	14	47	19	0	198

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

2.1.6 Follow-up of dossier evaluation

2.1.6.1 ECHA decisions

By the end of 2012, 143 deadlines given by compliance check decisions and 30 deadlines given by testing proposal decisions had expired and the follow-up procedure is meant to be started. In 2012, due to the other more urgent priorities, ECHA was only able to conclude on 65 follow-up evaluations for ECHA decisions with passed deadlines. In 55 cases of compliance checks targeted on substance identity, ECHA concluded the follow-up by sending a second decision to the registrant seeking further clarification. In one case, ECHA found the information in the dossier being compliant with the testing proposal decision and therefore sent an Article 42(2) notification and completed the evaluation. In the remaining nine cases (one testing proposal examination and eight compliance checks) the information was regarded as not corresponding to the request in the decision and the respective Member State competent authority as well as the national enforcement authorities have been asked to enforce ECHA's decision. Since such communications started only recently, enforcement results are not yet available.

2.1.6.2 Quality observation letters

Although not legally binding, the quality observation letters contain a target date and the responses are checked when this target date has passed. In 2012, 63 deadlines had passed. In 47 cases, ECHA received an updated dossier (74 %). No follow-up cases of quality observation letters were completed as the examination of testing proposals had been prioritised. The conclusions of the cases are pending and results will be available in 2013.

2.1.6.3 Decisions under Article 16(2) of Directive 67/548/EEC

A second group of decisions requiring follow-up work relates to 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 Articles 135(1) and 51 of the REACH Regulation. The Agency shall evaluate the compliance of the information submitted by the registrant upon such decision according to Article 42 of REACH (dossier evaluation follow-up).

Such registration dossiers for which the deadline has passed and information as set out in the respective decisions is not available are not in compliance with the legal requirements. Therefore, they may be subject to enforcement actions by the national enforcement authorities. Currently, ECHA is interacting with Member State competent authorities to coordinate its response to registrants.

In cases where registrants have updated their dossiers with the information required, ECHA notifies the Commission and the Member States of the information obtained and any conclusions made ("Article 42 (2) letter"). The follow-up is then completed.

There are in total 142 decisions for which the status is as follows:

- Dossier updates received (by 31 December 2012): 100
- Follow-up completed: 42

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[8].

2.1.7 Appeals

Registrants who consider that there are grounds to contest an ECHA decision can bring an appeal before ECHA's Board of Appeal. Such appeals may provide opportunities to clarify, for example, how REACH requirements are interpreted in ECHA decisions and for any mistakes to be corrected.

ECHA's Board of Appeal, which operates independently from the rest of the Agency, announces on its website each new case brought.[9] As of 2012, eight appeals related to dossier evaluation decisions have been brought before the Board: one in 2011, and seven in 2012.For substance evaluation, no appeals have been brought because no decisions have yet been adopted.

Of these eight appeals, one appeal was withdrawn by the appellant on 18 June 2012 after the Executive Director of the Agency rectified the decision (Case A-002-2012). For one case (A-005-2011) a public hearing before the Board took place at the Agency's premises on 12 December 2012.

It is expected that the Board will publish its decisions on the first evaluation appeal cases in 2013. It can be anticipated that the Board's decisions on these cases may provide useful information to ECHA and to other stakeholders about how to interpret REACH requirements.

2.1.8 The endpoint "reproductive toxicity"

In 2012, the Member State Committee was still not able to agree unanimously on the study protocol for addressing the information requirements of Annex IX and X 8.7.3 "Two-generation reproductive toxicity

8 http://echa.europa.eu/documents/10162/17238/prev_not_sub_registrants_qa_en.pdf
9 http://echa.europa.eu/about-us/who-we-are/board-of-appeal

study". Some members were in favour of requesting that the study follow the "Extended one-generation reproductive toxicity study (EOGRTS) test protocol (adopted as OECD TG 443 on 28 July 2011). However, other members could not agree on imposing the use of the new guideline (also in light of the existing EU method B.35) or could only accept its use with certain specifications.

ECHA therefore split all draft decisions requiring information on the endpoint in question, besides information on other endpoints, into two parts: one part to contain the testing agreed as a decision taken for sending to the registrant and another part to refer to the Commission for decision in the REACH Committee. This procedure enables the registrant to address the agreed information requirements without undue delay. The Commission did not decide on the approach in 2012 and the cases count in the present statistics as "draft decisions".

As mentioned in section 2.1.14, in 2012, the Member State Committee referred 22 such cases to the Commission for decision. In 2012, ECHA had focused on testing proposal examination and used its discretion of prioritisation to "target" its remaining compliance checks on priorities other than the two-generation endpoint to provide some time for decision. However, ECHA has now examined all testing proposals from the 2010 deadline and needs to focus on the core task of compliance checks. It thus anticipates more requests for a two-generation study in the near future. Therefore, for an efficient operation of ECHA's decision-making and for fulfilling the information requirements on reproductive toxicity, it is important that the Commission and the Member States resolve the remaining policy issue.

2.2 SUBSTANCE EVALUATION

Substance evaluation aims to verify whether a substance constitutes a risk to human health or the environment. Member State competent authorities are in charge of conducting the evaluation of substances. They will make a proposal to require further information from registrants, when the available information does not fully address the potential risks. This request may include a test beyond the standard information requirements of REACH. ECHA coordinates and supports the work of Member States. The ECHA Secretariat is also in the position to propose amendments on the draft decisions made by the Member States. After the consultation with the registrants and all other Member States, ECHA will take a decision on a substance.

Only registered substances can be subject to substance evaluation. The Community rolling action plan lists substances subject to substance evaluation. ECHA publishes an updated Community rolling action plan on an annual basis.

2.2.1 Preparation of the Community rolling action plan

The Community rolling action plan specifies the substances subject to evaluation over a period of three years. ECHA prepared the Community rolling action plan in close collaboration with the Member State competent authorities, taking into account the criteria for selection of substances[10] and the opinion of the Member State Committee (MSC). The Member States may also propose substances based on national priorities as specified in Article 45(5) of the REACH Regulation. Each year, ECHA updates and submits the updated draft Community rolling action plan to the Member States by 28 February, as Article 44(2) of the REACH Regulation requires. In practice, ECHA issues a pre-draft for the Community rolling action plan update in the preceding autumn to ensure the adoption of the Community rolling action plan during the first quarter of the financial year.

ECHA has published the procedure for establishing updates of the Community rolling action plan (PRO-0022.01) on its website[11].

10 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
11 http://www.echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures

2.2.1.1 Adoption of the first Community rolling action plan

The first Community rolling action plan, published on 29 February 2012, lists 90 substances for evaluation[12]. Those substances are due for evaluation in 2012, 2013 and 2014 by the volunteering Member States. Thirty-six substances are in the process of evaluation by 17 Member States during 2012.The current Community rolling action plan includes 23 and 31 substances for the years 2013 and 2014, respectively, and additional substances are to be included in the next Community rolling action plan update 2013-2015.

In this Community rolling action plan, the concerns focus on potential PBT-properties, endocrine disruption, carcinogenicity, mutagenicity and reproductive toxicity, in combination with wide dispersive use and consumer exposure.

2.2.1.2 The annual Community rolling action plan update 2013-2015

The first annual Community rolling action plan update for 2013–2015 has been under preparation in close collaboration with the Member State competent authorities. Three separate sources identified potential Community rolling action plan candidate substances:

- Member State competent authority notification (Article 45(5))
- Dossier evaluation (prioritisation of a case)
- IUCLID database: computer-assisted filtering and expert verification using selection criteria.

The proposal for the Community rolling action plan 2013–2015 update covered 116 substances. The list contained 63 newly selected substances and 53 substances carried over from the existing Community rolling action plan. The rapporteur Member States plan to evaluate these substances during 2013, 2014 and 2015. ECHA forwarded the draft for collecting opinions to the Member State Committee in mid-October 2012 and posted a public version on its website for information. ECHA anticipates the adoption of the Community rolling action plan 2013–2015 update in March 2013.

2.2.2 Evaluation of substances

According to REACH, the evaluation of substances listed for the first year starts on the day of publication of the CoRAP. From that date, the designated Member States have 12 months to evaluate substances and propose further testing. Thus, for the 36 substances subject to evaluation in 2012, the 17 Member States doing the work will submit a draft decision if applicable and a substance evaluation report to ECHA by 28 February 2013 at the latest. By the end of 2012, ECHA did not yet receive submissions from the Member States.

