Evaluation under REACH

Progress Report
2010

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ABBREVIATIONS

CAS	Chemical abstracts service
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
EC	European Commission
ECHA	European Chemicals Agency
ECVAM	European Centre for the Validation of Alternative Methods
EINECS	European Inventory of Existing Commercial Chemical Substances
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, bioaccumulative, toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
QOBL	Quality observation letter
RCR	Risk characterisation ratio
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
SAR	Structure activity relationship
SMILES	Simplified molecular input line entry specification
TCC	Technical completeness check
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
vPvB	Very persistent, very bioaccumulative

EXECUTIVE SUMMARY

Evaluation is the E in REACH. It is a fundamental part of the EU legislative framework that ensures the protection of human health and the environment from the potentially harmful effects of chemicals.

The safe use of substances starts under REACH with high quality registration dossiers and those dossiers are industry's responsibility – not ECHA's. Through the process of evaluation, ECHA is empowered to request additional information or order tests when essential data is missing. In addition, ECHA is providing recommendations for registrants to improve the quality of dossiers. This process is key in achieving the ultimate aims of REACH – a safer future for us all and a more competitive industry.

The REACH Regulation is relatively new and both ECHA and individual companies are learning to apply it for the first time. This early experience of evaluation is therefore valuable for all of us as the next registration deadline is already looming. The report gives a sense of ECHA's experience of evaluation and, crucially, feedback on the quality of the initial dossiers registered and evaluated. It also makes recommendations for registrants on how to improve their dossiers and help ensure a successful registration.

As registrants have a legal obligation to keep their dossiers up to date, they are encouraged to take a pro-active approach and update already registered dossiers taking into account the recommendations provided in this report – this will save everyone's time and money.

Three types of evaluation

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

1. The **compliance check** determines whether or not the information submitted is in compliance with the law. At least 5 % of the dossiers received by ECHA per tonnage band are compliance checked.
2. Examination of **testing proposals.** All dossiers containing proposals for higher-tier testing, including testing on animals are evaluated. The aim is to check that tests are justified and adequate, and thereby avoid unnecessary animal testing.
3. **Substance evaluation** checks whether the (collective) use of a substance may cause a serious risk to human health or the environment.

Dossier evaluation combines the first two types and is done by ECHA, whereas Member State Competent Authorities do substance evaluation. The decision-making process is broadly the same.

Statistics

In 2010, ECHA completed 70 compliance checks; another 21 were in the decision-making phase at year end; and the evaluation of 60 dossiers continued into 2011. Of the 70 completed dossiers, 12 resulted in an ECHA decision asking the registrant to provide further information; in 33 cases, data was not missing but recommendations were given for the registrants on how to improve their dossier quality; and in 25 cases, no action was needed.

ECHA screened 303 dossiers for on-site and transported intermediates to check if the registrations fulfilled the requirements to be considered as intermediates, or whether they should have been a normal registration. Eleven dossiers for transported isolated intermediates were compliance checked and in all cases, letters were sent to the registrants requesting further information.

ECHA started the examination of 123 testing proposals, adopted four final decisions and issued another eleven draft decisions. In three of the final decisions, the tests were requested as proposed by the registrant while in one decision the tests proposed by the registrant were modified.

Substance evaluation will formally start in 2012 and the criteria for prioritising substances for the Community Rolling Action Plan (CoRAP) and the timelines and processes leading to the first CoRAP have been agreed upon.

Quality

Many of the dossiers evaluated had at least some quality problems – whether they were selected at random or based on some specific concern. Of course these dossiers were the very first to be submitted and they represent only the tip of the iceberg in terms of numbers. It would therefore be unwise to imagine that they will be representative of dossiers received by the first registration deadline of 30 November 2010. However, industry can learn from their shortcomings to improve quality of the already submitted and the new dossiers in preparation. The most significant recommendations made in Chapter 3 are:

- The identity of the registered substance needs to be clearly described;
- Any adaptation to the standard testing regime must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X of the REACH Regulation; and a clear justification for any adaptation must be provided;
- The robust study summaries should contain enough detail to allow an independent assessment of the information provided;
- Classification and labelling should be in line with the hazards identified or with the harmonized classification and labelling of the substance;
- A proposal to do testing must be submitted first (for tests under Annex IX and X) before the test is done. Doing a test before getting ECHA's decision may lead to legal action;
- Registrants have an obligation to share data resulting from animal tests and to share the costs before submitting the dossier.

1 INTRODUCTION

1.1 Background and purpose of the report

The REACH Regulation[1] aims to improve the protection of human health and environment. In this context companies manufacturing or importing chemical substances are obliged to ensure that they can be used safely. This is achieved by generating information on the properties of the substances and on their identified uses, assessing the risks and developing and recommending appropriate risk management measures. The REACH Regulation requires EU companies to document such information in registration dossiers for chemical substances manufactured or imported in quantities of one tonne or more per year.

The evaluation of the registration dossiers verifies whether the information submitted by registrants is in compliance with the legal requirements and that the registrants generate new information when necessary, while avoiding unnecessary vertebrate animal testing. Substance evaluation aims at verifying, through a decision requesting further information from the registrant, whether a substance constitutes a risk to human health or the environment.

The Agency publishes a report on evaluation, as required by Article 54 of the REACH Regulation, by the end of February each year. This report describes the progress made in evaluating registration dossiers and in substance evaluation and makes recommendations to improve the quality of future registrations.

1.2 Information requirements for the registration of substances

REACH requires registrants to provide information on the intrinsic properties of a substance in the form of a registration dossier. The information required on intrinsic properties for each substance is dependant on the tonnage manufactured or imported[2]; the higher the tonnage, the more information needs to be submitted. For substances manufactured or imported in quantities of 10 tonnes per annum (tonnes p.a.) or above, the registration dossier must include a chemical safety report. For dangerous substances, i.e. substances which are classified or substances considered as persistent, bioaccumulative and toxic (PBT-substances), an exposure assessment must be included in the chemical safety report. The registrant has the responsibility to ensure that the identified uses are safe. All information must be submitted to the Agency in electronic format.

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

Where there is insufficient information on the intrinsic properties to meet REACH requirements, the registrant must generate new information[3] or, for tests at higher tonnage levels (100 tonnes p.a. or above), prepare a testing proposal[4]. The new information may be generated by using standard or alternative methods. The registrant may adapt the standard information requirements by using (Quantitative) Structure Activity Relationship ((Q)SAR) models, a weight-of-evidence approach, substance-grouping approaches (read-across) or *in vitro* methodology. REACH requires the use of alternative methods for generating

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

2 The tonnage ranges for data requirements (in tonnes per annum, tonnes p.a.): ≥ 1 – 10 tonnes p.a., ≥ 10 – 100 tonnes p.a., ≥ 100 – 1000 tonnes p.a. and ≥ 1000 tonnes p.a.

3 For endpoints mentioned in Annexes VII-VIII of the REACH Regulation

4 For endpoints mentioned in Annexes IX – X of the REACH Regulation

information wherever possible, in order to avoid unnecessary animal testing. However, any adaptation to the standard information requirements shall be dully justified.

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

1.3 Evaluation processes under the REACH Regulation

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

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

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

- In a **compliance check** ECHA can either evaluate the quality of the information in the whole dossier including the chemical safety report or can target the evaluation to a certain part of the dossier e.g. to the human health information or specific parts of the chemical safety report.
- In the **examination of testing proposals** ECHA evaluates all submitted testing proposals with the aim of checking that adequate and reliable data is produced and to avoid unnecessary vertebrate animal testing.
- **Substance evaluation** is launched when there is concern that a substance constitutes a risk to human health or the environment. The Member States carry out the scientific assessment required for substance evaluation.

All evaluation decisions include consultation with the registrant and the Member States. The consultation ensures that a decision for requesting further information is made only after a thorough consideration of all the available information including the opinion of the registrant and consensus being reached among the Member States.

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

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

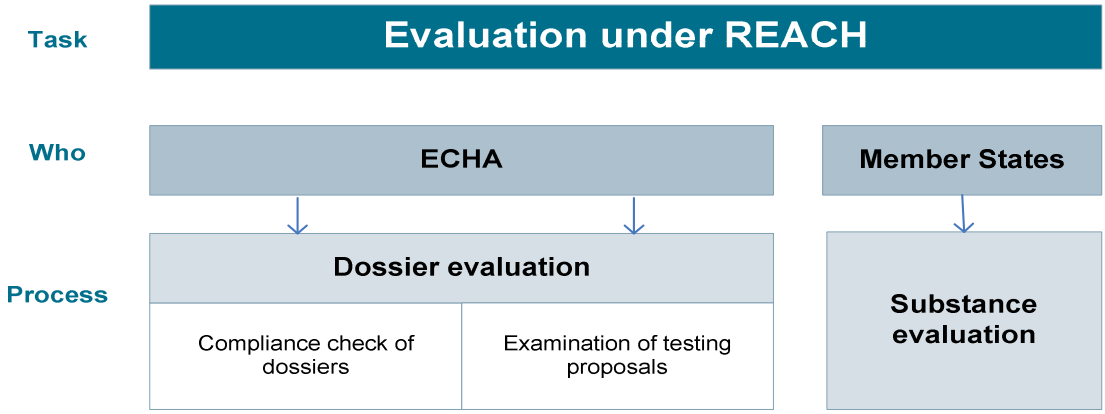

Figure 1: Evaluation processes under the REACH Regulation

1.3.1. Compliance check

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

The outcome of a compliance check may be:

- **No further action** is necessary since the information provided in the registration dossier is considered sufficient to fulfil the REACH requirements.
- A **quality observation letter** (QOBL) is sent to the registrant: when evaluating the dossiers the Agency may identify shortcomings which are not necessarily related to the lack of information. For example, the risk management measures proposed by the registrant may be inadequate if the proposed classification and labelling does not reflect the reported study results. In such cases, the Agency informs the registrant through a quality observation letter and asks for a revision of the dossier and submission of an updated version. Furthermore, it informs the Member States which may take action if the registrant does not clarify the issue.
- A **draft decision** is sent to the registrant when the Agency identifies that information required by REACH is missing. The draft decision lays down the missing data that is requested to be generated and submitted by a certain date. The decision-making process as described by the REACH Regulation is followed resulting in a legally binding decision.

1.3.2. Examination of testing proposals

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

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

published by ECHA on its website and third parties are invited to provide scientifically valid information and studies. When examining the testing proposal the grounds for conducting the proposed test are assessed, taking into account the dossier information and all relevant scientifically valid information received from third parties during public consultation. ECHA evaluates all testing proposals and information submitted by third parties within set deadlines[5]. The outcome is always a decision which may contain the acceptance or rejection of the testing proposal or it may define modified conditions for the test or suggest additional tests to be performed.

