ECHA
European Chemicals Agency

Evaluation under REACH

Progress Report
2009

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The report includes recommendations to potential registrants in order to improve the quality of future registrations. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice and does not represent the position that the European Chemicals Agency may adopt in a particular case.

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ABBREVIATIONS

CAS	Chemical abstracts service
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic or toxic for reproduction
CoRAP	Community rolling action plan
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
ESR	Existing Substances Regulation
HH	Human health
HPV	High production volume
(Q)SAR	Quantitative structure activity relationship
IUCLID	International Uniform Chemical Information Database
MSC	Member State Committee
MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, bioaccumulative, toxic
PNEC	Predicted no effect concentration
RA	Read-across
REACH	Registration, Evaluation, Authorisation, Restriction of Chemicals
SAR	Structure activity relationship
SMILES	Simplified molecular input line entry specification
SVHC	Substances of very high concern
TCC	Technical completeness check
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
vPvB	Very persistent, very bioaccumulative

EXECUTIVE SUMMARY

The REACH Regulation requires EU companies to submit registration dossiers for substances manufactured or imported in quantities of one tonne or more per year. The Agency assigns a registration number after checking that the dossier is complete. This initial check does not include an examination of the quality or the adequacy of the data submitted. REACH foresees that such quality assessment is carried out independently from the registration process, through a process called Evaluation. The European Chemicals Agency (ECHA) therefore separates the assessment of scientific quality from the registration process. This is done as the Agency must be able to process a high number of dossiers in a short time at the registration stage. Evaluation is a resource-intensive task, and consequently only a fraction of registration dossiers shall be evaluated.

REACH specifies three independent evaluation processes to meet three distinct objectives:

1. **Compliance check** is used to check whether the information submitted by registrants is in compliance with the legal requirements. The legislator has provided that at least 5 % of the registration dossiers must be checked.
2. **Examination of testing proposals** aims to avoid unnecessary animal testing. Registrants must seek permission to undertake certain tests by submission of a testing proposal. Testing proposals which include animal tests undergo public consultation. All testing proposals are examined.
3. **Substance evaluation** aims to clarify whether the use of a substance may cause harm to human health or the environment. The substances are selected by the Agency in cooperation with Member States. Prioritised substances are evaluated.

The Agency carries out the scientific assessment for compliance checks and for the examination of testing proposals, whereas Member States undertake assessment for substance evaluation. If the Agency or the responsible Member State concludes that additional testing or other information is required, it prepares a draft decision which is then adopted through a centralised decision-making process. All decisions made by the Agency must be unanimously supported by EU Member States. The need for unanimity underlines the intention of the legislator to avoid unnecessary (animal) testing. If unanimous agreement cannot be reached the European Commission makes the decision.

In 2009 the Agency received 406 complete registration dossiers and initiated evaluation of 35 dossiers (27 compliance checks, 8 examinations of testing proposals). ECHA has taken a decision for one testing proposal. Fourteen compliance checks were concluded: in seven cases a quality observation letter (see chapter 1.3) was sent to the registrant and in another seven cases the compliance check was closed without further action. For three dossiers a draft decision was prepared and sent to the registrants for comment before the end of the year. Substance evaluation will start after 2011; therefore the Agency is expected to report on this activity for the first time in 2012.

The previous chemical legislation was repealed when REACH entered into operation in June 2007. Member States did not conclude decision-making for many new chemicals notified under previous legislation. Agency has identified about 60 of these substances for further examination and invited the registrants to submit testing proposals. One testing proposal was subsequently received by the end of 2009.

The Agency organised workshops and webinars to give feed-back on key findings from the compliance checks to industry, and hence promote the quality of future registration

dossiers. In addition, a workshop with Member States was held to develop a common understanding of key elements and challenges in the evaluation process.

The Agency has found that the following problems occur most commonly in dossiers:

- The identity of the registered substance and the substance used for testing were not clearly described (precise composition and impurities).
- Testing was omitted based on inappropriate or poorly justified scientific arguments.
- The summaries of test reports did not include enough detailed information.
- Shortcomings related to the risk assessment and the recommended risk management measures.
- Omission of the classification and labelling information specified by the CLP Regulation.

The Agency therefore urges registrants to go through the list of recommendations in this report and thoroughly analyse the legal requirements and the relevant guidance and manuals to improve the quality of the dossiers.

1. INTRODUCTION

1.1. Background and purpose of the report

The European Chemicals Agency (ECHA) undertakes technical, scientific and administrative tasks, as set out in the REACH[1] and CLP Regulations[2]. The REACH Regulation requires EU companies to submit registration dossiers for chemical substances manufactured or imported in quantities of one tonne, or more, per year. Consequently, one of ECHA's major tasks is evaluating registration dossiers. The REACH Regulation distinguishes between phase-in and non-phase-in chemicals; this refers to chemicals that were subject to previous regulations, and are covered by transitional arrangements in REACH (i.e. phase-in), or chemicals that fall outside the transitional arrangements (non-phase-in), e.g. chemicals newly regulated under REACH. Since 1 June 2008, non-phase-in chemicals require a registration before manufacture or placing on the EU market. For phase-in chemicals, a transitional regime provides for later registration deadlines depending on the tonnage band or specific hazard characteristics given that they were pre-registered by 1 December 2008.

One of the aims of REACH is to ensure a high level of protection of human health and environment, and companies manufacturing or importing the chemical substances are obliged to ensure that they can be used safely. This is achieved by generating information on the properties of the substances, assessing the risks, and developing and recommending appropriate risk management measures. The evaluation of registration information ensures that registrants meet the REACH information requirements and generate new information when necessary, while keeping animal testing to a minimum.

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 the Agency has made in evaluating registration dossiers and makes recommendations to improve the quality of future registrations.

Further information about the Agency, the REACH and CLP regulations, together with guidance documents about the obligation of companies under the REACH and CLP Regulations can be found *on the Agency web site*.

1.2. Information requirements for the registration of substances

REACH requires registrants to provide information on the intrinsic properties of a substance. The information required on intrinsic properties for each substance is dependant on the tonnage manufactured or imported[3]; the higher the tonnage, the more information needs to be submitted. Submission includes a technical dossier and, for substances manufactured or imported in quantities of 10 tonnes per annum (tonnes p.a.) or above, a chemical safety report. For dangerous substances, i.e. substances which are classified or substances considered as persistent, bioaccumulative and toxic (PBT-substance), an exposure assessment must be included in the chemical safety report. All information must be submitted to the Agency in electronic format.