ECHA published two procedures describing a) the Community rolling action plan adoption and b) substance evaluation, including decision-making, on its website[13].

2.2.3 Support by dossier evaluation

Although compliance checks are not a prerequisite for conducting substance evaluations, ECHA is initiating compliance checks for a number of Community rolling action plan substances to ensure that the registration dossiers contain a basic dataset to assist the evaluating Member State in investigating the possible risks under substance evaluation. In this activity, ECHA takes into account the foreseeable time delay caused by the process in order to assure that the information will be included in the dossiers before substance evaluation starts.

12 http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
13 http://www.echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/public-procedures

2.2.4 Transitional measures

2.2.4.1 Notified new substances

Under the new chemicals legislation prior to REACH, Member State competent authorities were responsible for the evaluation of notified substances. For some of these substances, there are still outstanding information requests in the form of decisions prepared by Member State competent authorities under Article 16(1) Directive 67/548/EEC (for NONS substances). The respective substances are regarded as included in the CoRAP (Article 135 of REACH).

ECHA published these substances on its website on 5 September 2012 in the section "Transitional measures: complementary part to the CoRAP"[14]. The complementary part of the CoRAP will not receive new substances, but will disappear upon conclusion of all pending assessments.

2.2.4.2 Existing substances

Prior to the REACH Regulation, Member State competent authorities were responsible for the evaluation of certain substances or dossiers under the previous chemicals legislations. For some of these substances, the responsible parties did not provide all the information by the stated deadlines or the responsible Member State competent authority did not complete the evaluation, thus the substance evaluation process is still ongoing.

Article 136 of REACH considers the pending requests as ECHA decisions taken under REACH substance evaluation. At the end of 2012, there were seven such cases.

2.2.5 Follow-up of substance evaluation

As explained in paragraph 2.2.5 above, Directive 67/548/EEC, Article 16(1) and Regulation 793/93 decisions are now subject to substance evaluation and, accordingly, to the respective follow-up procedure.

After submission of information by the notifier (now registrant), the respective Member State competent authority will review that information and decide whether further information is needed or whether the substance is fully assessed (Article 46 of REACH). The Member State competent authority is required to complete the assessment of the substance within 12 months of receipt of this new information. If a registrant does not comply with an information request within the deadline, it constitutes an instance of non-compliance and normally leads to action by the national enforcement authority.

After the Member State competent authority has completed the evaluation, it considers follow-up actions for the substance. Such actions may be:

- Identification as a substance of very high concern (SVHC) and subsequently a need for authorisation;

A restriction proposal;

- A proposal for harmonised classification and labelling;
- Need for other EU-wide measures;
- Need for action at national level or voluntary action by industry;
- No action, the use of the substance is safe.

14 http://echa.europa.eu/en/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures

The rapporteur informs ECHA about the conclusion. ECHA informs the Commission, the other Member State competent authorities and the registrant.

2.3 EVALUATION-RELATED ACTIVITIES

2.3.1 Adaptation to technical progress

According to Article 13(3) of the REACH Regulation, the Commission or ECHA may recognise an international test method as being appropriate for use in registration dossiers. The European Commission has the opportunity to include a new method in the EU Test Method Regulation (EC) No 440/2008.

In certain cases, ECHA has 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 such method in the EU Test Method Regulation. In these cases, the Member State competent authorities and the Member State Committee have agreed to use such non-EU Test Methods on a case-by-case basis.

In 2012, the OECD published several new or updated Test Guidelines, which we present below:

Toxicity and bioaccumulation in aquatic organisms

On 2 October 2012, the OECD published a revision of three relevant environmental test guidelines, OECD TG 211 on Daphnia reproduction, OECD TG 229 fish short-term reproduction assay and OECD TG 305 on fish bioaccumulation including the dietary exposure.

The update of the OECD TG 211 on Daphnia reproduction reduces the variability observed in this test. It achieves this by requesting to supplement the reporting information on the number of living offspring per surviving parent with the total number living offspring produced at the end of the test per parent at the start, thus excluding accidental parental and/or inadvertent mortality from the analysis. The TG makes it possible to remove a source of error, namely the effect of inadvertent and/or accidental parental mortality if relevant. Moreover, the revised text offers additional statistical guidance for test design and treatment of results, and introduces a limit test option.

The OECD TG 229 fish short-term reproduction assay is an in vivo reproductive screening assay in the context of the "OECD Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals". Sexually mature male and spawning female fish are exposed to a chemical during a limited part of their life cycle (21 days). Two biomarker endpoints, serum levels of vitellogenin and secondary sexual characteristics are measured depending on the test species. Moreover, fecundity is monitored daily and the gonads are preserved and may be used for histopathology analysis to assess the reproductive fitness of the test animals and to add to the weight of evidence of other endpoints.

The updated OECD TG 305 bio-concentration in fish: aqueous and dietary exposure replaces the old protocol "Flow-Through Fish Test". As indicated by the new name, the main aim of this revision has been the incorporation of a dietary bioaccumulation study on fish, allowing the determination of the bioaccumulation potential of substances with very low water solubility. The guideline presents some recommendations regarding the selection of the proper exposure route. A complementary aim of the revision has been to reduce, when appropriate, the number of fish employed in the test. ECHA has already recommended the use of the draft version of this test during the dossier evaluation process; the publication of the revised OECD guideline provides further confidence for the registrants regarding the test conditions and guarantees the application of the principles regarding Mutual Acceptance of Data.

The publication on 1 August 2012 of the **OECD report 171 fish toxicity testing framework** ENV/JM/MONO 16 is also a major development regarding the overall approach for fish toxicity testing. Several revisions and new guidelines are currently under discussion including, among others, the update of the OECD TG 210 Fish, Early-Life Stage Toxicity Test, which is particularly relevant for measuring long-term toxicity in fish; therefore, registrants and other interested parties should watch out for further developments in this area.

Eye irritation and corrosion

On 2 October 2012, the OECD published a revision of the in vivo OECD TG 405 along with the new in vitro OECD TG 460 for the identification of ocular corrosives and severe irritants.

The update of OECD TG 405 acute eye irritation/corrosion focuses mainly on the use of systemic analgesics and topical anaesthetics without affecting the basic concept and structure of the test guideline. The inclusion of the use of analgesics and anaesthetics will substantially reduce or avoid animal pain and distress if in vivo ocular safety testing is still necessary. The sequential testing strategy for eye irritation and corrosion (supplement to the test guideline 405) has also been updated, given the recent developments in the field of in vitro/ex vivo methods, by describing the steps that are proposed to be taken before any new test are performed (in vitro/ex vivo and/or in vivo).

The OECD recommends the use of its new **TG 460 fluorescein leakage test method for identifying ocular corrosives and severe irritants** as part of a tiered testing strategy. The test method can identify substances with a limited applicability domain as ocular corrosives/severe irritants (EU CLP Category 1). If the chemical is not predicted as ocular corrosive or severe irritant with this test method, i.e. EU CLP Category 1, the chemical needs to be tested with one or more additional test methods (in vitro and/or in vivo). The fluorescein-leakage test method is only suitable for water-soluble chemicals (substances and mixtures). The OECD TG 460 contains more detailed explanations on the test method itself and, for example, on the specific limitations of the test.

Two additional OECD test guidelines are currently undergoing revision to broaden their applicability domain to predict also substances not classified as eye irritants (EU CLP no classification). These test guidelines are the OECD TG 437: bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants and the OECD TG 438: isolated chicken-eye test method for identifying ocular corrosives and severe irritants. It is highly recommended to follow the status of the revisions for these two test guidelines as well as potential new tests guidelines adopted by the OECD or EU Test Method Regulation.

In vivo mutagenicity

On 28 July 2011, the OECD adopted the test guideline for the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (TGR – OECD 488). The Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo has also had, since 1997, an adopted OECD test guideline (OECD 486). The current ECHA guidance considers both assays as suitable to cover gene mutation endpoint in vivo whenever required within the REACH regulatory context. Following the adoption of the test guideline for the TGR, there have been discussions, in particular at the Member State Committee, regarding which of these two in vivo mutagenicity assays should be used to cover gene mutation in vivo endpoint, when a positive in vitro gene mutation assay must be followed-up with an in vivo study. It was considered that further discussions were needed to clarify the scientific considerations related to this question. This is the reason why, on 4 October 2012, ECHA organised a Technical Discussion Session between experts to discuss the scientific adequacy for the use of these assays in somatic cells.