1.3.3. Decision-making process

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

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

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

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

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

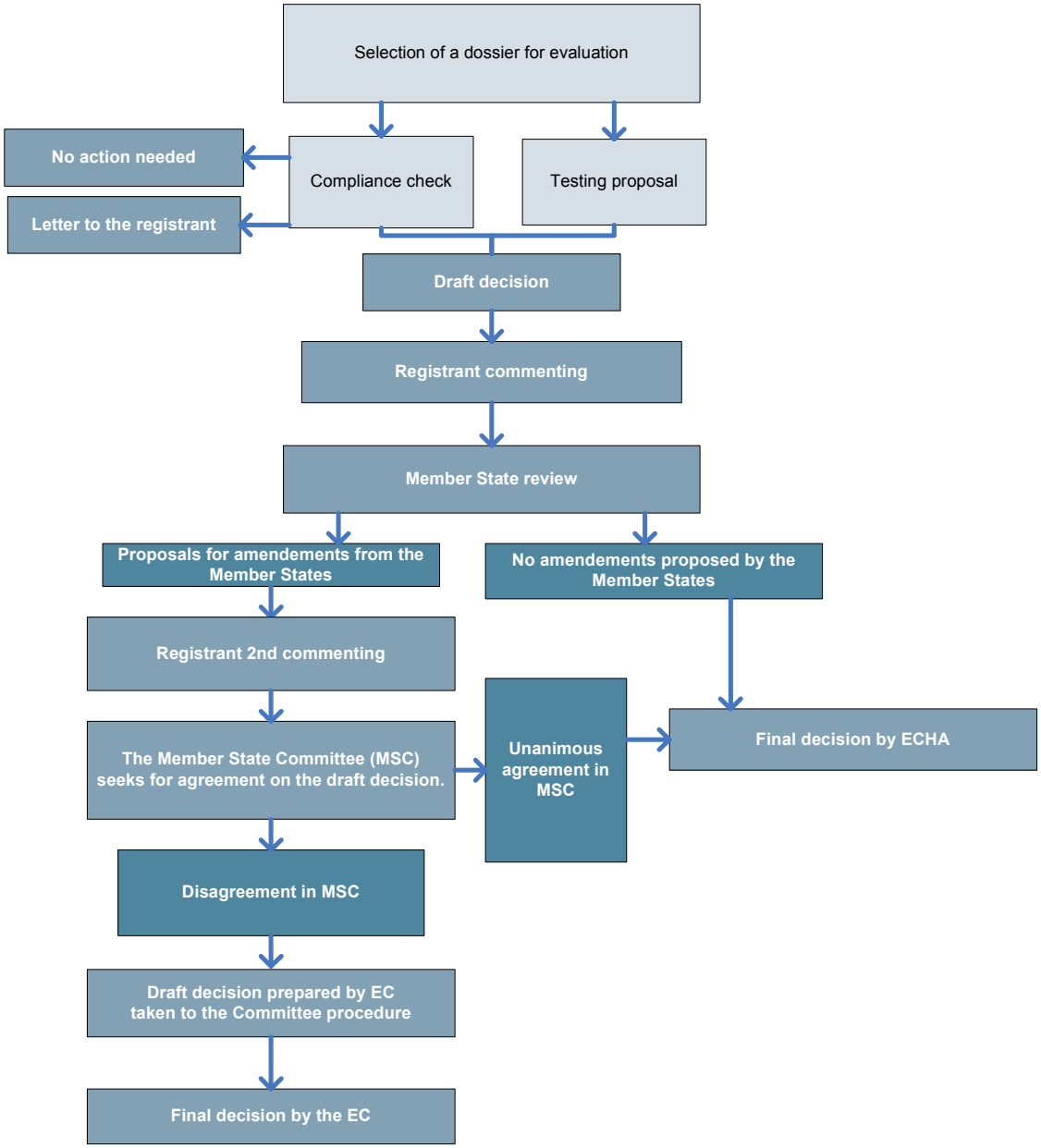

Figure 2: Dossier evaluation process; major steps; MSC = Member State Committee; EC = European Commission

1.3.4. Substance evaluation

Substance evaluation aims at verifying, through a decision requesting further information from the registrant, whether a substance constitutes a risk to human health or the environment. Substance evaluation is not limited to the assessment of the information contained in a single dossier but it may also take into account information from other sources. Another specific feature of this process is that information beyond the standard REACH information requirements can be requested. Thus, decisions regarding the type of information necessary to clarify the concern and whether there are any alternative methods suitable for deriving that information are taken on a case by case basis.

The following procedure applies for substance evaluation: if there are grounds for considering that a substance constitutes a risk to human health or the environment, the

substance is first placed on a list of substances to be evaluated, the Community Rolling Action Plan (CoRAP). The Agency will submit the first proposal for the CoRAP to the Member States by 1 December 2011. The Agency will then adopt the final CoRAP on the basis of opinion of the Member State Committee in early 2012. The plan will be updated annually (by the end of February).

CoRAP will also identify the Member State who will carry out the evaluation. Within twelve months of the start of the evaluation, the designated Member State may submit a draft decision to the Agency, which administrates the decision making. The process for decision making is analogous to the process used for compliance checks and examinations of testing proposals.

Once the registrant has provided the requested information, the relevant Member State examines it and informs the Agency of any conclusions reached. Based on the outcome of substance evaluation, the Member States may decide to impose national actions or initiate the adoption of EU-wide risk management measures (e.g. occupational exposure limits, EU-wide restriction, EU-harmonised classification and labelling).

2 PROGRESS IN 2010

2.1 Compliance check of registrations

2.1.1. Registrations made

By the end of 2010, over 21,600 registrations had been made under REACH. A break-down of registrations per tonnage band and status is presented in Table 1 below.

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

- The total number of registration dossiers represents the number of successful registrations by 31 December 2010, i.e. a registration number has been issued.
- The number of completed registrations differs from the number of submissions; this is because after submission, the dossiers undergo various checks at which point they may fail (see chapter 1.3).
- The total number of registrations reported below does not include the dossiers for on-site isolated intermediates since they are not subject to evaluation processes.
- The numbers reported do not include the dossier updates, i.e. each registration number is counted only once: if a dossier has been updated (e.g. tonnage upgrade or spontaneous update) only the latest submission is considered.
- The numbers in Table 1 include the dossiers containing testing proposals.

Table 1: Number of complete registration dossiers by the end of 2010

Tonnage per year	Registrations (non-intermediates)		Transported intermediates		TOTAL
	Phase-in[6]	Non-phase-in[7]	Phase-in	Non-phase-in	
1 - 10	765	528	775	460	4 844
10 - 100	751	137			
100 - 1000	1 351	77			
> 1000	14 592	55	2 158	13	16 818
TOTAL by status (phase-in/ non phase-in)	**17 459**	**797**	**2 933**	**473**	**21 662**

2.1.2. Compliance check of standard registrations

In 2010, the Agency examined under compliance check 151 dossiers: 135 of these checks were initiated in 2010 and 16 were carried over from 2009. Table 2 presents the number of dossiers undergoing compliance check in 2010. An overview of compliance checks

[6] Phase-in substances = substances subject to transitional arrangements in REACH

[7] Non phase-in substances = new substance to the EU-market

undertaken by the Agency since the beginning of evaluation processes is presented in Attachment 1.

Table 2: Compliance checks undertaken in 2010

	Phase-in	Non phase-in
No of compliance checks initiated in 2010	**39**	**96**
No of compliance checks carried over from 2009	**16**	
Total number of dossiers examined under compliance check in 2010	**151**	

By the end of 2010, 70 compliance checks were completed; another 21 were in the decision making phase and the evaluation of the further 60 dossiers continues in 2011. The outcome of the compliance checks in 2010 is presented in Figure 3.

Out of the 70 completed dossiers, 12 dossiers were concluded with a final decision requesting the registrant to provide further information; in 33 cases, quality observation letters were sent in order to allow the registrant to improve the dossier but not constituting a formal decision; another 25 dossiers were concluded with no further action.

Besides the 12 final decisions, the Agency originally issued another 22 draft decisions in 2010. One of these was withdrawn during the decision making phase due to further information provided by the registrant. The other 21 draft decisions are in the decision making phase and will be concluded in 2011.

For all compliance checks completed in 2010, all legal deadlines were respected (e.g. the possible draft decision was issued within 12 months from the start of the compliance check).

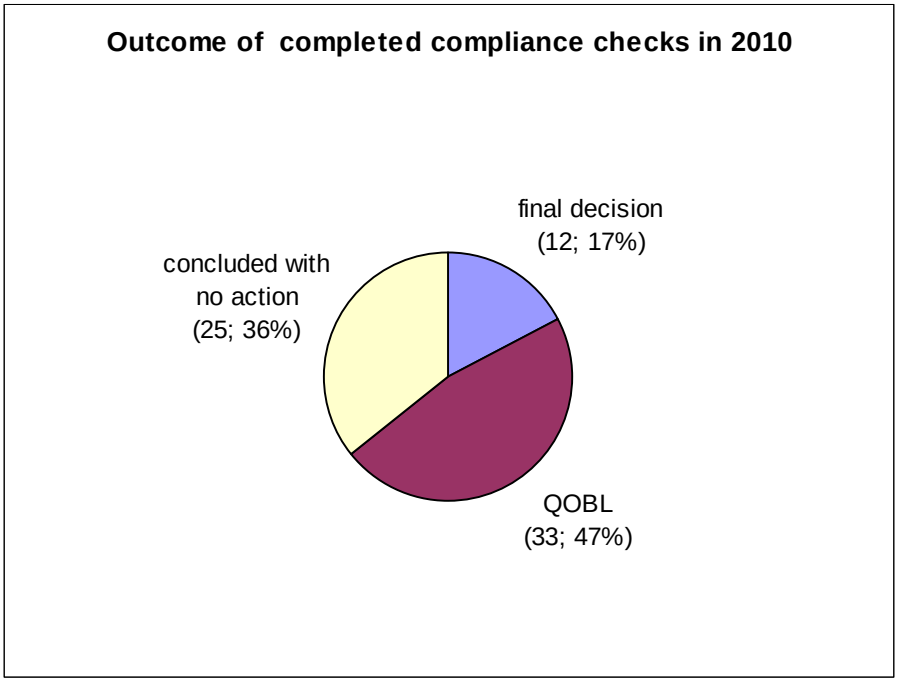

Figure 3: Outcome of compliance checks in 2010; QOBL= quality observation letter

The 12 final decisions were adopted as follows:

- Eight draft decisions were adopted as final decisions with no involvement of the MSC since there were no proposals for amendments received from the Member State Competent Authorities (MSCAs).
- Four decisions received proposals for amendments by at least one MSCA. These proposals for amendments were discussed in the MSC meetings. The Committee reached unanimous agreement on all four draft decisions and ECHA adopted the final decisions accordingly.

No draft decisions have been referred to the Commission so far. Also, none of the final decisions has resulted so far in an appeal.

The information requested by final decision from the registrants is summarized in Table 3.

Table 3: Information requested by the final decisions on compliance check

Type of information requested	No of decisions[8]
Information regarding identification and verification of the composition of the substance (REACH, Annex VI, 2.)	5
Flammability (REACH, Annex VII, 7.10.)	1
Self-ignition temperature (REACH Annex VII, 7.12)	1
Granulometry (REACH Annex VII, 7.14.)	1
Dissociation constant (REACH Annex IX, 7.1.6)	1
Screening for adsorption/desorption (REACH Annex VIII, 9.3.1)	1
Growth inhibition study aquatic plants (REACH Annex VII, 9.1.2)	1
In vitro gene mutation study in mammalian cells (REACH Annex VIII, 8.4.3)	1
Screening for reproductive/developmental toxicity (REACH Annex VIII, 8.7.1)	3
DNELs as part of the human health hazard assessment (REACH Annex I, 1.4.1)	1
PNECs as part of the environmental hazard assessment (REACH Annex I, 3.3.1)	1
Exposure assessment and risk characterisation for the use of the substance in preparations (REACH, Annex I)	1
Full justification for adapting the standard testing regime for the two-generation reproductive toxicity study (REACH Annex X, 8.7.3) in accordance with Annex XI, 1.5, i.e. read-across	1
Improved robust study summaries (Annex 1, 1.1.4 and 3.1.5)	4

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

As explained in chapter 1.3.1, in some cases the Agency invites registrants, through quality observation letters, to revise their registration dossiers and address shortcomings not related to formal data gaps. The types of inconsistencies addressed through quality observation letters are summarised in Table 4.