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[1] Regulation of the European Parliament and of the Council (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

[2] Regulation of the European Parliament and of the Council (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

[3] 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.

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 to meet a requirement of REACH, the registrant must generate new information[4] or, for tests at higher tonnage levels (100 tonnes p.a. or above), prepare a testing proposal[5]. The registrant may generate new information using standard or alternative methods. The registrant may adapt the testing regime by using Quantitative Structure Activity Relationship (QSAR) models, a weight-of-evidence approach, substance-grouping approaches (read-across) or *in vitro* methodology (see Annex 1). REACH requires the use of alternative methods for generating information wherever possible, in order to reduce animal testing. There may be no need to conduct a test if testing is considered scientifically unnecessary or technically unfeasible[6]. However, the registrant must always provide a detailed justification for using waiving and adaptation options.

Further information on requirements for registration can be found in: *Guidance in a nutshell on Registration data and dossier handling*.

1.3. Evaluation processes under the REACH Regulation

The Agency carries out a technical completeness check (TCC) when dossiers are submitted for registration, before it issues a registration number. The Agency checks each submitted dossier during the TCC to see whether necessary information has been provided and the appropriate fee has been paid. However, these checks do not include any assessment of the quality or adequacy of data. Quality and adequacy of data is assessed during the evaluation process of REACH.

REACH provides for three different evaluation processes, namely the compliance check, the examination of testing proposals (these two are called dossier evaluation) and the substance evaluation. In a **compliance check** the Agency examines the quality and adequacy of data provided by the registrant. **Examination of testing proposals** aims to avoid unnecessary animal testing. The Agency or the Commission decides whether testing is necessary, and may then provide permission for tests to be performed. The third evaluation process, **substance evaluation,** is launched when there is a suspicion that certain uses of a substance may cause harm to human health or the environment. The Member States carry out the scientific assessment required for substance evaluation.

All the evaluation decisions include consultation with the registrant and the Member States. It should be noted that, in a substantial number of cases, the time needed until a decision is made may exceed one year. The consultation ensures that a decision is made only after a thorough consideration of all available information including the opinion of the registrant and a broad consensus among the Member States. The process also ensures that no unnecessary vertebrate testing is requested.

The Agency or the relevant Member State examines the information provided by the registrant and informs the European Commission, the other Member States and the registrant of the conclusions made.

The findings from dossier and substance evaluation result in an improved risk management of the chemicals concerned and promote their safe use. The obligation to control the risks

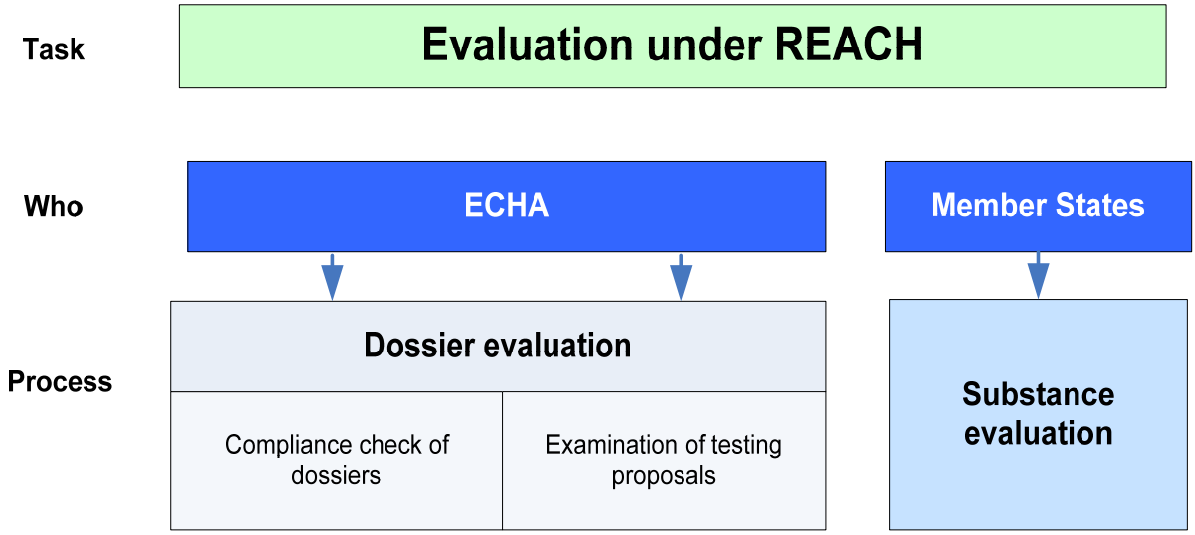
[4] For endpoints mentioned in Annexes VII-VIII of the REACH Regulation

[5] For endpoints mentioned in Annexes IX – X of the REACH Regulation

[6] Generic waiving and adaptation rules are given in Annex XI of the REACH Regulation

and to provide adequate risk management measures lies primarily 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 under the REACH Regulation
MSCA = Member State Competent Authority



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. When information is missing the Agency may request the registrant to generate and submit the missing information. The Agency can decide which dossiers are checked for compliance and whether the examination covers all or part of a dossier. The REACH Regulation requires that the Agency carry 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 in a period encompassing several years. The Agency will establish a timeframe for the 5% target in its Multi-Annual Work Plan and monitor its progress.

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. It should be noted that the Agency has no legal ability to oblige the registrants to include risk management measures that are more stringent than the ones proposed in the dossier. 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-harmonized classification and labelling).

1.3.2. Examination of testing proposals

The purpose of examination of testing proposals is to minimise the animal testing by avoiding unnecessary or inappropriate testing. The process is initiated by the registrant who submits a testing proposal to the Agency. The process can only be employed for the so-called higher-tier tests that are generally required for substances above 100 tonnes p.a.[7]. Registrants may also invoke this process if they believe that such higher-tier testing is needed for substances produced at lower tonnage levels. Some of the tests require a significant number of animals and so the need for testing must be examined.

The majority of tests examined in testing proposals concern testing for long term effects (organ toxicity, reproductive toxicity). The Agency evaluates all testing proposals within set deadlines[8] and the outcome is always a decision on a testing proposal. If the tests in the proposal involve vertebrate animals, the Agency publishes the proposal on its website and invites third parties to provide scientifically valid information. If appropriate information is provided by third parties, the testing proposal can be rejected.