The remit of this discussion was to determine the assays that are adequate for detecting chemicals that induce gene mutations, in somatic cells in vivo, for systemically-available agents. The main conclusions of the discussion can be summarised as follows. The UDS is adequate to detect some carcinogens that induce gene mutations in the liver. It was recognised that substance-specific reasons can justify the use of the UDS assay. The majority view was that UDS was not adequate for other tissues than the liver. The consequences for historically available data were discussed, but no conclusions were drawn.

The TGR is adequate to detect chemicals that cause gene mutations, is theoretically applicable to all tissues, although some practical limitations have been mentioned. To the question "Is the TGR preferred over the UDS?" the answer was "usually yes", although the UDS might be equally adequate in some cases. It was recognised that there may be substance-specific considerations to select a test. It was noted that, as the OECD test guideline for TGR is new, data gathered by using the test guideline is limited compared to other test guidelines (e.g. limited historical test data on non-carcinogens/control data, in particular negative control data). The outcome of future results acquired by the TGR test guideline should therefore be considered for further validation. ECHA plans to publish a summary report of the Technical Discussion Session on its website.

Further consideration of the implications of the outcome of this technical discussion is needed for the dossier evaluation process and an update of the relevant ECHA guidance. CARACAL has to be consulted before any decision on the prioritisation of guidance updates is taken, and a precise timing for such an update has not currently been determined. The technical discussion focused on scientific issues only, whereas decision on the potential guidance update should also take into account other factors such as costs or availability of testing facilities to perform the assays. ECHA's view at the moment is that a case-by-case discussion is needed for dossier evaluation until a generic policy line can be established. More discussion is needed on how to provide information to the registrants on the preferred test guidelines for mutagenicity testing in vivo.

Nanomaterials

In the relatively new legal and rapidly developing scientifically field of nanomaterials, the scope of registered dossiers (i.e. whether and how many nanoforms are included) is currently often unclear and the level of nano-specific information provided (i.e. substance characterisation, hazards, exposure and risks) shows significant room for improvement. ECHA and the Member State competent authorities agreed to develop a common approach to address the current information requirements in dossiers containing nanoforms, taking into account the scientific and legislative uncertainties in the framework provided by REACH. ECHA established a task force on nanomaterials in order to discuss scientific and technical questions relevant to nanomaterials under REACH and CLP. To increase further communication with its stakeholders and to disseminate best practice, ECHA has now published a dedicated web page[15] with the title "Nanomaterials", containing information about current activities, meetings outcomes, webinars and latest guidance.

Despite the fact that there are no specific provisions for nanomaterials in the text of the REACH Regulation; ECHA, the Commission and the Member State competent authorities consider that nanomaterials meet the REACH definition for substances and REACH requirements therefore apply. Many substances exist in different forms (solids, suspensions, powders, nanomaterials, etc.) and, under REACH, different forms can appear within a single registration of a substance. However, the registrant must ensure the safety of all included forms and provide adequate information to address the different forms in the registration, including the chemical safety assessment and its conclusions, as well as different classifications, where appropriate[16].

An assessment (performed on the ECHA database in 2011) on how nanomaterials have been addressed in REACH registrations showed that only a few (seven) substance registrations had selected "nanomaterial" as the form of the substance in voluntary fields. A further assessment identified additional substances with nanoforms. Many registrations for substances known to have nanomaterial forms do not clearly mention which forms are covered or how the information provided relates to the nanoform. Only limited information specifically addresses the safe use of the specific nanomaterials supposedly covered by the registration dossiers. The absence of an adopted definition of the term nanomaterials at the time of the first registration deadline of December 2010, the absence of detailed guidance to registrants on registration for nanomaterials and the general wording of the REACH annexes[23]can partly explain these findings.

15 Nanomaterials webpage on ECHA website:http://echa.europa.eu/chemicals-in-our-life/nanomaterials
16 COM (2012) 572. Second Regulatory Review on Nanomaterials, 3.10.2012 http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf

In October 2011, the Commission adopted a Recommendation on the definition of 'nanomaterial'[17]. ECHA understands that this recommendation does not define one (or a set of) specific validated methods for the characterisation of nanomaterials, and that this number-based definition is new and challenging. However, ECHA is implementing the European Commission recommendation on the definition of a nanomaterial as a benchmark in assessing substances within REACH and invites registrants to proactively characterise their substances in light of this definition. The characterisation of nanoforms of a registered substance is a prerequisite to the proper determination of hazards and subsequently risks of the substance in its nanoform. ECHA's current focus is seeking clarity on the physical-chemical characteristics of nanomaterials. To this end, it will use the available REACH instruments to obtain available data (e.g. in accordance with Article 36) or request the generation of new data (Article 41). Such a gradual approach, combined with a collaborative and constructive interaction with registrants and stakeholders, forms the first step towards a full safety assessment of nanomaterials under REACH.

In 2012, ECHA began to examine dossiers registered under REACH containing nanoforms. When elements in a dossier indicate that the substance or forms of the substance may fall under the definition of a nanomaterial, ECHA has issued requests for information. The requests focused on the characterisation of nanomaterials, in particular on the size distribution and on surface treatment. The analysis of the information received from the registrants was still ongoing at the editorial deadline. In some cases, the registrants either did not react at all, answered without providing the information requested, or did provide additional information on primary particle size and specific information on surface treatment.
In some cases, registrants commented on received draft decisions issued under the compliance checks that the now available recommendation for definition of nanomaterials does not provide clarity on how to address nanomaterials in REACH registrations. In particular, it does not specify which measurement methods would be appropriate.
A recent JRC report found that a combination of analytical methods and a description of the manufacturing process would be needed for a robust description of the material. In the same line, one of the main conclusions of the first meeting of the Group Assessing Already Registered Nanomaterials (GAARN) and the Nanomaterial workshop held in Helsinki in May 2012 was that "the use of several analytical techniques for characterising nanoforms (multi-method approach) was favoured"[18,19].

ECHA is currently identifying the proper follow-up actions.

Terrestrial Plants Toxicity Testing

The Member State Committee has established the following recommendations regarding toxicity testing on terrestrial plants:

- OECD TG 208 (Terrestrial plants, growth test) considers the need to determine the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution:

  - For short-term toxicity testing under REACH, ECHA considers three species as the minimum to achieve a reasonably broad selection. The short-term toxicity testing shall be conducted with species from different families, as a minimum with one monocotyledonous species and two dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

17 Commission Recommendation 2011/696/EU: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
18 ECHA (2012), Best practices – 1st GAARN meeting, ECHA-12-R-06-EN, European Chemicals Agency, September 2012http://echa.europa.eu/documents/10162/5399565/best_practices_physiochem_subst_id_nano_en.pdf
19 Workshop on Nanomaterials – Proceedings, ECHA-12-R-05-EN, European Chemicals Agency, September 2012 http://echa.europa.eu/documents/10162/5402174/2_workshop_on_nanomaterials_proceedings_en.pdf

  - In general, both OECD TG 208 with a minimum of six species and ISO 22300 are, in principle, suitable for covering long-term testing requirements on plants. However, the registrants should assess the available information on the substance as it may contain indications suggesting preferences for one specific guideline. In certain cases, both guidelines might be insufficient and higher tier studies should be considered by the registrant.

Registrants are requested to consider these recommendations in their dossiers and testing proposals. It should be noted that these recommendations cover standards cases. Higher tier testing strategies, including risk characterisation approaches based on Species Sensitivity Distributions, require specific testing approaches that should be defined case-by-case.

2.3.2 Support to registrants

2.3.2.1 Website section on evaluation

ECHA dedicated a section on evaluation on its website[20], providing an overview of the three independent evaluation processes under REACH: compliance checks, examination of testing proposals and substance evaluations. Since 2012, there are new sections to provide information on animal testing and on nanomaterials[21], a new section providing access to Technical and Scientific Reports, and a section with ECHA decisions from dossier evaluation processes[22].