Table 4: Type of shortcomings addressed through quality observation letters

Shortcomings/inconsistencies addressed through QOBLs	Number of QOBLs [9]
Substance identity	6
CSR related e.g. PNEC or DNEL derivation, exposure assessment, missing description of the waste stage	8
Classification and labelling	18
Guidance on safe use, e.g. sufficient advice on the prevention of exposure	6
Purity of test material	1
Insufficient level of detail/inconsistencies in robust study summaries	5
Identified uses, strictly controlled conditions, status as intermediate	11
Data sharing	3
Inconsistent information regarding tonnage band	2

2.1.3. Priority setting for dossier evaluation

The priority setting for compliance check has been described in the Guidance on dossier and substance evaluation and in the Guidance on priority setting for evaluation.

In line with the approaches described in these guidance documents, ECHA is currently applying priority setting for the evaluation of dossiers which includes three sets of criteria:

- criteria set out in the REACH Regulation
- random selection
- concern-driven selection

The weight 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 States Competent Authorities and members of the Member State Committee and other stakeholders.

The random selection allows for gathering a good overall picture of the quality of dossiers and for refining prioritisation criteria on the basis of frequently encountered causes of non compliance. The concern-driven approach aims at prioritising dossiers that are likely to contain shortcomings relevant to the safe use of the substance. The prioritisation of these dossiers should optimise the use of ECHA's resources for compliance check in terms of protection of human health and environment.

[9] In general, QOBLs addressed more than one inconsistency

With regard to the dossiers for which evaluation has been completed in 2010, the random selection applied to about 27% of selected dossiers (16 dossiers), while the remaining 73% (54 dossiers) were selected using concern-driven criteria. An overview of the compliance check outcome of both types of selected dossiers (concern-driven / randomly selected) is presented in Figure 4. The results show that the proportion of dossiers that were closed without any administrative action was similar for both types. The percentage of quality observation letters for the randomly selected dossiers was lower (37.5 %) than that for the concern-driven selection (50%), whereas a higher percentage of decisions (25%) was sent for the randomly selected dossiers than for the concern-driven selection (15%).

Although the outcome of compliance checks completed in 2010 suggests that the quality of the evaluated dossiers may be rather insufficient (17 % were concluded with a final decision and 47 % with a QOBL) it is important to realise that the quality of these (early submitted and selected) dossiers cannot be extrapolated to all dossiers which have been registered by 1 December 2010.

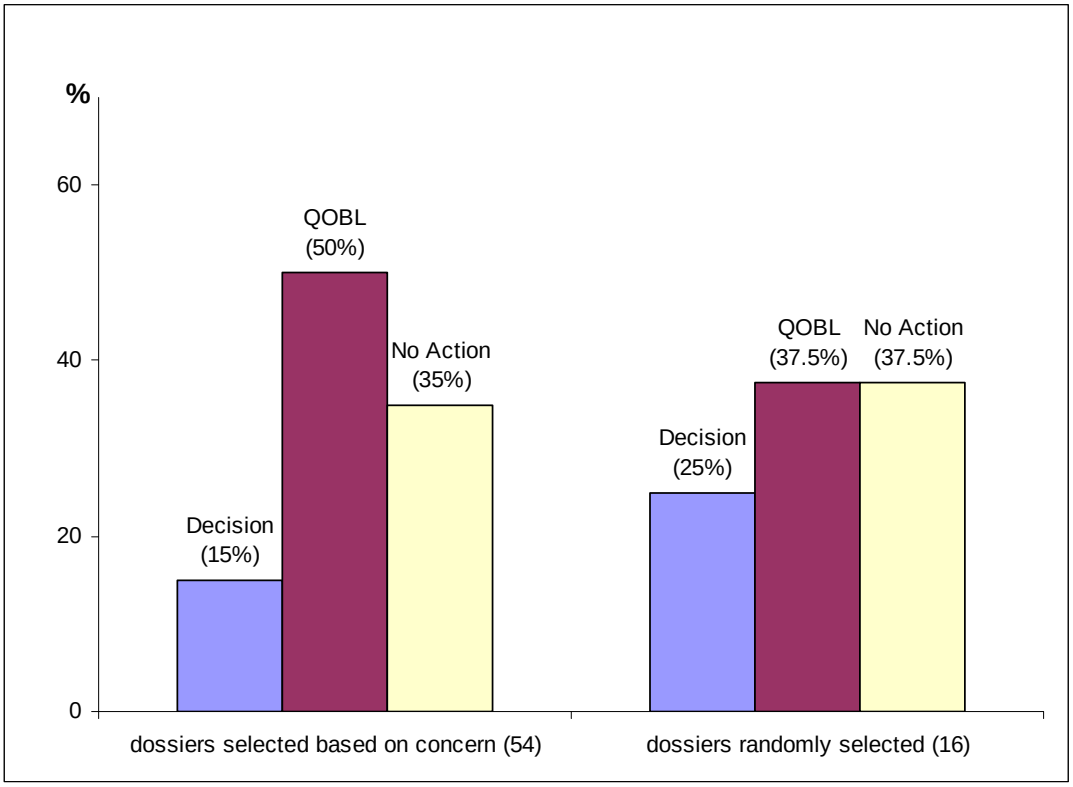

Figure 4:.Quality of dossiers for which compliance check has been completed in 2010

2.1.4. Dossiers for substances notified under Directive 67/548/EEC (unfinished NONS dossiers)

So called new substances are substances which were placed on the European Community market after 18 September 1981 i.e. substances that were not included in the inventory of substances on the Community market (EINECS-list). Similarly to the REACH Regulation, the information requirements were tonnage dependent under the previous legislation for notified substances (Directive 67/548/EEC).

Under the previous legislation the notifiers of substances were obliged to inform the relevant Member State in cases where the volume marketed or imported exceeded a tonnage level of 100 tonnes or 1000 tonnes p.a., respectively. The Member State was then obliged to assess

whether further testing should be required from the notifier. However, in some cases the Member States did not finalise the assessment and did not take a decision before the transitional regime of the REACH Regulation entered into force on 1 August 2008. It was therefore agreed that ECHA would evaluate these unfinished dossiers for notified substances manufactured or imported in volumes above 100 tonnes p.a. The relevant companies were invited to voluntarily propose testing or to update their existing dossiers by 30 November 2009.

ECHA sent 53 letters inviting the notifiers to submit testing proposals. In 19 cases the registrants updated their dossiers; of the 19 updates, four contained testing proposals. Based on the information provided by registrants and the relevant MSCAs it has been concluded that in 27 cases there is no need to open a compliance check according to Article 41 of REACH. Table 5 presents the status of the work on the unfinished dossiers for notified substances by the end of 2010.

Table 5: Status of work on unfinished dossiers for notified substances

Status	Number of dossiers
Letters sent inviting for testing proposals	**53**
Dossier updates received	19
➢ Dossier updates with testing proposals	4
Compliance check not initiated[10]	**27**
Reasoning of not initiating compliance check:	
➢ Manufacture ceased	3
➢ Closed due to intermediate status	6
➢ Other administrative reasons, e.g. verification of tonnage band <100 tonnes p.a.	18
Status of evaluation	
➢ Draft decisions in the decision-making phase (under compliance check or testing proposals)	13
➢ Final decision sent (under testing proposal)	1
➢ Concluded without administrative action	3
➢ Evaluation ongoing	9

2.1.5. Intermediates

REACH defines an intermediate as a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s) (Article 3 (15)). On-site isolated (Article 17) and transported intermediates (Article 18) can benefit from reduced information requirements provided they are used under strictly controlled conditions. On-site isolated intermediates are excluded from the evaluation processes under REACH.

In 2010, ECHA concluded a screening of 303 dossiers for on-site and transported isolated intermediates registered in 2009. The aim of the screening was to check at a very general

[10] Due to receiving a dossier update or pre-assessment made by ECHA in collaboration with MSCAs

level if these registrations fulfil the requirements to be considered as intermediates, or if they include substances requiring a normal registration. As a result of the screening, ECHA initiated compliance checks on eleven dossiers of transported isolated intermediates.

In all eleven cases quality observation letters were sent to the registrants of transported isolated intermediates requesting clarifications. Some examples of shortcomings found in the intermediate dossiers for which clarification was requested were:

- Status as an intermediate could not be verified and more information was needed to do so;
- Data on risk management measures and/or on strictly controlled conditions was missing or controversial.

Due to the fact that the definition and understanding of “strictly controlled conditions” has still been under development and the respective guidance has been updated only recently (December 2010), quality observation letters were sent only for cases that were clearly doubtful concerning their status as intermediate registrations.

ECHA also noted that many registrants of transported intermediates seem not to have met the requirement of Articles 17(2)(d) and 18(2)(d) to provide any available information on physico-chemical, human health or environmental properties. It does not seem plausible that this information does not exist as without basic information on e.g. physicochemical properties such as boiling or melting point it would not be possible to use the chemical in a process.

After receiving (or not receiving) the clarifying answer to the quality observation letter from the registrant by the set target date ECHA evaluates if the information is satisfactory to confirm the use and the strictly controlled conditions as required for intermediates. If the provided information is not adequate to prove intermediate use or no dossier update is received, ECHA can draft a decision and request information according to Article 10.

2.2 Examination of testing proposals

By the end of 2010 there were 574 registration dossiers containing testing proposals. The number may change slightly in the upcoming months, since some dossiers submitted close to the first registration deadline (1 December 2010) were still undergoing technical completeness check.

The 574 dossiers contained in total testing proposals for 1171 endpoints, out of which 709 were for vertebrate testing. Attachments 2 and 3 present an analysis of testing proposals in the registration dossiers received by the end of 2010. The total number of testing proposal endpoints refers to the total number of tests proposed in the registration dossiers, irrespective of tonnage band, relevance or substance. ECHA noted that in some cases, testing proposals have been submitted for the same substance, for the same endpoints, by several registrants. In other cases testing proposals were submitted for endpoints under Annex VII or VIII, for which normally tests results should have been included in the registration dossiers. However, these cases are rather rare and represent less than 5 % of the registration dossiers with testing proposals.

In 2010 the Agency examined 123 dossiers containing testing proposals: seven were carried over from 2009 and another 116 were initiated in 2010. From the total of 123 dossiers with testing proposals under examination, 99 dossiers contain proposals for vertebrate studies which require a consultation of third parties. Such consultation was held for 22 substances; the remaining 87 will be held in 2011. During the examination of testing proposals, it has been identified, in certain cases, that the dossier contained some shortcomings likely to affect the safe use of the substance. Therefore, ECHA decided to further initiate compliance check for 5 dossiers with a testing proposal.

2010

ECHA adopted four final decisions under examination of testing proposals in 2010 and issued another 11 draft decisions. Three draft decisions were withdrawn during the decision-making process due to the following reasons:

- cease of manufacture[11]
- downgrade of tonnage
- withdrawal of the testing proposal by the registrant.

Table 6 presents an overview of examination of testing proposals in 2010. For all examinations the legal deadlines were respected.