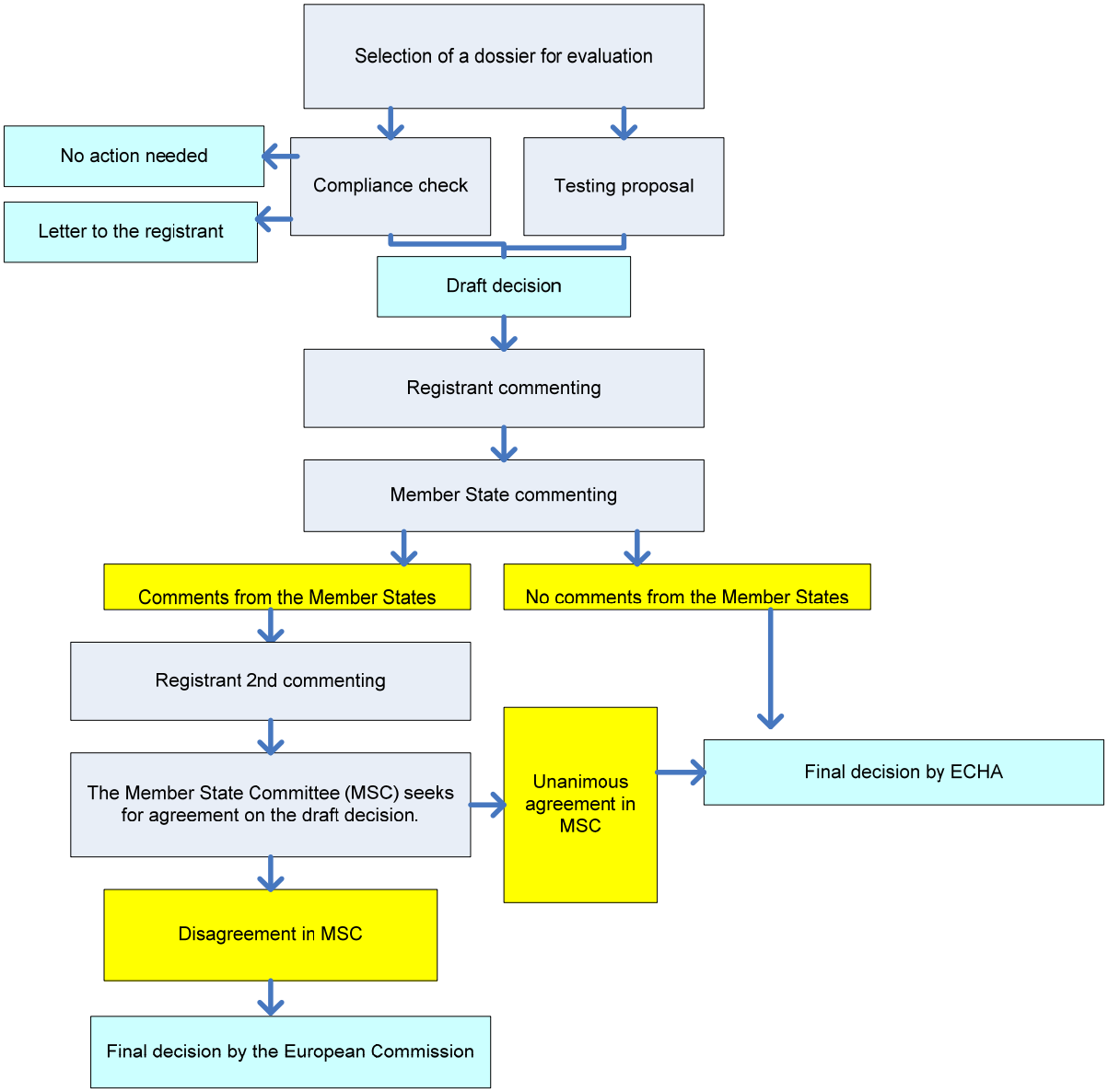
1.3.3. Decision-making process

The decision-making process is the same for the compliance check and the examination of testing proposals. 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 comments. At any stage, on the basis of the comments, the Agency may revise the draft decision. In cases where the Agency receives comments from the Member States, it will forward the draft decision to the Member State Committee (see Annex 2). The Member State Committee must seek agreement on the draft decision within 60 days. If the Member State Committee reaches unanimous agreement, the Agency makes the decision accordingly. In cases where there is disagreement, the matter is referred to the European Commission for its decision-making under the committee procedure.
In cases where the Agency receives no comments from the Member States, it makes the decision as notified without involvement of the Member State Committee.

[7] Studies that are mentioned in Annexes IX and X of the REACH Regulation (requirements above 100 tonnes p.a. and 1000 tonnes p.a.)

[8] For non-phase-in (new) substances the examination takes place in 180 days of receipt of the dossier with a testing proposal. For phase-in (old) substances there are three deadlines (01/12/2012, 01/06/2016 and 01/06/2022) depending on the registration deadlines.

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



1.3.4. Substance evaluation

Substance evaluation may be initiated when there is suspicion that a substance may constitute a risk to human health or to the environment. The substance evaluation clarifies such suspicion by requesting further information on a specific substance for which registration dossier(s) is/are available. 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, it is decided case by case what type of information is necessary to clarify the concern and whether there are any alternative methods suitable for deriving that information.

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[9].The Agency will submit the first proposal for the list of substances to the Member States by 1 December 2011. The Agency adopts the final list on the basis of opinion of the Member State Committee. The list will be updated annually. After the assessment 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 the compliance check and the examination of testing proposals.

Once the registrant has provided the requested information, the relevant Member State examines it and informs the Agency of any conclusions made. In a case where the initial suspicion is confirmed, 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-harmonized classification and labelling).

[9] Community Rolling Action Plan, CoRAP

2. PROGRESS IN 2009

2.1. Compliance check of registrations

The Agency received 10 complete registration dossiers in 2008 and 406[10] dossiers in 2009 (Table 1), with 44% of the dossiers for substances in the lowest tonnage band (1- 10 tonnes p.a.)