2.3.2.2 Interaction with registrants during dossier evaluation

The REACH Regulation provides the right for registrants to comment formally on a draft decision within a period of 30 days of receipt. The registrant must submit such formal comments in writing, using a form provided on the ECHA website. In this way, registrants can exercise the right to respond to the proposed requests for further information and may, at this stage, use this opportunity to bring the dossier into compliance by submitting an updated dossier with available additional information.

Normally, in the notification letter of the draft decision, ECHA offers the possibility to discuss the scientific and legal rationale behind the draft decision informally (for more details, see Evaluation Reports 2010 and 2011). Following any such interaction, the registrant may achieve compliance by updating the registration dossier. If the dossier update contains the required information, it may result in a modified or withdrawn draft decision. Depending on the outcome of the interaction, ECHA may agree to wait a reasonable and justified period of time for an updated registration dossier before referring its draft decision to the Member State competent authorities.

ECHA does not have the resources to offer this informal interaction in the case of batch processing of decisions on selected dossiers as described in section 2.1.5above. In such cases of targeted compliance checks, ECHA will instead offer participation in webinars providing tips and hints on how to improve compliance of the registration dossier. ECHA records the presentations given in those webinars and makes them available on its website.

Once ECHA has referred a file to the Member State competent authorities in accordance with the decision-making procedure (Article 51), ECHA cannot consider new information submitted in updated registration dossiers until the decision is adopted and the deadline for updating the dossier has passed. Any other approach would lead to an interruption of the complex and ongoing decision making process. To ensure an efficient flow of information, ECHA advises registrants to use the tools of commenting on the draft decision in the given time. This is without prejudice to Article 22, i.e. the obligation to update spontaneously the registration dossiers when new data become available.

20 http://echa.europa.eu/regulations/reach/evaluation
21 http://www.echa.europa.eu/chemicals-in-our-life
22 http://echa.europa.eu/regulations/reach/evaluation/requests-for-further-information/evaluation-decisions

2.3.2.3 Interaction with registrants during substance evaluation

As under dossier evaluation, the REACH Regulation provides the right for registrants to comment formally on a draft decision within a period of 30 days of receipt. Under substance evaluation, the registrants and evaluating Member States are encouraged to start an informal dialogue very early in the process, even before the substance evaluation starts, (both for substances listed on the Community rolling action plan and candidate substances). There may be many registrants of the same substance so it is important that registrants start coordinating and communicating with each other as early as possible in the process. It is important to gain a common understanding between registrants and the evaluating Member State about the initial concern identified and whether the evaluating Member State can take any new information submitted in an updated registration dossier into account for the substance evaluation. Member States have agreed a common approach on interaction with registrants during the substance evaluation processes. If the dialogue has not already started upon publication of the Community rolling action plan, the moment the evaluation of the substance starts, the evaluating Member State will usually contact the registrants and offer the opportunity to meet to discuss technical issues related to the evaluation of the substance.

2.3.2.4 Transparency of the decision-making process

If a decision drafted by the Agency receives proposals for amendments by any Member State competent authority, the Member State Committee will discuss the proposals. Regular stakeholder observers of the Member State Committee may attend the open sessions of the meetings. However, ECHA cannot provide any documents related to the decisions or the proposals for amendment made by the competent authorities to these observers. A representative of the registrant (case owner) may also attend the meetings during the initial discussion of their own case by the Member State Committee. During 2012, 24 case owners used this opportunity and participated in the Committee's discussions in the meetings (52% of the 46 cases addressed). Additionally, ECHA started publishing non-confidential versions of its decisions (CCH and TP) by the end of 2012, and intends to make new ones available on its website on a monthly basis.

2.3.2.5 Stakeholders' Day

The European Chemicals Agency hosted its seventh annual Stakeholders' Day Conference on 23 May 2012. The conference offered participants the latest news and updates from ECHA, European industry associations and NGOs. As in previous years, ECHA offered participants the possibility to book one-to-one sessions with the Agency's scientific experts to discuss specific topics and to receive advice and guidance for key processes relevant to the implementation of the European chemicals legislation. The full programme, presentations and video streams can be found on ECHA's website[23].

2.3.2.6 Webinars on dossier evaluation

ECHA started a new series of webinars "How to bring your registration dossier in compliance with REACH – Tips and Hints", where the Agency summarises its findings from dossier evaluation to support the registrants. ECHA delivers these webinars on a quarterly basis and provides practical advice to registrants on a general level as well as detailed tips on specific endpoints. The webinars are a valuable source of information and are open to all registrants.

On 27 September 2012, the first of this series of webinars gave information on the targeted approach of the Agency towards compliance checks and summarised general recommendations observed throughout the submitted dossiers. It gave practical advice on the endpoints octanol–water partitioning coefficient (e.g. how to choose the experimental method), aquatic toxicity (when is it possible to adapt the testing regime) and gen-toxicity (testing strategy).

The webinars are open for all. To register for an upcoming webinar or to watch an already delivered webinar, please follow our webinar web page[24].

23 http://echa.europa.eu/en/view-article/-/journal_content/40bb6ef5-03b0-496f-8c4c-a8f8d04ab68c
24 http://echa.europa.eu/en/support/training-material/webinars

2.3.2.7 Webinar on substance evaluation

To give practical advice for registrants who hold a registration for a substance included in the CoRAP and to promote the coordination needed amongst registrants of the same substance, ECHA gave a webinar "What should every registrant know about substance evaluation" in October 2012. Additionally a Quick Guide was prepared; "Substance evaluation – Tips for registrants and downstream users". The key messages are:

- Check on ECHA's website if your substance is proposed and finally included in the Community rolling action plan.
- Appoint one registrant to coordinate communication to the evaluating Member State and ECHA. Speak with one voice while providing the formal comments.
- The coordinator should have early contacts with the evaluating Member State, especially regarding the first year substances in the Community rolling action plan.
- Any dossier updates relevant to the substance should be sent before the substance evaluation starts. Otherwise the Member State may have difficulties in taking into account the information as the time available for the evaluation cannot be stopped.
- Agree who shall perform the tests requested in the substance evaluation decision.

More information is available on ECHA's website.[25]

2.3.2.8 Update of REACH guidance relevant to evaluation

ECHA continued updating the guidance in 2012. ECHA updates its guidance on information requirements and chemical safety assessment 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.

Furthermore in 2012, ECHA further improved the accessibility of the guidance by continuously publishing "lighter" versions of guidance documents and explanatory documents (e.g. guidance-in-a-nutshell on data sharing, practical guides, fact sheets) in multiple languages.

ECHA invites registrants to take note of these new documents and update the relevant parts of their dossiers accordingly where appropriate. ECHA will take into account the new approaches described in the guidance during ongoing and future dossier evaluation processes.

In order to extend the Guidance with advice on how to address information requirements of **substances in the nanoform**, ECHA made new Appendices to parts R7a, R7b and R7c of the Guidance on Information and Chemical Safety Assessment available on 30 April 2012. On 25 May 2012 appendices to parts R8, R10 and R14 followed.

20 November 2012 - **application of the CLP criteria:** Update was needed to include in Part 3 Health Hazards sections on specific concentration limits for the four hazard classes: Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Reproductive Toxicity and Specific Target Organ Toxicity - Single Exposure (STOT-SE). It also addresses the new Annex (CLP Annex VI) on the determination of specific concentration limits for substances classified as reproductive toxicants.

22 November 2012 - **Parts R7a (sections 7.1 and 7.2) and R9**: Remediating misleading and inaccurate information on physical hazards and improving consistency with the CLP guidance document on physical hazards. The update of sub-chapter R.7.1 was necessary because the criteria in Article 14 of the REACH

25 http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

Regulation for determining whether a chemical safety assessment needs to be carried out have been amended to refer to the CLP Regulation rather than the Dangerous Substances Directive. As a consequence, Chapter R.9: Physical-chemical hazards became obsolete[26].

28 November 2012 - **Part E**: Updating table E 3.1 on qualitative risk characterisation for health hazards.

28 November 2012 - **Guidance for nanomaterials:** Corrigenda to chapters not already covered by the new Annexes published replacing at the same time references to Directives 67/548/EEC and 1999/45/EC by references to CLP.