Table 6: An overview of the examination of testing proposals in 2010

Substance type	TOTAL	Dossiers with vertebrate studies	Draft decisions[12]	Final decisions	Terminated	Carry over to 2011
Phase-in	96	80	0	0	1	95
Non phase-in	27	19	8	4	2	21
TOTAL	123	99	8	4	3	116

The final decisions were adopted as follows:

- One decision has been adopted with no involvement of the MSC since there were no proposals for amendments from the Member States
- Three decisions were adopted after unanimous agreement in the MSC.

In one final decision, the tests proposed by the registrant have been modified, while in the other three decisions, the tests were requested as proposed by the registrant. No draft decisions were referred to the Commission. Also, none of the decisions has resulted so far in an appeal. Table 7 presents the tests requested through the final decisions.

[11] New registration will be required if manufactured/imported again

[12] Draft decisions which did not become final by 31 December 2010

Table 7: Tests requested in the final decisions

Tests requested under evaluation of testing proposals	Number of decisions[13]
Stability in organic solvents and identity of relevant degradation products (REACH Annex IX, 7.15)	1
Viscosity (REACH Annex IX, 7.17)	1
Sub-chronic toxicity study (90-day) in rats, oral route (REACH Annex IX, 8.6.2)	2
Developmental toxicity test in rats, oral route (REACH Annex IX, 8.7.2)	2
Two-generation reproductive toxicity test in rats, oral route (REACH Annex X, 8.7.3)	1

Response to scientific information submitted by third parties for testing proposals involving animals

REACH requires that new testing of a substance involving vertebrate animals is only carried out as a last resort. To ensure that the best use has been made of existing information ECHA publishes all testing proposals involving vertebrate animals, for endpoints specified in Annexes IX and X under REACH, on ECHA website before taking a decision on the proposal. Once published, third parties have 45 days to submit "scientifically valid information and studies that address the relevant substance and hazard endpoint, relating to the testing proposal" (Article 40 (2) of REACH). All scientific information thus collected is taken into account by ECHA in preparing the final decision.

REACH does not oblige ECHA to respond in detail to the third parties who submitted information. The final decisions on testing proposals contain in the statement of reasons the evaluation conclusions on such third party information. However, these conclusions have been available only to the concerned registrants as addressees of the testing proposal decision.

ECHA has noted the increasing demand for feedback regarding third party information and has recently decided that the response to scientific information submitted by third parties for testing proposals involving animals will be published on the ECHA website. The information will be extracted from the final decision and published regularly as a response to each testing proposal public consultation.

The benefit of this approach is that the input of stakeholders who contributed during the public consultation is recognised and the assessment of the contribution is communicated in a transparent way. It aims to increase the understanding and knowledge of third party stakeholders of the evaluation process, and thus lead to improved contributions over time.

2.3 Follow up of dossier evaluation

Article 42 of the REACH regulation foresees that ECHA shall examine any information submitted as a consequence of a decision taken under Articles 40 or 41. Once the dossier evaluation is completed, ECHA shall notify the Commission and the Competent Authorities of the Member States of the information obtained and any conclusions reached.

[13] In some decisions, more than one test was requested

If deemed appropriate, the information obtained from this evaluation shall be used by the Competent Authorities for the purposes of prioritising the substance for substance evaluation (Article 45(5)), preparing an Annex XV dossier for the identification of substances of very high concern to be included in Annex XIV (Article 59(3)) and preparing of a restriction proposal (Article 69(4)). ECHA will use the information obtained for the purposes of substance evaluation falling within the scope of Article 44 of the REACH Regulation.

As the time set to provide further information has not yet elapsed in many cases it is too early to report on follow-up with detailed characteristics/statistics. First statistics will be presented in the 2011 evaluation progress report.

A second group of decisions requesting follow-up work is represented by the decisions taken by the Member State Competent Authorities requesting notifiers to provide further information according to Directive 67/548/EEC. After the entry into force of REACH, those decisions became ECHA decisions according to Article 135 of the REACH Regulation. The information requested shall be evaluated by Member State Competent Authority or by the Agency depending on the legal basis of the original decision taken by the Competent Authority.

This concerns 255 decisions for which the status is as follows:

- Dossier update received (by 31 December 2010): 58
- Pending decisions: 197
  - deadline forthcoming : 18
  - deadline passed: 145
  - no deadline set**:** 34

Out of the 58 updates received, 31 fall within the scope of dossier evaluation, i.e. the updates are to be examined by ECHA. The underlying decisions have been taken by Member States and are to be regarded pursuant to Article 135(1) of the REACH Regulation as dossier evaluation decisions. 27 updates are to be regarded as substance evaluation decisions under Article 135(2) of the REACH Regulation and are consequently to be examined by MSCAs. More information on the process is provided in the document *'Questions and Answers for the registrants of previously notified substances'*

The registration dossiers for which the deadline to provide the requested data as set out in the respective decisions has passed are considered not to be in compliance with the legal requirements and are subject to enforcement by the national authorities. Currently ECHA is interacting with MSCAs to coordinate its response to registrants. Reminders will be sent to registrants about the pending requests.

2.4 Substance evaluation

The Member States will start the substance evaluation in 2012, after the Community Rolling Action Plan (CoRAP) has been established. The Agency has in 2010 started preparations for this process. The Agency organized a workshop with the Member States in order to agree on the criteria for prioritising substances for evaluation and the timelines and processes leading to the first list (see chapter 2.7).

2.5 IT tools to support priority setting for dossier evaluation

ECHA is currently developing IT applications to enable some automatic analysis of the data being submitted in the context of REACH. IT applications will process the data from REACH-IT, IUCLID and other databases in order to support ECHA priority setting purposes by automatic implementation of priority setting criteria (see 2.1.3).

The application extracts data from these different sources in order to generate, for each dossier or submission, a set of 'characteristics' describing it. Five categories of characteristics are especially relevant for prioritisation. They are related to the following aspects of the dossier:

- Administrative aspects (e.g.: whether joint submission obligations are fulfilled, whether and for which end points opting-out is used)
- Study type and quality indicators (e.g.: number and nature of claimed data adaptations, any study not compliant with good laboratory practice (GLP)
- Substance (hazardous) properties (e.g.: endpoint value falling within or outside a pre-defined range, indicators of potential PBT properties)
- Classification (e.g. substance is labelled as Toxic, Harmful or Dangerous to the Environment)
- Exposure and Uses (e.g.: pre-defined criteria for wide, dispersive uses).

IT tools for priority setting can in this way increase efficiency of evaluation work, assist on decision making by providing indications of different levels of concern (risk or hazard based), promote harmonisation of decisions at international level and avoid replication of assessment work already performed by others.

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

The Member State Committee plays an important role in the decision making process of dossier evaluation. It is responsible, among other things, for seeking unanimous agreement on draft decisions referred by the Agency to the Committee. Each Member State has appointed one member to the Committee. Nominated representatives of stakeholder organisations may be admitted as regular observers to the meeting of the Committee or its working groups upon request of members of the Committee or the Management Board and subject to confidentiality requirements.

In 2010 the MSC rules of procedure were amended in order to allow case-owners and stakeholder observers to attend those parts of the MSC meetings where dossier evaluation cases are discussed. According to the revised rules of procedure, a case-owner, *i.e.* a concerned registrant or a representative of a group of concerned registrants in the case of joint submissions may be admitted as an observer when their specific case is addressed by the Committee. Unless confidentiality rules prevent participation, both nominated representatives of stakeholder organisations and case-owners concerned may, as appropriate, be admitted to the Committee meetings when draft decisions on dossier evaluation are presented and initially discussed by the Committee. However, they would not be allowed to attend the agreement reaching phase of the meetings. This decision aims to balance between the confidentiality required in such cases and the transparency of the decision-making process.

More information can be found at

http://echa.europa.eu/about/organisation/committees/memberstate_en.asp

2.7 Support to registrants

2.7.1. Interaction with the registrants

The REACH Regulation provides the right for registrants to formally comment on a draft decision within a period of 30 days of receipt. Such formal comments have to be provided in a written format within a template provided by ECHA. In this way, registrants are given the right to be heard on the proposed administrative action on the one hand, and, on the other

hand registrants can use this as an option to improve the information submitted and, if possible, to bring the dossier into compliance by submitting an updated dossier already at this stage.

It was observed in the first dossier evaluations, that it would be helpful to registrants if they received scientific and legal background information in order to better understand the information requests in the draft decision and the decision-making process.

Therefore ECHA decided to initiate a new approach and provide registrants with the opportunity to receive additional scientific and legal background information on the draft decisions in the form of an oral discussion. This interaction with the scientific officers of the Agency is meant to provide the registrants with a better understanding of the scientific and legal reasoning of the draft decision and of the principal possibilities to bring the dossier into compliance. By no means does this interaction replacing the formal commenting process for the registrant and the obligation to provide further information via an updated dossier. The scientific officers do not act as advisors to the registrant on any specific case but address the principle options available and which are described in detail in the guidance on information requirements.

The notification letter of the draft decision provides details on the formal commenting period and commenting format for the registrant. In addition, it offers the possibility to informally discuss the scientific rational behind the draft decision. To establish such an exchange the registrant has to contact ECHA within 10 working days of the date of the draft decision and identify the items to be discussed. All interactions are organised within the 30 days of the formal commenting period. The outcome of the discussion should result in a better understanding of ECHA's draft decision. If the discussion reveals that further information or argumentation is available to the registrant but not yet included in the dossier, the registrant may explain the situation in his formal comments and may decide to update the dossier with this further information. In exceptional cases registrants may be allowed a period of up to three months to provide a more complex scientific argumentation for the adaptation of standard information requirements missing in the dossier at the time of evaluation.

In all cases ECHA has to evaluate the newly submitted information with regard to its compliance with the REACH requirements. The outcome may lead to an amended draft decision.

ECHA started the implementation of this interaction in a pilot phase in autumn 2010. So far the interaction has been positively perceived by registrants. ECHA recommends that registrants receiving a draft decision, in case of questions, take advantage of the offer to interact and informally discuss the scientific and legal background of the draft decision with the scientific officers of the Agency.

2.7.2. Webinars

Webinars are interactive information sessions hosted online and consisting of presentations, video and other interactive features such as questions and answers. Webinars are available for up to one thousand participants and can be viewed anywhere with a computer and internet access. ECHA started to organise webinars in 2009 and continued with this activity in 2010. Most of the webinars organised in 2010 dealt with registration issues. Nevertheless, several webinars were relevant for evaluation:

- Substance identity: key concepts, common problems and dossier preparation relevant to substance identity; 25 January 2010
- Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR) Part I: legal requirements and general framework of the CSA, hazard assessment, use description, exposure assessment and risk characterisation as well as a short update on available tools and guidance; 9 March 2010

- Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR) Part II provides information on the aim and conceptual basis of Chesar, an overview of the functionalities of the tool and the release plan; 26 March 2010.

More information can be found at: http://echa.europa.eu/news/webinars_en.asp

2.7.3. Stakeholders' day

In 2010, ECHA held the 4th and 5th Stakeholders day events, on 19 May and 4 October respectively. Over 350 experts from the chemical industry and stakeholders from the EU, Russia, China, Japan, Brazil, India and the United States participated in each event.

In 2010, these events provided for the fist time the opportunity to participants to meet ECHA experts in one-to-one sessions and discuss in detail the problems they were facing. Over 100 participants took advantage of this opportunity in each event and their feedback was highly positive. Scientific experts from ECHA involved in dossier evaluation participated in these events and gave advice on the information requirements to be fulfilled in order for a dossier to be in compliance with REACH requirements.