Table 1: Number of complete registration dossiers received in 2009

Tonnage per year	Registrations (non-intermediates)		Transported intermediates		TOTAL
	Non-phase-in	Phase-in	Non-phase-in	Phase-in	
1 - 10	90	12	70	7	
10 - 100	19	10	81	18	
100 - 1000	8	8			
> 1000	7	58	7	11	
TOTAL per phase-in status	124	88	158	36	
TOTAL per registration type		212		194	406

Phase-in substances = substances subject to transitional arrangements in REACH
Non-phase-in substances = new substance to the EU-market

The Agency initiated three compliance checks in 2008 and 27 checks in 2009. Six of the 30 compliance checks were related to phase-in substances and 24 to non phase-in[11] substances. Of the compliance checks, 20 were carried out for low tonnage substances. None of the selected dossiers were for a transported intermediate.

[10] This figure includes registration dossiers for transported but not for on-site intermediates, the latter are exempted from the evaluation by ECHA.

[11] The REACH Regulation distinguishes between old (phase-in) and new (non-phase-in) chemicals. Since 1 June 2008, new chemicals require a registration before manufacture or placing on the EU market. For old chemicals, a transitional regime provides for later registration deadlines depending on the tonnage band or specific hazard characteristics.

Table 2: Number of compliance checks in 2008 and 2009

Tonnage per year	2008		2009		TOTAL
	Non-phase-in	Phase-in	Non-phase-in	Phase-in	
1 - 10	3	-	14	3	20
10 - 100	-	-	6	-	6
100 - 1000	-	-	1	2	3
> 1000	-	-	-	1	1
TOTAL per phase-in status	3	-	21	6	30
TOTAL	3		27		

Phase-in substances = substances subject to transitional arrangements in REACH
Non-phase-in substances = new substance to the EU-market

Of these 30 dossier evaluations, 15 were completed by the end of 2009. In seven cases a quality observation letter (see chapter 1.3.) was sent to the registrant and in the other eight cases the compliance check was closed without further action. For an additional three dossiers, draft decisions were prepared and sent to the registrants for comment.

Table 3: Outcome of compliance checks at the end of 2008 and 2009

Outcome	Number of dossiers	
	2008	2009
Decision	-	-
Quality observation letter	-	7
Concluded without action	1	7
Draft decision	-	3
Completed checks in total	1	14
Carried over to the next year	2	16

2.2. Examination of testing proposals

The first eight testing proposals were received by ECHA in 2009, and five of those concerned non-phase-in substances. Six proposals for studies on vertebrate animals were submitted; the majority requested reproductive toxicity testing, with one proposal for an *in vivo* mutagenicity test and one for a repeated dose toxicity test.

The Agency started examining seven testing proposals before the end of 2009. By the end of the year, one decision was made on a testing proposal after unanimous agreement in the Member State Committee. The registrant was requested to carry out two vertebrate animal studies, one physico-chemical study and one ecotoxicological study. In addition, the Agency

prepared a draft decision on another testing proposal. The examination of the testing proposals will be continued in 2010.

Table 4: An overview of the examination of testing proposals by the end of 2009

Substance type	TOTAL	Dossiers with vertebrate studies	Draft decisions	Final decisions	Carry over to 2010
Phase-in	3	1	0	0	3
Non-phase-in	5	4	2	1	4

Phase-in substances = substances subject to transitional arrangements in REACH
Non-phase-in substances = new substance to the EU-market

2.3. Substance evaluation

Substance evaluation did not start in 2009. The Agency will submit the first draft list of substances to be evaluated to the Member States by 1 December 2011, at the latest. However, the Agency already started discussions with the Member States and the Commission in a Workshop in September 2009 in order to reach a common understanding on the scope and purpose of substance evaluation (see chapter 2.6.).

2.4. Substances notified and assessed under the previous legislation

The REACH Regulation provides transitional measures[12] for previously notified[13] substances and for existing substances. In principle, the transitional measures foresee that decisions made by the Member States Competent Authorities prior to the implementation of REACH, become Agency decisions and that the registrants need to comply with those decisions. Thus, for those substances for which there are previous decisions addressing any data gaps, the relevant registrant(s) are obliged to generate the information and to submit it to the authorities. Following this, Member State competent authorities will review the new information and make conclusions for any possible follow-up actions.

2.4.1. Notified substances

Notified 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). Similar to the REACH Regulation, the information requirements were tonnage dependent under the previous legislation for notified substances (Directive 67/548/EEC).

Within the current terminology notified substances correspond to non-phase-in substances under REACH. In everyday language they can be called new substances.

Under the previous legislation the Member States decided upon further testing programs for the notified substances. After the testing had been carried out, the notifiers submitted the results to the relevant Member State which was obliged to examine the information

[12] Articles 135, 136(1) and 136(2) of the REACH Regulation

[13] Under Directive 67/548/EEC substances were 'notified' instead of registered. Notified substances are those that were not listed in the EINECS inventory in 1981. In other words notified substances were considered as new substances placed on the market after 1981 and the substances in the EINECS inventory were considered as existing substances.

provided. For substances which decisions had been made but testing had not been completed by the time the REACH Regulation entered into force, the legislator provided for transitional measures. According to these provisions the Member State decisions became Agency decisions. As a consequence, the notifiers have to submit the missing information electronically to the Agency by the deadline specified in the Member State decision. Either the Member States or the Agency carries out the examination of the new information depending on the legal basis of the original decision.

These transitional measures apply in total to about 270 dossiers. So far the Agency has received nine updates. Four of them have been forwarded to the relevant Member State for evaluation, and the Agency started evaluating five dossiers in 2009.

There is a second group of notified substances which requires follow-up work from the Agency. Under the previous legislation the notifiers of substances were obliged to inform the relevant Member State in case 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 request further testing from the notifier. However, in some cases the Member States did not finalise the assessment and did not make a decision in time. For such substances, there is a high likelihood that relevant safety information is missing and thus additional testing may be necessary to meet the legal requirements. The Agency therefore has decided to evaluate unfinished dossiers for notified substances manufactured or imported in volumes above 100 tonnes p.a. This concerns approximately 60 dossiers. The relevant companies were invited to voluntarily propose testing or to update their existing dossiers by 30th November 2009. The Agency received one testing proposal and nine updated dossiers by the end of 2009. The Agency was informed that the production of a substance was ceased or downgraded in four cases. Some of the substances were transported intermediates. If intermediates are used under strictly controlled conditions, the data requirements under REACH are considerably lower than under the previous legislation and further information is not required.