ECHA recognises the need for stable guidance in advance of a registration deadline. To this end ECHA will voluntarily impose a **six-month moratorium** on the publication of new guidance documents on the REACH Regulation **from 1 December 2012 until 31 May 2013.**

2.3.2.9 Practical guides on dossier evaluation

Downstream users of substances on their own and in mixtures have duties under the REACH Regulation. More specifically, downstream users need to check whether the safety data sheets (SDS) received covers all their use and the conditions of use of a substance (on its own or in a mixture). This check includes the foreseeable use of these substances further down the supply chain. Practical Guide 13: How downstream users can handle exposure scenarios[27] gives practical advice on how to carry out such a check and the actions that should be undertaken, based on the outcome of that check.
In order to **demonstrate the safe use** of substances, registrants need to fulfil the information requirements of REACH. Practical Guide 14: How to prepare toxicological summaries in IUCLID and how to derive DNELs provides information on how to fill in the toxicological summaries in section 7 of IUCLID and on how to derive no effect levels, the level of exposure, which is the highest tolerable. The document also explains how the conclusion from the hazard assessment affects the scope of the exposure assessment as well as the type of risk characterisation.

Practical Guide 1: **How to report in vitro data** was updated in September 2012. The update contains a new section (3.7) on how to use in vitro test data to fulfil a standard information requirement for an in vivo test. This new section gives instructions on how to fill in the IUCLID dossier in order to pass the technical completeness check, if suitable in vitro methods are available to cover the in vivo information requirement.

ECHA has issued Practical Guide 15 on "How to perform a qualitative human health assessment and report it in a Chemical Safety Report" on 20 November 2012. The guide supports registrants in performing a **qualitative risk characterisation** for human health effects where establishing a threshold (i.e. DNEL) is not possible. It describes which methodologies and tools registrants can apply how to select appropriate risk management measures and how to document the qualitative assessment in a chemical safety report. Examples from typical occupational settings illustrate these aspects.

On 22 November 2012, ECHA published an update to the Practical Guide 3: **How to report robust study summaries**. Section 3 for physicochemical endpoints of the Practical Guide contains a modification to reflect the updated sub-chapter R.7.1 Physicochemical properties within the Guidance on information requirements and chemical safety assessment R.7a: Endpoint specific guidance. Sections 4 and 5 for the environmental and human health endpoints of the Practical Guide now take into account the new and revised OECD Test Guidelines (TG), e.g. OECD TG 305 Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD TG 443 Extended One-Generation Reproductive Toxicity Study and OECD TG 405 Acute Eye Irritation/Corrosion[28].

2.3.2.10 Illustrative examples of a chemical safety report and exposure scenarios

Registrants are required to submit a CSR as part of their registration dossier for substances manufactured

26 http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf
27 http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf
28 http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

or imported in quantities of 10 tonnes or more per year. The report provides a summary of all the relevant information used when carrying out the chemical safety assessment for their substance. To facilitate companies in complying with their obligations under REACH, ECHA has developed an illustrative chemical safety report.

ECHA has published this "illustrative example"[29] of a full chemical safety report with the objective of illustrating:

- 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);

- how to improve the quality and consistency of chemical safety reports and to resolve common shortcomings identified by ECHA through dossier evaluation;

- the format of the report generated when using ECHA's chemical safety assessment and reporting tool, Chesar;

- IUCLID 5.4 and Chesar 2.1 files needed to generate the full CSR.

ECHA also published practical examples of exposure scenarios covering industrial, professional and consumer end uses on its website with the aim of establishing a common understanding between industry and authorities of the information that an exposure scenario should contain[30].

2.3.2.11 Chesar

Chesar is a tool developed by ECHA that aims to help companies carry out their chemical safety assessments and prepare their chemical safety reports and exposure scenarios for communication in the supply chain. Chesar supports registrants to carry out their safety assessments in a structured, harmonised and efficient way.

With the release of version 2.0 in 2012, Chesar includes the importing of substance-related data directly from IUCLID, describing the uses of the substance, identifying risk management measures if needed, carrying out exposure estimates and demonstrating control of risks. Based on this, Chesar 2.0 generates the CSR and exposure scenarios for communication in an electronic exchange format and as a text document. It also facilitates the re-use (or update) of assessment elements generated in a single Chesar instance or imported from external sources.

On 24 October 2012 ECHA released Chesar 2.1. After already covering assessment tools for the environment and workers, an exposure estimation tool for consumers is included for the first time. Chesar 2.2 will support the generation of exposure scenarios for communication up and down the supply chain (planned release in the first quarter of 2013).

The Chesar tool and supporting documentation (i.e. user manuals) are available on the ECHA website[31].

2.3.2.12 ECHA–Stakeholder Exchange Network on Exposure Scenarios

In 2012, ECHA continued to work with industry and other stakeholders on improving the REACH exposure scenario via the Exchange Network on Exposure Scenarios (ENES). Two events gathered together participants from industry, MSCAs and ECHA to share good practice on the content essentials for the environmental aspects of the exposure scenarios (ENES2, May 2012) and on the development of tools to help those who carry out a

29 http://echa.europa.eu/support/practical-examples-of-chemical-safety-reports
30 http://echa.europa.eu/support/practical-examples-of-exposure-scenarios
31 http://chesar.echa.europa.eu/

chemical safety assessment and generate exposure scenarios (ENES3, November 2012); for example specific environmental release categories (SpERCs), specific consumer exposure determinants (SCEDs) and use mapping libraries. SpERCs help companies to refine the inputs for the exposure estimation models for substances and thereby generate a more accurate estimation of environmental impact and how to control it. SCEDs will provide a similar approach for substances destined for the consumer domain. The use mapping library, developed by sector organisations in the supply chain [European Chemical Industry Council (Cefic) and the Downstream Users of Chemicals Coordination Group (DUCC)], helps registrants who prepare the chemical safety assessment by encouraging downstream users to provide them with a more coherent set of information on how and under what conditions they use substances. This will eventually improve the quality of the assessment and thereby the information communicated down the supply chain in the form of safety data sheets.[32]

The exchange of practical experience and proposals for solutions led to a number of conclusions regarding good practice in deriving and communicating exposure scenarios. As one of the actions, ENES published these conclusions, which refer to the structure and presentation of information in the exposure scenario, the content essentials on environment in the exposure scenario for communication, and the required interactions among the registrants of a substance. ENES aims for such conclusions to help manufacturers and importers, distributors, and downstream users in their process for continuous improvement in the development and use of the REACH exposure scenario. The conclusions were presented in an ECHA Newsletter (August 2012 edition) on pages 13 and 14[33].

2.3.2.13 Workshop on read-across

On the matters of read-across assessment, ECHA hosted an Experts workshop at the beginning of October 2012. The workshop contained two parts. Part 1 on 2 October consisted of a closed session to exchange views between ECHA, the Commission and the Member States. The second part was organised with the active support of Cefic's long-range Research Initiative and was open to various stakeholders[34].

2.3.3 Intermediates

ECHA has now undertaken a more systematic IT-screening of the approximately 5 500 registrations for intermediates. The analysis of the reported uses in these dossiers revealed that 2388 dossiers included uses that do not, or are very unlikely to, fulfil the definition of intermediates and/or are used under strictly controlled conditions. These dossiers with deficiencies and a potential for incompliance represent 760 substances.

The Agency has sent letters to 574 registrants with potentially non-compliant intermediate registrations, asking them to carefully review the reported uses and update their registration dossiers within three months. ECHA has also added to this letter practical advice for registrants on how to better report intermediates in IUCLID 5.4 or how to update the registration to a full Article 10 Registration.

32 http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios
33 http://echa.europa.eu/documents/10162/13584/echa_newsletter_0412_en.pdf
34 http://www.echa.europa.eu/en/view-article/-/journal_content/c6dd5b17-7079-433a-b57f-75da9bcb1de2

3 Recommendations to 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.

The most frequently found shortcomings in registration dossiers addressed by an ECHA decision related to substance identity (66 %), exposure assessment and risk characterisation (23 %), sub-chronic toxicity study (18 %) and prenatal developmental toxicity study (26 %). These frequently encountered issues are detailed together with other observations in the sections below.

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

3.1 IDENTIFY THE SUBSTANCE CLEARLY

Unambiguous substance identification is a pre-requisite to all REACH processes. Any chemical risk management activity is dependent on the identification of the substance involved, starting from the substance actually manufactured to the test material that is selected for evaluating its properties and assessing the risks.