The new IT tool Chesar for chemical safety assessment and reporting, developed in close collaboration with industry was introduced during the 4th Stakeholders day.

More information can be found at http://echa.europa.eu/news/events_en.asp

2.7.4. Practical guides

Practical Guides aim to provide practical tips and explain the Agency's processes and scientific approaches. Practical Guides are produced by ECHA, under its sole responsibility. They are not formal Guidance (which is established under the formal guidance consultation process involving stakeholders). However, they communicate and explain the Guidance in a practical way providing more operational detail on different issues. Practical Guides are often triggered by ECHA's observations on the needs of stakeholders and represent a channel to communicate these observations and analyses to a wider audience.

In 2010, ECHA issued 10 practical guides. Practical Guides 1-6 and Practical Guide 10 are especially relevant for evaluation since they deal with adaptation to standard information requirements, robust study summaries and avoiding animal testing.

2.8 Interaction with Competent Authorities and other partners

2.8.1. Workshop on Examination of Testing Proposals

On 27-28 April 2010 ECHA hosted a workshop to discuss the practical implementation of the evaluation process of testing proposal examination under REACH. The workshop was attended by representatives from the Competent Authorities of the Member States (MSCA) and the members of the Member State Committee (28 countries were represented, i.e. the 27 Member States and Norway), the Commission (DG Enterprise and Industry and DG Environment) and ECHA.

The goal of the workshop was to promote common understanding about the principles of the examination of testing proposals, including its scope and relation with the compliance check, and the use of non-testing approaches.

2.8.2. Non-test methods workshop

On 23-24 September 2010 ECHA held an experts workshop on dealing with uncertainty related to the application of non-test methods under REACH. The workshop focused on identifying current scientific challenges in the regulatory acceptance of non-test data and particularly on read-across/grouping arguments used in REACH registration process.

The workshop was attended by experts in the field of non-test methods from Member States, the European Commission, industry bodies and non-governmental organisations as well as experts from other EU institutions or other international organisations.

More information can be found at

http://echa.europa.eu/news/events/non_test_methods_workshop_2010_en.asp

2.8.3.Workshop on substance evaluation

On 18-19 October 2010 ECHA organised a workshop with Member States Competent Authorities on Substance Evaluation. The workshop paved the way for the first list of substances to be evaluated, the so-called Community Rolling Action Plan (CoRAP).

The workshop covered four issues: 1) Substance Evaluation and risk management, 2) Development of risk-based criteria to prioritise substances for evaluation, 3) Establishing the Rolling Action Plan and 4) Practical cooperation between ECHA and the Member States Competent Authorities.

The criteria for prioritising substances for the CoRAP were broadly agreed as were the timelines and processes leading to the first list. The list will be updated yearly and will cover a rolling three year period. The first CoRAP will be established in February 2012 and Member States will then complete the evaluations of the first year of the plan within twelve months. The second and third year planning is subject to review.

3 RECOMMENDATIONS TO REGISTRANTS

Dossier evaluation processes undertaken in 2010 reveal that in general registrants fulfil their obligations under REACH regarding information requirements. However, it has been identified that various issues need to be further improved and deserve the attention of all registrants.

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

The most frequent shortcomings observed in registration dossiers referred to unclear substance identity, waiving (omission) of certain tests without a proper justification and insufficient level of detail provided in the robust study summaries. These are detailed together with some other more general issues in the sections below.

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

3.1 Information requirements

3.1.1. Substance identity

A registration under REACH is structured around the identity of the registered substance. Substance identification therefore constitutes an essential element for the purpose of the evaluation processes under REACH and needs to be unambiguous and accurate. Qualitative and quantitative analytical data generated on the substance as manufactured are required in order to confirm this information.

ECHA has made the following observations during dossier evaluation with regard to substance identity:

- For a significant number of dossiers, clear information on the identification of the registered substance was provided. It has been noted that registrants of pre-registered phase-in substances have paid growing attention to this aspect.
- For a number of registrations the information provided was, however, insufficient to establish and verify the identity of the registered substance. The most frequent shortcomings observed were missing spectra, insufficient analytical information and inconsistencies between the composition and the analytical data provided.

The following recommendations are made to the registrants regarding substance identity:

- The information provided needs to be sufficient to allow identification of each substance. It is therefore necessary that each requirement in section 2 of Annex VI is addressed. The information provided shall be specific for the substance. The chemical identifiers specified shall be consistent with each other.
- Qualitative analytical data is necessary to confirm the identity of the substance. A spectral dataset including infra-red, ultra-violet/visible and nuclear magnetic resonance spectra or mass spectra is normally required. It should be noted, however, that these analytical methods are not always appropriate for all substances. For instance for

inorganic substances, the use of X-Ray Diffraction (XRD) or X-Ray Fluorescence (XRF) should also be considered.

- Particular attention should be given when providing information on the quantification of the substance: the information on the concentration of the (main) constituents and impurities shall be supported by comprehensive quantitative analytical data. The analytical data shall be generated on the substance as manufactured on the manufacturing site(s). The information shall be consistent with the composition specified in the registration dossier.
- For UVCB[14] substances, details regarding manufacturing process shall be provided as appropriate, e.g. identity of the starting materials, ratio of reactants, operating parameters (e.g. temperature, pressure), information on the specific constituents/group of constituents present in the substance, (e.g. carbon number, degree of branching per carbon number, presence of tertiary/ quaternary carbons and their relevance).
- When completing their dossiers, registrants are strongly advised to follow the recommendations provided by ECHA during the inquiry process.

Further information can be found in the *Guidance for identification and naming of substances under REACH.*

3.1.2. Performance of tests to meet the standard information requirements

The REACH legislation requires that tests are to be conducted in accordance with recognised test methods (see Article 13(3)). In general, the tests present in the registration dossiers follow this general line. However, a number of shortcomings have been noted with regard to the tests performed, which are presented below:

- The description of the test results in the (robust) study summaries for some human health endpoints did not allow an assessment to me made as to whether the test was performed at the maximum tolerated dose as required by the relevant guideline.
- The purity of test material used to perform some tests was in some cases outside the purity range reported for the registered substance.
- For UVCB substances, in a number of cases, only one of the constituents in the UVCB substances was used to perform the tests; however, no further justification was provided as to why that constituent was the most relevant for undertaking the tests.
- For certain tests (e.g. acute aquatic toxicity), results from preliminary studies, for example screening tests, were considered equivalent to definitive studies; while preliminary screening may be used to identify whether there is a concern, it is not considered appropriate to fulfil the information requirements.
- In some physico-chemical tests, the concentration of the test material used was too high or too low compared to the recommendations of the guidelines(e.g. for tests on surface tension); for dissociation constant sometimes only one value was reported although there are more dissociating groups.

Recommendations with regard to performing tests:

- The description of the test results should be sufficient to assess that the highest dose was in fact the maximum tolerated dose.
- For substances that hydrolyse (very) rapidly, it is recommended to perform the tests on water solubility and partition coefficient with the degradation products; this is important in order to evaluate further ecotoxicological tests undertaken. Also certain ecotoxicity

[14] Substances of unknown or variable composition, complex reaction products or biological materials

studies are recommended to be made with the degradation products; for further guidance (see Guidance on information requirements and chemical safety assessment Chapter R.7b: Endpoint specific guidance).

- Definitive tests shall be undertaken for ecotoxicological endpoints further to screening, in order to fulfil the data requirements and be considered appropriate for classification and labelling.
- For poorly water soluble substances certain short-term aquatic ecotoxicological tests may not be relevant as the amount of the test substance in solution will be low. Moreover, in many cases equilibrium (uptake from the water phase) will not be reached in a short-term toxicity test. In such cases registrants are recommended to consider undertaking chronic ecotoxicological tests instead (as indicated in column 2 of the Annexes).
- For the assessment of the bioaccumulation potential, depending on the physical chemical properties a fish dietary bioaccumulation test may be more relevant than an aquatic bioaccumulation study for example for substances with a high logKow / (very) poorly water soluble substances.
- It is not acceptable to submit results for granulometry tests undertaken with a substance which is different from the registered substance since this is considered a clear example of incompliance and would therefore lead to a draft decision. This is because granulometry is strictly related to the manufacturing process and may differ, for example, even for the same substance, from one production site to another. Granulometry constitutes an important property which may trigger further inhalation toxicity tests and appropriate risk management measures.

3.1.3. Adaptation of standard information requirements

The REACH legislation provides registrants with the possibility to adapt the standard information requirements based on the rules listed in column 2 of Annexes VII-X and Annex XI of the regulation. Appropriate use of these options allows registrants to avoid unnecessary testing, including animal testing.

In certain cases, tests do not need to be conducted for a particular endpoint if it is not considered necessary in a specific case. Column 2 of Annexes VII-X gives endpoint specific rules under which a test does not need to be conducted. Additionally, Annex XI includes several additional options under which it is possible to omit standard testing. These are when testing does not appear scientifically necessary, it is technically not possible or when substance-tailored exposure-driven testing may be applied.

It is acknowledged that in a significant number of the evaluated dossiers the rules for adaptation are known and well used by the registrants (the correct basis was chosen and sufficient justification was provided where necessary). However, in a number of cases, the adaptations were either poorly justified or not justified at all. Below there are some examples of generic and endpoint specific shortcomings observed with regard to the use of adaptation of standard information requirements.

Generic

- The legal reference for adaptation of the standard testing regime was not specified (e.g. column 2 of Annexes VII-X or a section in Annex XI);
- A scientific valid argument was not provided why a specific adaptation in column 2 of Annexes VII – X or a section in Annex XI has been used;
- Adaptation according to column 2 was incorrectly used.

Physico-chemical properties

- REACH allows adaptation (according to the rules specified in Column 2 of Annexes VII-X) for certain endpoints for inorganic substances; for example, tests like octanol-water partition coefficient, flash-point and biodegradation are scientifically unjustified for inorganic substances. It has been observed that in some cases, registrants "extrapolated" this option for adaptation to other types of substances, e.g. coordinative compounds or organometallic compounds. Since such "extrapolation" is neither foreseen under REACH nor scientifically justified, for substances other than inorganic, data shall be provided or a suitable argument for omission of data shall be selected and documented.
- In an important number of dossiers, registrants submitted for the endpoint "flammability" the results of a flammability test according to the EU Method A10. However, quite often, flammability in contact with water and pyrophoricity (EU Method A12 and 13) are not addressed. For the majority of the substances, these properties are not of concern and they can be easily omitted based on a consideration of the structure and experience and use.
- In some cases, a waiving statement was submitted for octanol-water partition coefficient. However, no calculated value was provided nor an explanation/justification for omission of the test.
- Hydrolysis has sometimes been used as a waiving argument for omitting certain physico-chemical tests for the registered substance, e.g. water solubility or octanol-water partition coefficient; although not mentioned under Column 2 adaptations, this argument might be considered valid provided that adequate data on hydrolysis are included in the dossier. However, in some cases the registrants did not submit information on hydrolysis (e.g. for information requirements in Annex VII) while using it to waive certain tests.

Environmental hazards

- Column 2 adaptations allow waiving of higher tier biodegradation tests (simulation testing in water, sediment and soil according to Annex IX) if the substance is readily biodegradable; however, in some cases, the registrants waived simulation tests although the chemical safety assessment indicates the status of the substance as persistent/very persistent.
- Column 2 in Annex IX and X allows waiving of a number of environmental tests, based on the outcome of the chemical safety assessment; in some cases, the registrants used these adaptations without providing further explanation in the chemical safety report (CSR) and in the endpoint study record as to why this adaptation could be justified.
- Column 2 in Annex IX and X provides the possibility to waive certain environmental tests based on exposure considerations. For example, terrestrial toxicity tests may be waived when direct or indirect exposure is unlikely. In some cases, the registrants assessed the direct exposure in order justify omission of the test, however they did not address the indirect exposure. In other cases, the registrants did not provide any justification when using exposure considerations to waive certain environmental tests.