In order to identify the substances for which follow-up is necessary the Agency prepared guidance for the Member State Competent Authorities. This document was released on 9th October 2009 (*D(2009)4051 Action plan for ECHA and Member State Competent Authorities on the implementation of transitional measures for the evaluation of previously notified substances (Article 135 of Regulation (EC) No 1907/2006)*). Also the document *'Questions and Answers for the registrants of previously notified substances' (release 5)* has been published on the website of the Agency.

2.4.2. Existing substances

Existing substances are listed in the inventory of substances on the Community market (EINECS-list). They were on the market before 18 September 1981 and were subject to a different regulatory regime than the notified substances.

Existing substances correspond to phase-in substances under REACH. In everyday language they can be called old chemicals.

The previous legislation[14] did not require the companies to generate data systematically for existing substances. Instead, industry had to gather the available information and submit it to the Commission. Based on this information, the Commission selected and included 141 high production volume substances into priority lists. These substances were allocated to

[14] Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances

Member States for carrying out a risk assessment. Some of these risk assessments resulted in a request to generate additional information. Such testing was still ongoing for 13 substances when the REACH Regulation entered into force. In addition to the substances included in the priority lists, 16 substances with suspected PBT[15] properties were identified and listed. For these substances, further testing to clarify the PBT properties was requested by the Commission. In total, there are 29 substances affected on the lists (see Annex 3).

Once the requested information for these substances is submitted by the industry, the responsible Member State will examine the new data and update the risk assessment. The Agency will publish the updated risk assessments made by the Member States on its website.

In December 2009 the Agency received information on two substances:
- Benzyl butyl phthalate (CAS 85-68-7) from Norway
- Nickel (CAS 7440-02-0) from Denmark

In order to ensure a consistent and effective conduct of the evaluation of the remaining existing substances the Agency prepared guidance for the Member State Competent Authorities. The final document was released on 7th April 2009 (*D(2009)1037) Guidance on transitional measures for the evaluation of existing substances (Articles 136(1) and 136(2) of Regulation (EC) No 1907/2006 (REACH)*). The designated Member States for assessing certain substances were published on the Agency website: *http://echa.europa.eu/chem_data/transit_measures/info_regs_en.asp*.

2.5. Capacity building

The Agency evaluates the quality and adequacy of the data provided in a dossier, any justification for not submitting information and the relevance of the results from the different studies for a sound risk assessment. When there is missing information, it is listed in a draft decision and other observations may be raised in letters to the registrant. The Agency's scientific conclusions must be robust and communicated clearly, in addition to being legally sound and enforceable decisions. The decision may be appealed before the Agency's Board of Appeal and subsequently challenged before the Court of Justice of the European Union.

Consequently, the staff carrying on the work on evaluation must have expertise not only in their scientific field but also in administrative and legal issues, and the Agency therefore dedicated substantial resources in 2009 for the training of staff.

The training consisted of different modules relevant for:

- the REACH legal framework;
- hazard identification
- classification and labelling;
- exposure assessment and risk assessment

Both basic and advanced seminars were organised during the year and further training will be also provided in the coming years.

[15] PBT = Persistent, Bioaccumulative and Toxic

2.6. Support and advice

Workshop on Evaluation
On 22-23 September 2009 the Agency hosted a workshop to discuss the practical implementation of evaluation processes focussing on the compliance check and substance evaluation under the REACH Regulation. The goal of the workshop was to promote common understanding about the principles, priorities and focus of the evaluation activities. A common understanding at Member State level of the relationship between the evaluation task, the risk management and enforcement is essential for the proper functioning of the REACH Regulation.

Representatives from the competent authorities of the Member States (29 countries were represented, i.e. the 27 Member States and Norway and Iceland), the Commission (DG Enterprise and Industry, DG Environment and DG Joint Research Centre) and the Agency staff attended the workshop. Progress was made in this workshop but continued discussions at EU and at Member State level are still needed.

Workshop on Substance Identity
On 1 December 2009 the Agency hosted a workshop to clarify key substance identity concepts in the context of REACH processes such as inquiry and registration. This event was targeted for persons in companies who are responsible for preparation of registration dossiers and who have questions on substance identity related issues.

More information and presentations given in the workshop can be found in: *http://echa.europa.eu/news/events/substance_identity_workshop_2009_en.asp*

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. Two of the webinars in 2009 were especially relevant for evaluation issues as they included the following topics:

- Information requirements I; robust study summaries, weight-of-evidence approach and *in vitro* data; 30 November 2009
- Information requirements II; adaptations of information requirements, read-across, categories and QSARs; 10 December 2009

The first webinar was attended by 278 lead registrants and the second by 198. During the webinars lead registrants generated in total 91 questions relevant to the topics. Answers to the questions were communicated to the participants either during the webinars or via Helpdesk.

More information and presentations given in the webinars can be found in:
http://echa.europa.eu/news/webinars_en.asp

3. RECOMMENDATIONS FOR REGISTRANTS

This section relates the experience gained so far from compliance checks and testing proposal examinations and gives recommendations to potential registrants. These recommendations contain technical and scientific terminology in order to make them most useful for registrants when preparing the technical dossier and the chemical safety report.

3.1. Information requirements

3.1.1. Substance identity

The REACH Regulation requires a separate registration for each substance. Hence it is essential to provide a complete, consistent and unambiguous description of the identity of the substance to be registered in the registration dossier in order to establish the legal right to manufacture and import the substance in the EU.

The information provided on the identity of the registered or tested substances was insufficient for a significant proportion of evaluation dossiers; it must enable unambiguous identification of a substance considered for evaluation purposes. The deficiency was observed more frequently in dossiers for phase-in substances. There were fewer deficiencies observed in non-phase in substances as they are checked by the Agency during the inquiry process, before the submission of dossiers.

Recommendations:

1. The information on substance identity must be submitted by each registrant individually and the information must be specific for the manufactured or imported substance.

2. Non-phase-in substances go through an inquiry process, where the identity of the substance is checked by the Agency before the substance is registered. The registrants of those substances should also learn from the Agency's responses to inquiries how to document substance identity for phase-in substances.

3. The information provided for substance identity must be consistent and allow unambiguous identification of the substance.