To this end, the REACH Regulation requires that clear information is available on the identity of the registered substances as specified in Section 2 of Annex VI. A (joint) registration must cover exactly one substance, the information given in each registration dossier shall correspond to that specific substance as defined by Article 3(1) and shall be sufficient for its identification.

The EC or CAS identifiers used to describe each substance shall be representative and coincide precisely with its identity. In principle, generic identifiers, which do not specifically correspond to the registered substance, are inappropriate for its identification. For substances of unknown or variable composition, complex reaction products or biological materials (UVCB substances), the source materials and most relevant steps taken during processing are crucial parameters for the identification of the substance. Therefore, it is fundamental to consider if the name and other identifiers chosen are sufficient to differentiate a substance from another.

If no specific EC or CAS identifier matching completely with the substance subject to the registration is available, the corresponding fields in the registration dossier shall be left empty. Registrants may report relevant CAS information, such as CAS numbers associated to generic EC entries covering but not corresponding exactly to the manufactured or imported substance in the specific field of the IUCLID dossier "Related CAS information".

Information that is specific to the substance that is actually manufactured or imported needs to be provided by each registrant, including any lead registrant. Each registrant shall generate qualitative and quantitative analytical data on the substance as manufactured and imported covering all of its grades. ECHA would like to stress that analytical information which has not been generated on samples of the substance from the supply

chain cannot be used to confirm its identity.

In cases where, after a compliance check process, the persisting non-compliance is such that the substance concerned by the registration cannot be identified, the registrations may be considered invalid. ECHA has identified such cases (e.g. potentially covering more than one substance or a different substance from the one actually produced). ECHA has started informing registrants in the compliance check draft decisions on the substance identity of these major incompliances and the possible consequence.

An updated dossier should be submitted to ECHA if registrants recognise that the information provided on the identity of the registered substance is not fully correct or specific enough. Furthermore, registrants are recommended to contact ECHA if the EC identifier used to describe the registered substance does not correspond specifically to the manufactured substance. For this purpose an enquiry can be sent to ECHA through the "ECHA Helpdesk contact form" which is accessible on the ECHA website.

Further information on how to identify a substance under REACH and how to report substance identity information in IUCLID registration dossiers is available on the ECHA website[35].

3.2 DEVELOP A PROPER TESTING PLAN

3.2.1 Identify your testing needs correctly

REACH Annex VI explains in its Guidance note the procedure that registrants should follow before they submit a proposal for testing a substance. More specifically, the note suggests a four-step approach: Step 1: Gather and share information; Step 2: Consider information needs; Step 3: Identify information gaps and Step 4: Generate information or propose testing strategy. While Step 1 includes specifically the exploration of existing data and the use of in silico methods, Steps 2 and 3 compile this information and compare it to the REACH requirements to identify data gaps. Only then, as the last resort, should the registrant consider testing.

3.2.2 Justify the relevance of the test material

A recurring 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 should identify the test material carefully when proposing a test and ensure that the material is also representative for all member registrations in a joint submission. Registrants need to demonstrate the relevance of the proposed or available test with the proposed or used test material for the substance registered. They also need to cover the substance registered in all the forms, compositions and/or grades through which it may be brought onto the market. In other words the registrants need to make the links between the substances registered, the forms sold and the materials to be tested.

The importance of the detailed description of the substance registered and the test material increases in such cases where registrants propose to use (present or future) results from testing of substances other than those subject to the respective registrations.

3.2.3 Propose the test required by REACH and wait for the decision before testing

Normally, registrants need to submit testing proposals when they want to generate information addressing

35 Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) http://echa.europa.eu/documents/10162/13632/substance_id_en.pdf and Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) http://echa.europa.eu/documents/10162/13653/substance_id_report_iuclid_en.pdf.

Annex IX and X information requirements. ECHA then examines the tests proposed and evaluates whether there is indeed data gaps, the proposed tests are adequate and necessary to fulfil the information requirements. ECHA informs the registrant by decision whether it requests testing. Only then registrants can proceed and generate the information as requested.

3.3 ADAPT THE INFORMATION REQUIREMENTS CORRECTLY

Toxicological, ecotoxicological, environmental fate and physicochemical properties of chemicals have to be determined for hazard and risk assessment. Information from new studies, especially animal studies, are only required when other scientifically valid means cannot determine the properties adequately. Hence, the registrants may be able to 'adapt' the standard information requirements under REACH using other information instead and thereby avoid unnecessary animal testing. They can do so using specific adaptation possibilities provided for in column 2 of the Annexes VII to X or the general adaptation rules given in Annex XI.

In particular, Annex XI of the REACH Regulation refers to using existing information, i.e. non-standard or non-GLP studies, in vitro studies, human epidemiology data, information from structurally-related substances (i.e. 'read-across' and 'chemical categories'), predictions from validated QSAR models and use of the weight of evidence approach. Nevertheless, it is important to understand that such non-standard information has to be equivalent to the information obtained from the standard studies. In other words, information that the standard method would generate must be available for all the key parameters with a comparable low level of uncertainty and the result must be suitable for adequate risk assessment and classification under the CLP Regulation. Registrants have to justify these adaptations of the standard testing regime in the registration dossier by providing scientific explanations based on factual evidence. If they fail to do so, ECHA will request information to be generated by testing using the standard test protocol.

3.3.1 Use non-standard methods with due diligence

Registrants should be careful in using tools developed in research and development projects and other innovative techniques for predicting properties and for data waiving as these are not necessarily suitable as regulatory tools for REACH and CLP. Registrants are advised to be mindful of the limitations from such predictions, which will depend on the particular model used and may be case specific. Nevertheless, it may be that non-standard and innovative predictions can serve to build up a fuller picture of the substance property as part of a weight of evidence approach or inform registrants for designing a testing strategy, even if the property cannot be predicted adequately for REACH and CLP using the technique alone.

There is more information on the evaluation section of the ECHA website[36] and in section 3.11 on 'Adaption of Standard Information Requirements' of the 2011 Evaluation Report[37].

3.3.2 Grouping of substances and read-across approach

The REACH Regulation allows under certain conditions laid down in Annex XI Section 1.5 for grouping of substances and read-across as a means to meet information requirements without the need to test every substance for every endpoint.

Category and analogue approaches are a means to group substances while read-across is the technique for predicting an intrinsic property of a target substance, for which there is a data gap, from available information on source substances. Read-across is specific for each information requirement (endpoint) and should remain within this boundary. While read-across between different endpoints is not possible, there might be situations where information from an endpoint other than the one in question may inform on the

36 http://echa.europa.eu/regulations/reach/evaluation
37 http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf

possibility of read-across, i.e. provide supporting evidence, whether a certain read-across would be possible or not.

It is important to distinguish between two steps when preparing a read-across prediction: 1) identifying potential candidate substances serving as the source of information, and 2) the actual process of predicting the required information on a property of the target substance, i.e. reading across.

Read-across depends on adequate information on the identity and composition of the source (whether registered under REACH or not) and target substances. It also depends on the quantity and nature of impurities in either substance because differences in these characteristics can affect the intrinsic properties of the substances. In particular, multi-constituent and UVCB-substances raise additional challenges for read-across because the substances may have complex characteristics, which the prediction needs to take into account. Therefore, a read-across case should address the issue of the detailed composition of source and target substance, with special attention on the constituents relevant for the read-across.

At the core of this approach, there needs to be a read-across hypothesis, which explains the basis of the rationale for predicting the relevant property from one substance to another (i.e. why the prediction is possible). This hypothesis may be based on chemical similarity, on trends in changing properties across a group of substances or on mechanistic considerations. For example, there may be evidence of rapid transformation, so that the toxicologically active species are identical for both the source and target substances. However, the hypothesis must also explain why inevitable differences in the structures between the source and the target substances do not, or at least not significantly, affect the property under consideration (i.e. toxicological activity) and thus the predictive power of the read-across.

The read-across hypothesis needs supporting scientifically credible information, i.e. factual evidence, to be acceptable. This evidence, i.e. experimental data, confirms (or disproves) the validity of the hypothesis. The factual evidence must be available in the registration dossier, best in the form of robust study summaries in endpoint study records, in order to enable ECHA to assess the validity of the read-across hypothesis.