Human health hazards

Toxicological tests have been omitted in some cases with the justification that "there are no toxicological effects"; in none of the cases evaluated so far was adaptation used to predict potential toxicological effects and subsequent classification of the substance. Below are some examples of adaptations used for toxicological tests which are considered inappropriate:

- Omission of an *in vitro* gene mutation test in mammalian cells (Annex VIII) based on negative findings in lower tier mutagenicity tests

- Omission of screening for reproductive/developmental toxicity test (Annex VIII) based on negative findings in a 28 days repeated dose toxicity study
- Omission of sub-chronic studies (90 days) based on negative findings in a 28 days study
- Omission of tests based on exposure considerations; however, no further exposure information was submitted, since the substance was not classified for human health.

ECHA provides the following **recommendations** with regard to the use of adaptation of standard information requirements:

***Generic*:**

- Any adaptation to the standard testing regime must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X of the REACH Regulation.
- Registrants need to provide sufficient justification for any adaptation and need to document this clearly in the technical dossier.
- It is very important that registrants select the most appropriate adaptation and develop further argumentation to support that particular adaptation; for example, if testing is deemed technically not possible (Annex XI, 2), it shall be justified with arguments focused on this adaptation possibility. It is confusing and not acceptable if the justification is dealing with another adaptation possibility such as a Weight of Evidence approach (Annex XI, 1.2).
- When exposure based adaptation is used, there should be a clear indication that this is the case through well documented exposure scenarios, risk characterisation or strictly controlled conditions.
- Scientifically sound and transparent justifications shall be provided for any waiving statement.

Endpoint specific recommendations:

***Physico-chemical endpoints*:**

- For the tests on pyrophoricity and flammability in contact with water, waiving statements shall be provided, where appropriate, or alternatively test results should be submitted.
- A calculated value shall be provided when waiving octanol-water partition coefficient or appopriate justification for omission of the test

Environmental fate

- When water solubility and partition coefficient are waived based on rapid hydrolysis, data shall be provided to prove that the substance would hydrolyse rapidly in environmental relevant conditions; for example analysis obtained from the ecotoxicology testing programme i.e. tests results on hydrolysis shall be included even if they are not specifically requested for the registered tonnage band. For substances that hydrolyse rapidly to perform the tests on water solubility and partition coefficient on the parent substance is not realistic. If it is not intended to perform a full hydrolytic stability test, then procedures for performing a reduced test of stability should be included as part of the solubility test. Whether the parent and/or the degradation products are analysed, strong consideration should be given to the value of the result in the performance of the ecotoxicological testing programme.
- Annex VIII specifies that further biodegradation tests shall be considered by the registrants. However, it does not specify which tests to choose. It is therefore recommended to undertake enhanced or inherent biodegradation studies (as illustrated in Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment, Table R 11-2). If a substance is observed to be readily biodegradable

or inherently biodegradable based on the above tests, then the substance is deemed not to be persistent/very persistent. This existing data can be provided as a sound justification for the omission of higher tier biodegradation testing (simulation tests) as per Annex IX.

- When biodegradation simulation testing according to Annex IX is not performed, there should be a clear indication through the PBT assessment and risk characterisation in the CSR as to why these tests have not been undertaken; furthermore, the registrant shall indicate through the PBT assessment, the status of the substance as very persistent (vP).

Human health

- Toxicological tests cannot be omitted using as argument "low toxicity profile" or "no toxicological effects"; column 2 of Annexes IX and X, and Annex XI, Section 3 specify the combined criteria which shall be used to omit certain toxicological tests, e.g 90 day repeated dose toxicity study or reproductive toxicity study.
- In certain cases, it is possible to omit lower tier toxicological tests when data is available from higher tier tests. For example, negative findings in a 28 days repeated dose toxicity test cannot be an argument for waiving a sub-chronic toxicity study; on the other hand, if results from a 90 day repeated dose study are available, then a 28 days study may be omitted.

Exposure based considerations

REACH allows for waiving of studies based on the exposure scenarios developed for the substance. According to Annex XI, 3, exposure based adaptation is possible for tests in section 8.6 and 8.7 of Annex VIII and tests in Annex IX and X. In order to qualify for exposure based adaptation, the registrant needs to develop exposure scenarios for the substance. In addition, the registrant needs to provide adequate justification and documentation for the adaptation, which shall be based on thorough and rigorous exposure assessment. In addition, exposure based waiving may be used to omit testing when the registrant can demonstrate that strictly controlled conditions as described in Article 18(4)(a) to (f) apply to the substance.

When exposure based adaptation according to Annex XI is used to waive certain tests, then **exposure assessment and risk characterisation according to Article 14(4)** and Annex I, 5 **is required independent of whether any of the criteria are met to classify the substance as dangerous or as PBT/vPvB**. In other words, even if the substance is not classified, the registrant shall include exposure assessment and risk characterisation at least to cover those endpoints for which testing has been omitted based on the exposure consideration.

For environmental exposure based adaptation based on column 2 of Annexes VII-X, registrants need to provide a qualitative argumentation to support why such exposure is absent or not significant, e.g. due to specific uses of a substance. For example, at least a qualitative assessment of the likelihood of environmental exposure shall be performed to demonstrate that direct exposure (e.g. through waste water treatment plant) and indirect (e.g. through sludge) is unlikely.

Further information can be found in *Practical Guide 4: How to report data waiving.*

3.1.3.1 Use of existing data

Annex XI, 1.1.2 of the REACH Regulation details the conditions under which data obtained from experiments not carried out according to GLP or to the test methods referred to in Article 13(3) of the REACH Regulation shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3).

In 2010, ECHA evaluated a number of dossiers which included such data. Strong scientific judgement is needed in these situations to decide on the reliability of such studies to replace guideline GLP studies.

Recommendations for using existing data to fulfil the information requirements:

- The data provided shall be adequate for classification and labelling and/or risk assessment.
- The data shall be scientifically valid for the particular endpoint.
- Adequate documentation is provided to assess the quality of the data.
- The data provided shall ensure adequate coverage of the key parameters foreseen to be investigated in the current test guidelines.

Specific attention to endpoint: *In vitro* gene mutation study in bacteria (Ames test)

According to Commission Regulation (EC) No 440/2008 laying down tests methods, the *in vitro* gene mutation study in bacteria should be performed in accordance with the current OECD TG 471. This version of the EU Test Method B.13/14/OECD TG 471 is in force since 1997 and introduced the need for performing the test in at least 5 strains of bacteria whereas the former version of OECD TG 471 only required testing in a minimum of 4 bacterial strains. The required 5th bacterial strain, i.e. either *Escherichia coli WP2* uvrA, *Escherichia coli* WP2 uvrA (pKM101) or *Salmonella typhimurium TA102*, has the potential to detect certain types of mutagens, such as cross-linking agents or oxidising mutagens, which the 4 bacterial strains recommended in the former version of the OECD TG 471 may not detect.

Therefore ECHA considers that the *in vitro* gene mutation studies performed before the new OECD Guideline 471 entered into force do not provide an adequate and reliable coverage of the key parameters foreseen to be investigated in the EU Test Method B.13/14/OECD TG 471 and therefore does not meet the condition laid down in Annex XI, 1.1.2 (2) of the REACH Regulation (equivalency of data).

Consequently the registrants shall consider the following options:

- When only data from an *in vitro* gene mutation study in 4 bacterial strains is available, (e.g. for requirements under Annex VII), registrants shall provide data for the 5th strain specified in the current test guideline.
- When other data is available (e.g. higher tier mutagenicity tests), registrants need to make a scientific judgement in a weight of evidence approach in order to consider whether the data provided by the 5th strain is covered by other data submitted in the registration dossier. If this is the case, the absence of the data on the 5th strain shall be clearly justified in the dossier.

3.1.3.2 Weight-of-evidence approach

This approach may be applied if there is sufficient information from **several independent sources** leading to the conclusion that a substance does or does not have a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

It has been observed that the number of dossiers containing a weight-of-evidence approach is higher than expected, especially for phase-in substances. Some of the most frequent shortcomings observed in the use of weight-of-evidence approach are:

- Submission of data from several secondary sources (handbooks); however, all sources quoted making reference to the same primary source.
- No information is provided in the robust study summary but only the final result.
- The endpoint is not flagged for weight-of-evidence.

Recommendations:

- Weight-of-evidence approach **must be flagged** in the dossier; the flag can be used only if more than one study is provided for a hazard endpoint.
- When data from a single secondary source is used, it is essential to provide further supporting evidence e.g. QSAR predictions, manufacturing data, data taken from material safety data sheets, etc.
- When only handbook data is submitted for a certain endpoint, they should be at least from two secondary sources making reference to independent peer reviewed primary sources.
- **Robust study summaries** shall be provided for each study used in the weight-of-evidence approach.
- All relevant information for the hazard endpoint should be addressed and a justified weight should be assigned to it in the overall assessment.
- The quality of the available data, the consistency of the results, the severity and the type of effect of concern and the relevance of the available data for the hazard endpoint should be considered.

Further information can be found in the *Practical Guide 2: How to report weight of evidence.*

3.1.3.3 (Quantitative) Structure-Activity relationships [(Q)SARs]

Annex XI, 1.3 of REACH foresees that results of (Q)SARs may be used instead of testing when specific conditions are met.

Evaluation of data generated using (Q)SAR models showed that in certain cases, (Q)SAR models fulfilled the conditions outlined in REACH Annex XI, 1.3 either as stand alone for the prediction of certain properties or as part of supporting evidence in hazard assessment. In other cases, data generated by (Q)SAR were considered inadequate as they did not provide sufficient information for predicting the presence or absence of certain properties, e.g. long term toxicity.

The following **recommendations** are provided with regard to the use of (Q)SAR. They shall be considered by both the registrants when submitting (updated) registration dossiers and third parties when submitting information during the public consultation process of examination of testing proposals.

- The set of information on the (Q)SAR model shall be provided in the (Q)SAR Model Reporting Format (QMRF), or in the corresponding IUCLID field; a QMRF is necessary for assessing the validity of the model.
- The use of (Q)SAR models as supportive evidence in hazard assessment is recommended. Information generated by expert systems on the presence or absence of alerts may provide valuable information in the overall of test data.
- QSAR model predictions may be used in a weight-of-evidence approach, in correlation to test data, in order to develop and support justification for read-across and grouping approaches.
- QSAR model predictions can often help in deciding on integrated testing strategy (ITS) strategy when examining chemical categories.

Further information can be found in the *Practical Guide 5: How to report (Q)SARs.*

3.1.3.4 In vitro methods

Results obtained from suitable *in vitro* methods may indicate the presence of a certain dangerous property or may be important in relation to understanding the mode of action of the substance.

To date ECHA has received a limited number of dossiers including solely *in vitro* methods to cover certain endpoints. *In vitro* methods used were either validated and/or adopted (EU or OECD) methods or methods undergoing a validation process.