4. The information provided in the relevant technical dossier fields must be sufficient to enable identification of each substance.

    a. The naming convention of well defined substances and UVCB-substances (substances of unknown or variable composition, complex reaction products or biological materials) must be strictly applied as outlined in the guidance '*Guidance for identification and naming of substances under REACH*'.
    b. The analytical information provided must confirm the composition of the substance.

5. The data requirements listed in Annex VI, 2 of the REACH Regulation must be fulfilled or the registrant must provide scientific justifications if it is not possible to derive the required information.

Considering the high number of dossiers for phase-in substances which will be registered in 2010, the Agency urges companies to ensure that all relevant information on the substance identity is included in the technical dossier.

Further information can be found in the *Guidance for identification and naming of substances under REACH.* See also chapter 2.6. of this report for information about the Workshop on Substance Identity.

3.1.2. Adaptation of the standard testing regime

The REACH legislation enables registrants to adapt the standard information requirements general rules for adaptation as specified in Annex XI; besides that, specific rules are provided in column 2 of Annexes VII-X.

- The general rules allow testing to waive if:

  - it does not appear scientifically necessary
  - it is technically not possible
  - Annex XI.3 on substance-tailored exposure-driven testing applies.

- The specific rules define detailed criteria for adapting requirements for each hazard endpoint and tier of testing.

The Agency has found that some waivers for testing have been poorly justified. For a significant proportion of dossiers (5 of 16), studies for reproductive or repeated dose toxicity were waived with an inadequate justification. In all five cases the registrants predicted the absence of toxic effects, but without providing the scientific justification required by the legislation.

REACH obliges registrants to use animal testing as a last resort and Annex XI offers several options to avoid this type of testing. However, waiving of animal testing must not compromise the safe use of substances. Therefore, REACH Regulation contains several conditions that must be fulfilled to benefit from waiving possibilities. Therefore, any adaptations to the standard information requirements need a scientific sound justification and documentation. The following sections provide more details in this regard.

In this context, the Agency reminds registrants that any adaptation to the standard testing regime must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X.

3.1.2.1. 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 has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There have only been a few registration dossiers evaluated so far which included a weight-of-evidence approach.

Recommendations:

1. 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.
2. Weight-of-evidence **must not be flagged** if the registrant intends to waive a study.

3. **Robust study summaries** must be provided for each study used in the weight-of-evidence approach.

4. All relevant information for the hazard endpoint should be addressed and a justified weight should be assigned to it in the overall assessment.

5. 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.*

3.1.2.2. Quantitative Structure-Activity Relationship (QSAR) -models

The [(Q)SAR] [(quantitative) structure-activity relationship] approach seeks to predict intrinsic properties of chemicals by using various databases and theoretical models, instead of conducting tests. Based on knowledge of chemical structure, QSAR quantitatively relates characteristics of the chemical to a measure of a particular activity. QSAR should be distinguished from SAR, which makes qualitative conclusions about the presence or absence of a property of a substance, based on a structural feature of the substance.

In a substantial number of cases the description of the (Q)SAR models, their applicability and their adequacy was inadequate.

Recommendations:

1. In order to use (Q)SAR predictions instead of testing, they must meet the conditions set out in the REACH Regulation Annex XI, 1.3.

2. For filling data gaps the use of (Q)SAR analysis may be used as part of **a weight-of-evidence approach or an integrated testing strategy (ITS)**.

Further information can be found in the Guidance on information requirements and chemical safety assessment in Chapter R.6: (Q)SARs and grouping of chemicals and in the *Practical Guide 5: How to report (Q)SARs*

3.1.2.3. *In vitro* methods

A test performed *in vitro* (Latin: in the glass) is performed in a controlled environment, such as a test tube or Petri dish, and does not use a living organism. A test performed *in vivo* (Latin: in the living) is using a living organism e.g. vertebrate animals.

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. In this context suitable means sufficiently well developed according to internationally agreed test development criteria (e.g. the European Centre for the Validation of Alternative Methods pre-validation criteria).

The Agency has reviewed results obtained by *in vitro* methods in a number of cases. Although no particular shortcomings were observed, the following recommendations are given.

Recommendations:

1. 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.

2. Where a pre-validated method is used, the registrant should assess the method according to the ECVAM pre-validation criteria and justify its suitability for use in the registration dossier.

3. 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.

4. *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).

5. 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 weight-of-evidence approach.

6. 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.*

7. 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/*

3.1.2.4. Grouping of substances and read-across

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every hazard endpoint. Preferably, a category should include all potential members of similar substances. REACH Annex XI 1.5 sets out minimum requirements for the application of this concept.

The justification for the use of a read-across approach was insufficient in a substantial number of cases.

Recommendations:

1. 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.

2. **Substance identity** must be specified and documented for all relevant members of the category, including purity / impurity profiles. *Guidance for identification and naming of substances under REACH* should be applied. See also chapter 3.3.1 in this report.

3. 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.

4. 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. Also different routes of exposure should be taken into account. Studies on toxicokinetics may improve the robustness of the read-across hypothesis.

5. 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. It is also important that the reliability indicator (Klimisch score) reflects the *assumptions* of similarity. Thus, score 1 (reliable without restrictions) should normally not be used for results derived from read-across.

6. 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 Guidance on information requirements and chemical safety assessment in Chapter R.6: (Q)SARs and grouping of chemicals and in the Practical Guide 6: *How to report read-across and categories.*

3.1.3. Robust study summaries

A **robust study summary** is a detailed summary of the objectives, methods, results and conclusions of a full study report. It must provide sufficient information to make an independent assessment of the study and minimise the need to consult the full study report.

A **study summary** is a summary of the objectives, methods, results and conclusions of a full study report that provides sufficient information to make an assessment of the relevance of the study.

A key study is the most relevant study for an endpoint. The reliability indicator (Klimisch score) for a key study must generally be 1 or 2 (1 = reliable without restrictions, 2 = reliable with restriction, 3 = not reliable, 4 = not assignable).

The quality of robust study summaries and the level of detail in them were insufficient to make an independent assessment in a substantial number of cases.

Recommendations:

1. A robust study summary should always be provided for the key studies of a substance for which a chemical safety report is required (i.e. substances manufactured or imported in quantities of 10 tonnes p.a. or above).

2. The registrant should ensure that a study summary, at the very least, is provided for the key studies on substances below 10 tones p.a.; robust study summaries are preferred.