When, in the case of testing proposals, the above-mentioned factual evidence is weak or absent, i.e. in case of data poor categories, registrants intending to generate data for read-across for future registrations should ensure that the aim of their testing plan is to produce the necessary factual evidence, which will either confirm or disprove the hypothesis. The testing plan may contain a tiered approach. It contains in any case decision points (milestones) and decision criteria for confirmation or rejection of the hypothesis. It would also need to include an alternative plan for action, in case the hypothesis fails. An adequate testing plan includes a commitment from the registrant to generate, in a tiered approach where appropriate, all the data required to conclude on the validity of the read-across for the property under consideration, and a timeline for delivery of such information.

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[38] (Chapter R.6 of the REACH Guidance on Information requirements, Practical guide No. 6, and Good practices formulated in the previous Evaluation Reports).

3.4 REPORT THE STUDIES ADEQUATELY

ECHA can only assess information provided by registrants in their registration dossier correctly and exhaustively, if the respective information has an agreed structure and is complete. Each information source needs its own study endpoint record containing a study summary or robust study summary[39]. This also applies

38 http://echa.europa.eu/regulations/reach/evaluation
39 http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

in principle to calculated values[40]. ECHA has observed a number of cases, where the registrant added one or several calculated values to a statement of adaptation of the standard testing regime according to Annex XI in the same endpoint study record. In other cases, several values from a variety of sources shared one endpoint study record in IUCLID. In such cases, ECHA cannot conclude on the validity of the information provided and consequently requires the registrant to address the information requirement and generate the required information using the standard test. ECHA puts a significant amount of resources in explaining its reasoning leading to a draft decision as precise as possible. If the addressed registrant eliminates the shortcomings mentioned in the draft decision and updates his dossier in time (i.e. within 30 days), ECHA closes the case accordingly.

3.4.1 Physicochemical properties

In reporting the studies covering physicochemical endpoints, ECHA recommends the following points to consider:

- One single value from a secondary data source is insufficient (Annex XI, 1.2).
- Check identical values from different sources (e.g. handbooks) carefully, because the primary source is likely to be the same.
- Report as many details on the setup of the study as possible (i.e. prepare a robust study summary) of studies not following an accepted guideline.
- Fill in the study result type properly (e.g. when indicating “experimental study”, make sure the value is not taken from a secondary source like a handbook).
- Fill one endpoint study record per constituent for multi-constituent and UVCB substances.
- When adapting the standard testing regime and replacing the experimental value by a prediction from alternative methods, provide information about each prediction in its own endpoint study record.

ECHA found inadequacies in the above areas during the course of targeted compliance checks on the octanol–water partition coefficient, which is a key parameter predicting environmental fate and basic toxicokinetic behaviour of substances. Additionally, for this particular endpoint, two more recommendations apply:

- For complex mixtures, in HPLC, a range of values should be presented with an indication of the proportion of each substance within a given range to allow the significance of these results to be reflected in the risk assessment (i.e. if various peaks are obtained they all should be integrated to have info about both the partition coefficient and the percentage of each peak).
- When the substance decomposes upon contact with water, information for relevant degradation products may be needed for the risk assessment (e.g. PBT and CSA).

3.4.2 Human health

In reporting the studies covering human health endpoints, ECHA recommends the following points to consider:

- Justification for adaptations to the standard testing regime needs to be sufficiently documented.

40 http://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf

- Read-across and weight of evidence: The dossier needs to contain a comprehensive scientific justification and documentation of the underlying evidence. Where reference is made to one or more studies with structurally related compounds these studies need to be described with sufficient detail and specifically the robust study summary of the key studies must be included in the IUCLID file.

- Reference to other assessments, such as risk assessments under the Existing Substances Regulation, monographs of the International Agency for Research on Cancer, and assessments under other regulatory frameworks (e.g. Plant Protection Products Regulation): A simple reference, (e.g. web link) is not sufficient: (robust) study summaries of the relevant studies need to be included in the IUCLID dossier; the assessment report should be attached to section 13 of the IUCLID dossier, especially when it is not publically available.

- Physicochemical properties: Where physicochemical properties are given as reason that a test cannot be conducted this argumentation must be supported by reliable evidence in form of a robust study summary and corresponding classification and labelling for the respective property, if warranted.

- Comet assay: There is at the moment no adopted OECD test guideline available. An OECD expert group is currently working on the drafting of a test guideline for the in vivo Comet assay with a target date for adoption in 2014. The in vivo Comet assay is mentioned in the REACH guidance document (R7a) as one of three recommended in vivo assays to follow-up on positive results observed in in vitro genotoxicity studies. On a case by case basis, the in vitro comet assay may, together with data from other sources, contribute to the weight of evidence determination 0f information on mutagenicity. In case the in vivo Comet assay is used or proposed by the registrant to cover an information requirement, the followed or suggested test protocol must be described in detail and be in accordance with current scientific best practice, so that ECHA can evaluate the acceptability of the generated data.

3.4.3 Environment

3.4.3.1 General recommendations

In reporting the studies covering environmental endpoints, ECHA recommends the following points to consider:

- Highly insoluble substances:

  - Possible to adapt information requirements for toxicity to the aquatic environment only if indications are available that aquatic toxicity is unlikely – justification on why aquatic toxicity is unlikely need to be well developed and backed up by facts;

  - The water solubility study needs to be present in a separate endpoint study record as robust study summary to confirm the lack of concern regarding aquatic toxicity;

  - If releasing components or elements – justification shall include comparison of (potential) solubilised levels and toxicity;

  - A transformation/dissolution study may be needed for inorganic chemicals; all relevant components/ elements should be measured.

- Poorly water-soluble substances:

  - The long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water-soluble.

- Substances that are unlikely to cross biological membranes:

  - When using this argument for adapting information requirements, the justification needs to be well developed and backed up by facts.

- Rapidly hydrolysing substances:

  - The environmental relevance of the hydrolysis kinetics to be considered when deciding what to test: substance and/or degradation products (see OECD Guidelines for the Testing of Chemicals No. 23[41]);

  - Degradation products to be assessed for their concern/risk.

- Substances reacting with water and other substances for which aquatic testing is not technically feasible:

  - Degradation products to be assessed for their concern/risk;

  - RMMs or testing on relevant degradation products should be considered.

- The OECD test protocols 204 “Fish, Acute Toxicity Test” and 202 “Daphnia sp. Acute Immobilisation Test” are not covering long-term aquatic endpoints.

- QSAR results need to be documented properly and used as weight-of-evidence rather than standing alone, especially when using the result for the calculation of predicted no effect concentrations for different environmental compartments.

- The hazard data on aquatic toxicity in the dossier need to match with the environmental classification

- Biodegradability:

  - Adaptation of microbial inoculum means that inoculum is in contact with the tested substance before initiating the biodegradation test e.g. aeration and washing with mineral media does not fulfil the criteria for inoculum adaptation;

  - If a substance is disintegrating rapidly upon contact with water, the further (bio)-degradation of the hydrolysis products need to be demonstrated.

3.4.3.2 Testing strategies for long term toxicity

When the registrant concludes that he needs to generate information on long term toxicity for the environment, he should consider the following:

Annex IX requires information on long-term toxicity to aquatic invertebrates, normally Daphnia, and fish. If information on these requirements is missing, the registrant has to propose testing for both endpoints. As the REACH Guidance (Chapter R.7.8) indicates stepwise testing, ECHA expects registrants to follow that approach and offer a testing plan as part of their proposal.

Long-term toxicity testing on fish might not be necessary, if information on long-term effects on algae and aquatic invertebrates (e.g. Daphnia) is available and there is information available demonstrating that fish are equally as or less sensitive as aquatic invertebrates. In such cases, normally an aquatic PNEC can be derived from the long-term Daphnia study with an assessment factor of 50. If the resulting RCR values are less than one (< 1) and there are no other indications that a long-term fish test is required, it is normally not necessary to perform a long-term fish study.

41 http://masetto.sourceoecd.org/vl=22536361/cl=11/nw=1/rpsv/ij/oecdjournals/1607310x/v1n5/s21/p1

Similarly, certain terrestrial studies do not need to be conducted if a number of physicochemical, fate, toxicity, and RCR conditions are met.

For further information, see ECHA Guidance R.7.8[42].