In general, the registrants used *in vitro* methods in accordance with the adaptations specified under Annex XI, 1.4 of the REACH Regulation; the studies submitted were well reported and with a sufficient level of detail. However, in some cases, the registrants did not include a detailed protocol of the *in vitro* method used. Such a detail report is crucial when using a method that has not been formally validated, in order to evaluate whether the method fully complies with the specific rules for adaptation provided under Annex XI, 1.4.

Below there are some examples of shortcomings identified with regard to the use of *in vitro* methods:

- Submission of an *in vitro* study to cover standard information requirements for eye irritation as specified in Annex VII of REACH; the study is currently under validation process. The registrant provided only brief summary of the results; reported as such the study cannot be considered as acceptable to cover the eye irritation endpoint either in case of a positive or negative result.
- Submission of an *in vitro* study on Skin corrosion to cover the endpoint of Skin irritation and corrosion. The test was well performed and conducted in accordance with the principles of good laboratory practice; a sufficient level of detail has been provided; the result of the test was negative. However, the study only examined whether the substance has corrosive or non-corrosive potential. Since information on skin irritation or non-irritation potential has not been examined, the data submitted is considered insufficient to cover the information requirements for Skin irritation and corrosion as requested in Annex VII.

Recommendations:

Skin irritation-corrosion

Annexes VIII-X requires an *in vivo* test to assess Skin irritation/corrosion. However, there are currently several *in vitro* methods available that can be used in a weight-of-evidence approach, to fully replace animal testing.

It is generally agreed that the EU B.46 (OECD 439) *in vitro* methods for Skin irritation represent a full replacement of the respective *in vivo* method (OECD 404) in a tiered testing strategy and in conjunction with *in vitro* skin corrosivity tests, if necessary. It should be noted that B.46 method does not address corrosivity; therefore, in case of positive result in a B46 test, a test addressing skin corrosion has to be performed.

It is recommended that the following testing strategy is followed when performing in vitro tests to assess skin-irritation and corrosion (see also *Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance)*

- Skin corrosion shall be tested first; in case of positive results, no further testing is necessary; the substance shall be classified accordingly.
- If the results of the skin corrosion test is negative, then a skin irritation study according to EU method B.46 shall be performed; if the result is positive, no further testing is necessary but classification of the substance.
- A negative result in the B.46 test does not need to be confirmed by additional testing.

Consequently, the default testing strategy would stop after testing skin irritation *in vitro*. No further *in vivo* testing would be required.

It shall be reminded that the B.46 method is not applicable for certain chemical categories, coloured substances, vapours and substances that easily decompose.

Other recommendations regarding *in vitro* tests

- Data generated by *in vitro* test methods (validated and pre-validated) can be used under REACH, provided that the information for the hazard endpoint is sufficient for the purpose of classification and labelling and/or risk assessment.
- Where a pre-validated method is used, the registrant should assess and document the method according to the ECVAM[15] pre-validation criteria and justify its suitability for use in the registration dossier.
- Advanced *in vitro* technologies may provide valuable information on mode of action of the substances and assist in building a read-across and category justification.
- *In vitro* data produced by other methods (i.e. non-prevalidated methods) can be used only as supportive information (e.g. as part of a weight-of-evidence justification).
- A detailed, clear description of the results, the test conditions and the interpretation of the usefulness of the results should always be provided in the registration dossier. This is necessary if the study is used as a key study or as part of a tiered testing strategy within a weight-of-evidence approach.
- Limitations of the method should be clearly communicated; for example *in vitro* test methods may not replicate all of the metabolic processes relevant to chemical toxicity that occur *in vivo.*
- In all cases the conditions set out in the REACH Regulation Annex XI, 1.4 must be met.

Further information can be found in *Practical Guide 1: How to report in vitro data* and in http://ecvam.jrc.it/.

3.1.3.5 Grouping of substances and read-across approach

Grouping and read-across approaches provide a suitable basis for data gap filling for regulatory purposes providing that certain conditions are satisfied. This avoids the need to test every substance for every endpoint. REACH Annex XI 1.5 sets out minimum requirements for the application of this concept.

In 2010, ECHA evaluated several read across approaches submitted either by the registrants as part of the information requirements under REACH or by third parties during the public consultation (in the process of examination of testing proposals). In certain cases the read-across approach was used adequately in order to fulfil the information requirements, both for vertebrate and non animal testing; the information provided was deemed appropriate for the purposes of classification and labelling and, where relevant, for risk assessment. However there have been cases where the information provided as not robust enough or not adequate to fulfil the information requirements.

The following recommendations are made with regard to the use of read-across and grouping approaches under REACH:

- Results from the read-across approach should be adequate for the purpose of classification and labelling and/or risk assessment, have adequate and reliable coverage of the key parameters addressed in the corresponding test method, and cover an exposure duration comparable to or longer than the corresponding test method.

[15] European Centre for the Validation of Alternative Methods

- Accurate data on the substance(s) composition shall be provided in order to assess whether the predicted effects are caused by the substances themselves and not from impurities or other constituents, which are not accounted for in the composition of the target substance.
- Reliable information on the physicochemical properties that are relevant for biological effects shall be provided in order to allow making robust assumptions on the fate of the substance in the environment or in biological organisms.
- Preferably the physical-chemical information used in order to support a read-across approach shall be generated using a test method as specified in the Test Method Regulation (EC) No 440/2008 or OECD Guidelines.
- The documentation must detail which hazard end-points are covered by the read-across, and the source chemical which is used for the read-across must be identified.
- The **read-across hypothesis** and **justification** for it must be detailed in the dossier. An acceptable read-across justification is normally based on multiple lines of evidence.
- Studies on toxicokinetics may improve the robustness of the read-across hypothesis. Theoretical assumptions based on robust criteria together with modelling approaches are considered useful in the overall evaluation.
- Common break-down products have to be justified with supporting information. It should be considered if for different routes and duration of exposure and for different type of effects the hypothesis for common break-down products is appropriate.
- Analysis of the test data together with predictive properties generated by QSAR tools (e.g OECD QSAR Toolbox) is essential for providing good justification for read-across approaches.
- Consideration of mode of action or other mechanistic information need to be provided when the data available allows for doing so.
- The endpoint should be especially well defined when different types of mode of action are addressed, as well as when different routes and duration of exposure are present, and the type of effect is different (local versus systemic toxicity). Assessment of the overall data should be done in a Weight of Evidence approach to allow sound conclusions as to which endpoint are covered by read-across/grouping.
- Where substances have been accepted as members of **categories** under other regulatory programs (for example OECD HPV categories), the registrant should refer to such categories in the dossier. The registrant must nevertheless include all available information (including information which became available after assessment in the other regulatory programme) and reassess the validity of the category.
- A comparison of **experimental data for hazard endpoints for all category members** (a data matrix) is recommended, ideally highlighting trends within the category.

Further information can be found in the *Practical Guide 6*: *How to report read-across and categories.*

3.1.4. Robust study summaries

REACH requires registrants to submit the information for the different endpoints in the form of robust study summaries. In general, a robust study summary is required for the key studies of substances manufactured or imported in quantities of 10 tonnes p.a. or more. At least a study summary shall be provided for the key studies on substances below 10 tonnes p.a.

Shortcomings observed with regard to robust study summaries:

- There is an insufficient level of detail reported in the robust study summaries which prevents making an independent assessment of the study.
- Very often, for physico-chemical properties, only the final result is included in the robust study summary, with no further details regarding the method used, conditions of the test undertaken, etc.
- There are inconsistencies between the information provided in the robust study summaries and the chemical safety report.

Recommendations:

- The robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study and minimising the need to consult the full study report. Registrants are encouraged to provide quantitative summaries (i.e. a table of means and standard deviations) for parameters that are perturbed.
- The information contained in the robust study summaries must be consistent with the information provided in the chemical safety report.
- The identity of the test material and its relevance for the registered substance must be described in the robust study summary.
- Registrants shall review and check the studies in order to assess whether they are compliant with the Test Method Regulation (EC) No 440/2008 prior to submission.
- In the "Applicant's summary and conclusions" field of the IUCLID endpoint study record, it should be made clear whether or not the quality criteria (validity, reliability, repeatability) have been fulfilled and which conclusions were derived from the underlying data.
- The registrant should explain the relevance of the effects observed in the study for classification and labelling and/or for risk assessment.

Further information can be found in the *Practical Guide 3: How to report robust study summaries*.

3.2 Intermediates

Isolated on-site and transported intermediates can benefit from reduced information requirements provided they are used under strictly controlled conditions. In 2010, ECHA evaluated a number of isolated transported intermediates and, outside the dossier evaluation process, screened a number of dossiers for on site isolated intermediates. The following shortcomings have been identified:

- The information provided in the dossier was not sufficient to verify the status of the substance as an intermediate.
- Data on risk management measures and/or on strictly controlled conditions was missing or controversial.
- Information leading to the classification and labelling was not provided (e.g. although the substance was classified, the studies conducting to classification were not included in the dossier).

Recommendations:

- The dossier should include a clear description of intermediate use: by definition an intermediate is a substance used in the manufacturing of another substance whereby the intermediate is itself transformed into that other substance.

- The registration dossier for isolated intermediates shall include details of the risk management measures applied, including details on the rigorous containment and the control and procedural technologies to minimise emissions.
- For transported intermediates the dossier shall include the registrant's confirmation from all the users further down the chain that the substance is used under strictly controlled conditions.
- Registrants are invited to take note of the updated guidance on intermediates and update their dossier accordingly.

Further information can be found in the *Guidance on intermediates (version2)*

3.3 Classification and labelling

REACH requires that information on classification and labelling shall be included in the registration dossiers for all substances, irrespective of the tonnage band. Classification and labelling (C&L) involves an evaluation of the intrinsic hazard of a substance or mixture/preparation and a communication of that hazard.

ECHA notes that in general, registrants fulfilled their obligations regarding C&L. However, in a significant number of cases, it has been noted that there are deficiencies with regard to classification and labelling; this also represented the most frequent shortcoming addressed through quality observation letters. The issues observed were:

- Classification and labelling was not in line with the hazards identified in certain tests, e.g. registrants did not use the study giving rise to the highest concern for self-classifications.
- Deviations from harmonised classification and labelling

Recommendations:

- The substance shall be placed in the appropriate hazard category based on the results of the tests and criteria for classification provided by the CLP Regulation
- Registrants shall not deviate from the harmonized classification and labelling for substances already included in Annex VI of the CLP Regulation. However, in case that new data becomes available which might trigger changes in the harmonized classification, registrants may submit a proposal for revision to the relevant MSCA.

Further information can be found in the *Guidance on the preparation of dossiers for harmonised classification and labelling.*

3.4 Chemical safety assessment

REACH requires registrants of substances manufactured or imported at volumes above 10 tonnes per annum to provide a chemical safety report (CSR) documenting that the risks arising from the manufacture or use of the substance are adequately controlled. An exposure assessment with appropriate exposure scenarios must be included in the CSR when the registrant concludes that the substance meets the criteria for being classified dangerous (hazardous) or is assessed to be a PBT/vPvB.

ECHA has examined a number of chemical safety reports over 2010 in order to verify compliance with requirements set out in Annex I of the REACH Regulation. **The shortcomings identified are detailed below:**

Hazard assessment

- In some cases information from existing international or national assessments of the substance was not included in the chemical safety report, although publicly available.

- No justification was provided when deviating from the results of an existing international or national assessment of the substance.
- Quite often there were significant inconsistencies between the data provided in different IUCLID entries and those in the CSR.
- For substances that hydrolyse rapidly, there was no indication of the PBT/vPvB assessment for the degradation products.
- A DNEL or PNEC was not derived based on the study giving rise to the highest concern without proper justification.
- Assessment factors used in derivation of DNEL or PNEC differed, in some cases, from default values provided in the guidance documents without proper justification.
- No justification was provided as to why a DNEL/PNEC was not derived.