3. An adequate justification must be provided in the robust study summary for selecting a study as a key study.

4. A robust study summary should be provided for all studies that are used as part of a **weight-of-evidence** approach.

5. A robust study summary should be provided for non-key studies demonstrating a **higher concern** than a key study.

6. A robust study summary should be provided when the study gives **ambiguous results.**

7. A robust study summary should be provided when the study is performed according to **non-standard protocols.** Any significant deviations from the test guideline should be described and justified.

8. The identity of the test material and its relevance for the registered substance must be described in the robust study summary. See chapter 3.1.1. in this report.

9. The registrant should explain the relevance of the effects observed in the study for classification and labelling and for risk assessment.

10. In the "Applicant's summary and conclusions" field of the IUCLID endpoint study record, it should be made clear

    a. whether or not the quality criteria (validity, reliability, repeatability) have been fulfilled and
    b. which conclusions were derived from the underlying data.

11. The information contained in the robust study summaries must be consistent with the information provided in the chemical safety report.

12. A general rule for providing information in the robust study summaries is that more information is better.

Further information can be found in the *Practical Guide 3: How to report robust study summaries* and in the Guidance on Registration, section "*8.2.2.6.1 Guidance on when to provide a robust study summary or a study summary when filling the technical dossier with information on each specific endpoint*".

3.2. Risk assessment and risk management

For all registered substances, the registrant is obliged to provide guidance on safe use (e.g. first-aid measures, accidental release measures, exposure controls, personal protection measures, information on the disposal). In addition, for a substance manufactured or imported at volumes above 10 tonnes p.a., the registrant is obliged 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 substance is considered to be hazardous.

In a number of cases, the Agency identified shortcomings related to the risk assessment and the recommended risk management measures.

Recommendations:

1. The study providing the most relevant information on the effects of the substance should be selected as the key study for the identification of the DNELs[16] and PNECs[17].

    a. When selecting the key study, possible variables (e.g. conduct, adequacy, relevance of test species, quality of results, etc) should be taken into account. Normally the study or studies giving rise to the highest concern should be used to establish the DNELs or PNECs.
    b. If the study giving rise to the highest concern is not used, then this must be justified.

2. The registrant should apply the assessment factors described in the guidance for the derivation of the DNELs and PNECs; deviations from the guidance should be justified.

3. All the conditions under which a substance is used must be described in the chemical safety report.

4. All identified uses must be covered with exposure scenarios when exposure assessment is required.

5. All routes of exposure and hazard endpoints must be covered in the exposure assessment as well as all life cycle steps; if routes of exposure are identified as irrelevant this must be justified transparently.

6. The risk management measures should be realistic and compatible with the operational conditions described in the exposure scenarios.

7. For substances classified as skin sensitizers it is required to specify the material of the protective gloves used in the risk assessment, including the breakthrough time.

8. The proposed classification and labelling must correspond to the reported study results.

Further information can be found in: *Guidance in a Nutshell Chemical Safety Assessment*.

16 DNEL = Derived No Effect Level

17 PNEC = Predicted No Effect Concentration

3.3. Classification and labelling according to the CLP-Regulation

The recently adopted CLP[18] Regulation introduces new classification criteria and obliges companies apply these criteria from 1 December 2010. Registration dossiers submitted before 1 December 2010 must be updated without undue delay unless the proposed classification and labelling was already included according to these new criteria.

In a number of cases, the Agency observed that registrants did not include in the dossiers, Classification and Labelling as specified by the CLP Regulation.

Recommendations:

1. The Agency recommends that all registrants who plan to register a substance or update their existing registration dossier before 1 December 2010, include in dossiers the classification and labelling as specified in the CLP Regulation. This avoids the need for a dossier update by 3 January 2011[19].

2. When potential registrants place a substance on the market, which is not already registered (phase-in substances below 1000 t p.a.) they are obliged to notify the Agency of classification and labelling information for the substance as specified in the CLP Regulation by 3 January 2011.

[18] Regulation of the European Parliament and of the Council (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

[19] Article 40 of the CLP Regulation

REFERENCES

Information about ECHA:
European Chemicals Agency
(http://echa.europa.eu)

ECHA and events
(http://echa.europa.eu/news/events_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 of the European Parliament and the Council (EC) No 1906/2006 (REACH Regulation).

Regulation (EC) 1272/2008 on Classification, Labelling and packaging (CLP Regulation).

Substance Directive 67/548/EEC and Existing Substances Regulation (EEC) No. 793/93.

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

European Commission test method regulation
(http://eur-lex.europa.eu/)

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

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/)