3.5 CLASSIFY ACCORDING TO THE CLP REGULATION

All substances must receive classifications following the criteria provided in Annex I to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). REACH Article 10(a) (iv) and Section 4 of Annex VI require registrants to provide the classification and labelling of the substance resulting from the application of Title I and II of Regulation (EC) No 1272/2008. Therefore, the classification and labelling in accordance with the CLP Regulation and the underlying information related to the respective hazards must appear in the registration dossier. This applies from 1 December 2010 for all registrations. For registrations submitted prior to 5 May 2011, the transitional measures ended on 30 November 2012. The Commission adapts the regulation to technical progress when indicated. ECHA advises registrants to refer from now on to the second adaptation to technical progress (2nd ATP), which came into force on 1 December 2012.

3.5.1 Harmonised classification

A registered substance subject to harmonised classification according to the CLP Regulation carries this classification and must receive the respective label. If the registrant has information on hazard classes or differentiations not addressed by the harmonised classification, the registrant needs to classify the substance for those hazard classes and differentiations (Article 4(3) of the CLP Regulation).
When registrants have information leading to a different hazard class than provided by the harmonised classification and labelling, they need to send a proposal according to Article 37 of the CLP Regulation to the competent authority of the Member State where their business is located or they place the substance on the market.

3.5.2 Physical hazards

The CLP Regulation and its 2nd ATP prescribe the methods to use for the hazard assessment of physicochemical properties. For a given endpoint, these methods may not be EU methods but United Nations' methods. In such cases, the EU methods do not necessarily apply when considering data requirements under REACH. For more information, see the update of the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7A[43].

3.5.3 Environmental hazards

The 2nd ATP of the CLP (Commission Regulation (EU) No 286/2011) included a revision of the criteria for the environmental classification based on the results of long-term studies (chronic toxicity) and a new hazard class for substances and mixtures hazardous to the ozone layer, which are mandatory since 1 December 2012. The implementation of the revised environmental classification criteria also allows the possibility to set a separate M-factor for substances classified as Chronic 1 where the classification relies on chronic toxicity data.

The main difference regarding the previous system is that registrants must consider and apply the criteria for both acute and long-term hazards independently. Thus, based on the available information (acute and/or chronic toxicity studies), a substance may require classification for both, Aquatic Acute Hazards and Aquatic

42 http://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf
43 http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

Long-term Hazards. For example, in terms of the classification, it is not sufficient to classify the substance as category Chronic 1, H410; substances may also require a classification as category Acute 1, H400. For labelling purposes H410 is sufficient, but not for classification. Similarly, registrants shall set M-factor(s) for both acute and long-term hazards separately, where appropriate, and report both M-factors, even when both values coincide.

3.5.4 Human health hazards

The 2nd ATP of CLP also includes new criteria for the human health classification. The main change is the addition of sub-categories for respiratory and skin sensitisation. The sub-categorisation bases on occurrence in humans and/or potency in animal studies. A sub-categorisation is not necessary, when data are insufficient to support a sub-category.

3.6 ASSESS THE CHEMICAL SAFETY

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 to carry out exposure assessment and subsequent risk characterisation 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;

b) the substance is assessed to be persistent, bio accumulative, and toxic (PBT) or very persistent and very bio accumulative (vPvB).

3.6.1 Use description

Registrants are required to provide a brief general description of the identified uses in section 3.5 of their technical dossier. This description should cover all uses of the substances during its life cycle.
When exposure assessment is required, the short titles of the exposure scenarios are to be consistent with the use description in section 3.5 of the technical dossier and with section 1.2 (and the exposure scenario annex) of the extended safety data sheet.

When a registrant intends to benefit from the reduced information requirements for intermediates registered under article 17 or 18, the use description in the technical dossier must be consistent with the intermediate status of the substance and strictly controlled conditions of using intermediates.
In 2012, ECHA has undertaken a more systematic IT-screening of the approximately 5 500 registrations for intermediates. The analysis of the reported uses in these dossiers revealed that 2 388 dossiers included uses that do not, or are very unlikely to, fulfil the definition of intermediates and/or are used under strictly controlled conditions. These dossiers with deficiencies and a potential for incompliance represent 760 substances.

The Agency has sent letters to 574 registrants with potentially non-compliant intermediate registrations, asking them to carefully review the reported uses and update their registration dossiers within three months. ECHA has also added to this letter practical advice for registrants on how to better report intermediates in IUCLID 5.4 or how to update the registration to a full Article 10 Registration.

In order to support future reporting of uses in a harmonised, easy to understand life cycle structure, ECHA has updated section 3.5 of IUCLID. ECHA invites registrants to follow the logic of the updated IUCLID

templates in their use description. The information on the manufacture, formulation, end-uses (by workers and consumers) and service life can be reported in six different tables, representing the life cycle of a substance:

- Processes/activities at manufacture of the substance;
- processes/activities at formulation (producing mixtures from substance as such or substance in a mixture);
- processes/activities with the substance as such or in mixture at industrial sites other than manufacture and formulation;
- process/activities by professional workers using the substance as such or in a mixture;
- uses of chemical products (substances as such or in mixtures) by consumers;
- article service life: activities or processes with articles containing the substance (as the result of the use of the substance by workers or consumers).

In the updated IUCLID templates, the use descriptor lists are available in drop down lists, and only those descriptors that are applicable at a certain life cycle stage are available. ECHA expects this functionality to reduce inconsistencies in use reporting.

It is important to keep in mind that the life-cycle of a substance ends if the substance has been transformed into another manufactured substance (intermediates) or into any reaction product that is not a manufactured substance (substance reacting on end-use). Uses of such reaction products are not to be reported under section 3.5 of the technical dossier for the registered substance.

When describing the uses registrants may wish to consider the following advice in order to improve consistency and comprehensibility:

- Registrants should provide intuitive use names (desirably in terminology harmonised at level of downstream sectors) and provide a short explanation on the process/activities covered. Registrants should not rely on standard use descriptors only as they are too generic to make sufficiently transparent (to authorities and customers) what a use is about.
- Registrants should describe all actual relevant uses. An attempt to describe all possible uses (regardless of any practical relevance) will not contribute to the quality of the use description. It may even create significant inconsistencies in the registration dossier and confusion in the extended safety data sheets communicated to customers.
- Member registrants should make sure that the use description in their technical dossier actually covers what they want to register. Copying the use description from other registrants or the generic CSR for a substance may for example lead to significant inconsistencies for companies intending to register the substance as an intermediate under Article 17 or 18. For example, consumer uses, uses by professional workers and substances in article service life are incompatible with the intermediate status of a substance.
- Registrants should choose the right level of differentiation among uses to reflect significant differences in the conditions between uses and to enable targeted communication of safety information to certain user groups. A too low level of differentiation may lead to complex, over conservative and difficult to understand exposure scenarios. A too high level of differentiation (too many uses identified) may lead to repetition/

duplication of the same generic exposure scenario information and hence to difficulties for the readers in identifying the really relevant information.

ECHA would like to make registrants aware that further REACH processes exploit the use descriptions in the registrations dossiers as input information when selecting dossiers and substances for evaluation and selecting substances for potential further regulatory actions such as the prioritisation of substances from the Candidate List to the Authorisation List (Annex XIV). Thus, registrants may wish to describe their uses as accurate as possible.

3.6.2 Qualitative risk characterisation

When a DNEL cannot be established, but hazards are identified, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario must be carried out (REACH Annex I, section 6.5).

A qualitative assessment differs from a quantitative assessment in that the risk cannot be characterised in the form of an RCR. Therefore, the registrant should provide solid and consistent arguments to support the conclusion that the operational conditions and risk management measures described in the exposure scenario are sufficient to avoid the likelihood of adverse health effects.

If a derived minimal effect level has been derived, the registrant should undertake a semi-quantitative risk characterisation. Control of risk is demonstrated if the risk characterisation ratio (RCR) is below 1 and additional arguments are provided that the control measures described in the exposure scenarios are suitable to minimise exposure.

ECHA published a practical guide advising registrants on how to undertake a qualitative risk characterisation on its website[44].

44 http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf

Concluding remarks

Previous annual evaluation reports already described a number of shortcomings and gave advice on how to avoid those. We advise the registrant to visit the evaluation web page[45] and consult the previous evaluation reports for more information. More information and advice will arrive during 2013 from a large number of compliance checks and from conclusions drawn on read-across and category approaches encountered during testing proposal examinations.

45 http://echa.europa.eu/regulations/reach/evaluation

References

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