Exposure assessment

- When exposure based adaptation was used to waive certain tests, this was not sufficiently supported by required documentation (e.g. description of strictly controlled conditions).
- Relevant routes of exposure were missing for specific substance properties (e.g. if the substance is classified for acute local effects, this exposure should be evaluated).
- Not all identified uses were covered by exposure scenarios.
- Regional assessment for the environment did not cover the whole life cycle of the substance and all identified uses.
- Exposure assessment for man via the environment has been omitted without appropriate justification.
- The specific occupational exposure control characteristics mentioned in Annex II 8.2.1 (e.g. material and breakthrough time of gloves) were not specified.
- Omission of the declaration that risk management measures are implemented and communicated (Part A of the CSR was empty).
- The exposure estimates reported in the CSR could not be reproduced using the same tool and the same input.
- Some steps of the life cycle were missing (e.g. service life and waste life stage).

Other:

- Release estimation for the environment was insufficiently justified.
- Description of operational conditions (OC)/risk management measures (RMM) was not complete (with regard to description of uses).
- No interim RMM were provided while waiting for results of further testing for risks being explored (e.g. tests under Annex IX or X for which a testing proposal has been submitted) as required under Annex I, 0.5 last paragraph.
- Risk characterisation for physico-chemical hazards omitted.

Recommendations:

- Reference to existing international or national assessments of the substance shall be included in the chemical safety report; appropriate justification shall be provided when deviating from the results of such assessments.
- Registrants shall thoroughly check consistency between the information provided in the IUCLID entries and the CSR.

- There must be consistency between descriptions in the Exposure Scenario and corresponding exposure estimation.
- There must be consistency between the hazards identified, DNEL and PNEC derivation and exposure assessment.
- Sufficient advice on risk management should be given to the users of the substance. For example, when wearing protective gloves is recommended, then the type of material and breakthrough time, with regard to the amount and duration of dermal exposure shall be specified.
- Use of non standard default values for release estimates shall be clearly justified.
- While waiting for results of further testing, registrants shall provide interim risk management measures put in place and recommended to downstream users, intended to manage the risks being explored.

3.5 Testing proposals

REACH foresees that for information requirements under Annexes IX and X, a testing proposal shall be submitted before undertaking tests. ECHA evaluates the need for testing and subsequently takes a decision addressed to the registrant accepting – with or without modifications - or rejecting of the proposed test.

Although this process seems to be straightforward and in general well understood, ECHA observed several deficiencies and even incompliance with regard to testing proposals:

- In some cases registrants submitted testing proposals for endpoints under Annex VII or VIII, where generally submission of tests results is requested. Such testing proposals are therefore not regarded as testing proposals under Article 40 of the REACH Regulation and not examined unless a specific rule for adaptation requests registrants to consider and propose further testing already at lower tonnage levels.
- In other cases, a testing proposal has been flagged in the registration dossier; however, further on in the dossier, the registrant indicated that the test is already on-going and therefore the whole aim of the testing proposal examination to avoid unnecessary testing could not be met at all.
- In certain dossiers data was generated for Annex IX or X requirements after REACH entered into force with no prior acceptance by ECHA of testing proposals.
- In general, registrants did not provide justification for undertaking the tests proposed; this makes it difficult to assess whether undertaking the test would be justified or not.
- Test substance and the test method were not justified in sufficient detail.

Concerning the consultation process, the information submitted by third parties on testing proposals involving vertebrate animals was usually not sufficient to fulfil the information requirement under REACH. In order to improve efficiency of the consultation process, ECHA decided to provide feedback regarding third party information (see chapter 2.2).

Recommendations to registrants:

- For Annex VII and VIII information requirements, tests shall be conducted with no prior submission of testing proposals; generally, testing proposals shall be submitted only for the generation of data under Annexes IX and X; however, Column 2 of Annexes VII and VIII may indicated the need to assess higher tier testing of Annexes IX and X already at a lower tonnage band level; only in the latter case is a testing proposal required.
- A testing proposal shall be submitted for tests under Annex IX and X before undertaking it; performing testing without an approving ECHA decision may lead to enforcement actions.

- It is recommended to provide adequate justification as to why the test is necessary to be performed.
- Substance to be tested (test material) and test method shall be specified in detail.

Specific recommendations for third parties submitting information during the public consultation:

- In order to be considered relevant, the information submitted during the public consultation should fulfil REACH information requirements specified for the endpoint under examination.
- Test data submitted should contain a sufficient level of detail in order to allow an independent assessment.
- If non-test data is provided, e.g. read-across, QSAR etc., they should fulfil the same requirements as the data submitted by the registrants and specified in REACH; see also Chapters on non-test data in this report.

3.6 Data sharing

Data and cost sharing is one of the core principles in the REACH Regulation which allows companies to reduce costs and avoids unnecessary testing on vertebrate animals.

ECHA noted that for some non-phase in substances, registrants failed to consider their obligations for sharing of data and failed to come to an agreement with other potential registrants. Subsequently, the potential registrants submitted waiving statements for certain tests explaining their currently ongoing data sharing disputes. ECHA also noted that some registrants are not familiar with the procedure to be launched in case of data sharing disputes.

ECHA reminds registrants about the following points with regard to data sharing which are laid down in the REACH Regulation:

- Registrants are obliged to share the data and costs on vertebrate testing.
- Registrants shall make every effort to reach an agreement on the sharing of information. In case of disputes a data sharing dispute claim may be lodged to ECHA. The registrant shall submit the information regarding data sharing disputes via a webform that can be found at http://echa.europa.eu/datasharing_en.asp following the procedure described there.
- Data sharing disputes shall be solved **before** submission of a registration dossier; a registration dossier which includes waiving statements such as “no agreement could be found for sharing the data” are considered incompliant.
- For studies which ECHA makes available to registrants under the 12 years rule, it may be that those study summaries are not sufficient to meet the requirements under the REACH Regulation; it is the registrant’s responsibility to assess those studies and consider obtaining/ generating additional information to make the dossier compliant.
- When using study summaries submitted more than 12 years earlier in notifications made under the national law implementing Directive 67/548/EEC, it is the registrants’ responsibility to fulfil their legal requirements relating to the chemical safety report and recommended risk reduction measures under Article 14(3) of the REACH Regulation.

More information can be found in *Guidance on data sharing* and on the ECHA website http://echa.europa.eu/datasharing_en.asp

REFERENCES

Information about ECHA:

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

ECHA and events
http://echa.europa.eu/news/events_en.asp

ECHA Webinars
http://echa.europa.eu/news/webinars_en.asp

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

Member State Committee work
http://echa.europa.eu/about/organisation/committees/memberstate_en.asp

The legislation:

Regulation (EC) No 1907/2006 (REACH Regulation)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20090627:EN:PDF

Regulation (EC) 1272/2008 on Classification, Labelling and packaging (CLP Regulation)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF

Dangerous Substance Directive 67/548/EEC and Existing Substances Regulation (EEC) No. 793/93
http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21276_en.htm#amendingact

Test methods:

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

Regulation (EC) No 440/2008 on test methods
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R0440:20090827:EN:PDF

Practical Guides

Practical guide 1: How to report *in vitro* data
http://echa.europa.eu/doc/publications/practical_guides/pg_report_in_vitro_data.pdf

Practical guide 2: How to report weight of evidence
http://echa.europa.eu/doc/publications/practical_guides/pg_report_weight_of_evidence.pdf

Practical guide 3: How to report robust study summaries
http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf

Practical guide 4: How to report data waiving
http://echa.europa.eu/doc/publications/practical_guides/pg_report_data_waiving.pdf

Practical guide 5: How to report (Q)SARs
http://echa.europa.eu/doc/publications/practical_guides/pg_report_qsars.pdf

Practical guide 6: How to report read-across and categories

http://echa.europa.eu/doc/publications/practical_guides/pg_report_qsars.pdf

Practical guide 10: How to avoid unnecessary testing on animals
http://echa.europa.eu/doc/publications/practical_guides/pg_10_avoid_animal_testing_en.pdf

Guidance:

Guidance for identification and naming of substances under REACH
http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC_I

Guidance in a nutshell on Registration data and dossier handling
http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance_registration_en.pdf

Guidance on intermediates
http://guidance.echa.europa.eu/docs/guidance_document/intermediates_en.pdf

Guidance on the preparation of dossiers for harmonised classification and labelling
http://guidance.echa.europa.eu/docs/guidance_document/clh_en.pdf

Guidance on data sharing
http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf

Questions and Answers for the registrants of previously notified substances
http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf

JRC computational toxicology website
http://ecb.jrc.ec.europa.eu/qsar/

JRC computational toxicology: reporting QMRFs
http://ecb.jrc.ec.europa.eu/qsar/

OECD guidance for the testing of chemicals
http://www.oecd.org/

Priority existing substances before the REACH Regulation entered into force
http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora

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

Waiving and adaptations
http://echa.europa.eu/doc/reach/reach_factsheet_testing.pdf

Attachment 1: Compliance check overview

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check[16]	120	45	**165**
Draft Decisions sent to the registrant[17]	2	19	**21**
Final Decisions	4	8	**12**
Quality Observation Letters	9	31	**40**
Compliance checks concluded with no further action	4	28	**32**

[16] Dossiers ever opened for compliance check notwithstanding their current status.

[17] Draft decisions which did not become final by 31 December 2010.

Attachment 2:
Testing proposals in registration dossiers by 31.12.2010

	Tonnage per year	Number of registration dossiers with testing proposal	Number of registration dossiers containing vertebrate testing proposal	Number of endpoints covered by testing proposals	Number of endpoints covered by testing proposals for vertebrate animals
Phase-in	1-10	4	4	9	6
	10-100	11	5	16	7
	100-1000	76	54	198	97
	>1000	425	322	843	533
	Intermediates	25	19	32	25
	Total phase-in	**541**	**404**	**1098**	**668**
Non phase-in	1-10	3	3	4	4
	10-100	6	4	11	7
	100-1000	17	12	40	23
	>1000	7	5	18	7
	Total non phase-in	**33**	**24**	**73**	**41**
Total		**574**	**428**	**1171**	**709**

Attachment 3: Testing proposals (TP) overview

		Phase-in	Non phase-in	Total
No of registered dossiers[18]	containing testing proposals	541	33	**574**
	containing testing proposals for vertebrate animals	404	24	**428**
No of endpoints	covered by registered testing proposals	1 098	73	**1 171**
	covered by registered testing proposals for vertebrate animals	668	41	**709**
No of third party consultations	closed	4	10	**14**
	ongoing on 31.12.2010	3	6	**9**
	planned	397	8	**405**
Dossiers with testing proposals opened for examination[19]		96	28	**124**
Draft Decisions sent to the registrant[20]		0	8	**8**
Final Decisions sent to the registrant		0	5	**5**
Terminated testing proposal examinations[21]		1	2	**3**

[18] Successfully registered (accepted and fee paid).

[19] Dossiers ever opened for examination notwithstanding their current status.

[20] Draft decisions which did not become final by 31 December 2010 nor withdrawn due to termination of TPE.

[21] Terminated at the decision-making stage upon further information provided by the registrant (e.g. cease of manufacture, tonnage downgrade or withdrawal of a testing proposal).

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