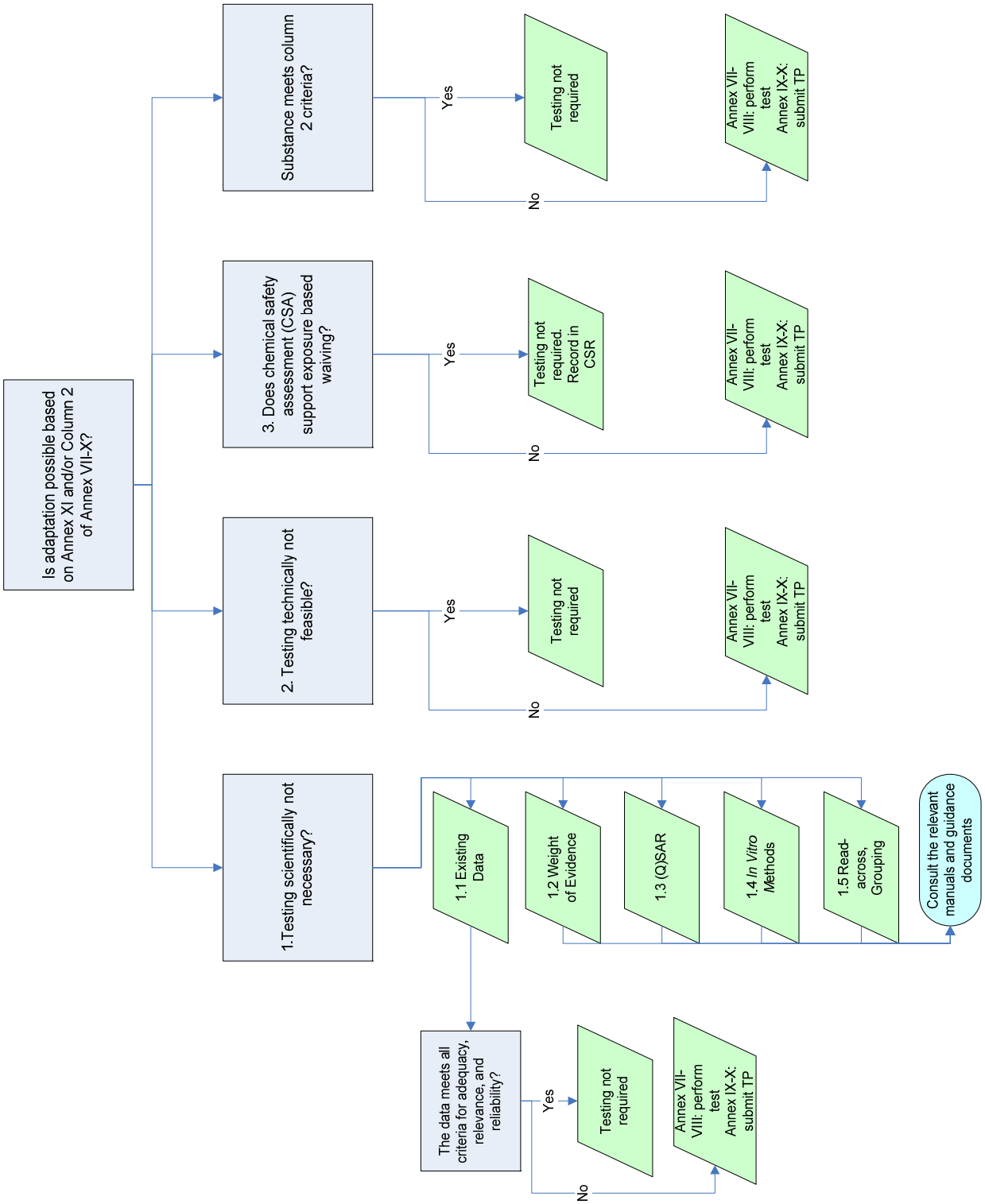
Priority existing substances before the REACH Regulation entered into force
(http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora)

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)

Webinars
(http://echa.europa.eu/news/webinars_en.asp)

Annex 1: Flowchart illustrating the options for waiving/adapting standard information requirements



Annex 2: Member State Committee

The Member State Committee is responsible for, among other things, resolving potential divergences of opinions on draft decisions proposed by the Agency and the Member States under Title VI, Evaluation, of the REACH Regulation. Each Member State has appointed one member to the Committee. The meetings of the Committee and its working groups are open to advisers, invited experts and observers. Representatives of certain stakeholder organisations are admitted to attend the meetings as observers.

Further information about the Committee work can be found in:
http://echa.europa.eu/about/organisation/committees/memberstate_en.asp

Annex 3: Finalisation of risk assessments for certain (29) existing substances

This list gives the names of the substances for which there are still pending data requirements and for which the designated Member State is going to prepare an updated risk assessment. The updated risk assessments will be published on the ECHA website: http://echa.europa.eu/chem_data/transit_measures/info_reqs_en.asp.

Any work completed on the priority existing substances before the REACH Regulation entered into force e.g. original risk assessment reports and Official Journal conclusions can be found on the ECB website: http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=ora

Einecs No	CAS No	Substance name	Rapporteur	Commission Regulation
287-477-0	85535-85-9	Alkanes, C14-17, chloro	UK	466/2008/EC
200-539-3	62-53-3	Aniline	DE	2592/2001/EC
281-018-8	83846-43-9	Benzoic acid, 2-hydroxy-, mono-C>13-alkyl derivs, calcium salts (2:1)	FR	465/2008/EC
201-622-7	85-68-7	Benzyl butyl phthalate	N	642/2005/EC
214-604-9	1163-19-5	Bis(pentabromophenyl)ether	UK/F	565/2006/EC 2592/2001/EC
208-764-9	541-02-6	Decamethylcyclopentasiloxan	UK	465/2008/EC
222-583-2	3542-36-7	Dichlorodioctylstannane	UK	465/2008/EC
254-052-6	38640-62-9	DIPN	SE	465/2008/EC
250-702-8	31565-23-8	Di(tert-dodecyl) pentasulphide	UK	465/2008/EC
239-622-4	15571-58-1	2-Ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	UK	465/2008/EC
248-227-6	27107-89-7	2-Ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]-thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	UK	465/2008/EC
284-578-1	84929-98-6	Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar′-di-C>13-alkyl derivs	FR	465/2008/EC
202-411-2	95-33-0	Ncyclohexylbenzothiazole-2-sulphenamide	DE	506/2007/EC

Einecs No	CAS No	Substance name	Rapporteur	Commission Regulation
231-111-4 232-104-9 222-068-2 231-743-0 236-068-5	7440-02-0 7786-81-4 3333-67-3 7718-54-9 13138-45-9	Nickel Nickel sulphate Nickel carbonate Nickel dichloride Nickel dinitrate	DK	466/2008/EC 565/2006/EC
202-696-3	98-73-7	Nitrobenzene	DE	466/2008/EC
256-798-8	50849-47-3	5-Nonylsalicylaldehyde oxime	NL	465/2008/EC
209-136-7	556-67-2	Octamethylcyclotetrasiloxane	UK	465/2008/EC
262-975-0	61788-44-1	Phenol, styrenated	UK	465/2008/EC
266-028-2	65996-93-2	Pitch, coal tar, high temp	NL	466/2008/EC
200-915-7	75-91-2	Tert-butyl hydroperoxide (TBHP)	NL	466/2008/EC
202-679-0	98-54-4	4-Tert-butylphenol	NO	466/2008/EC 506/2007/EC
246-619-1	25103-58-6	Tert.-Dodecanethiol	UK	465/2008/EC
262-967-7	61788-32-7	Terphenyl, hydrogenated	FIN	465/2008/EC
222-733-7	3590-84-9	Tetraoctyltin	NL	465/2008/EC
204-279-1	118-82-1	2,2′,6,6′-Tetra-tert-butyl-4,4′-methylenediphenol	AT	465/2008/EC
246-690-9	25617-70-8	2,4,4-Trimethylpentene	DE	466/2008/EC
250-709-6	31570-04-4	Tris(2,4-di-tertbutylphenyl) phosphite	UK	465/2008/EC
247-759-6	26523-78-4	Tris (nonylphenyl) phosphite	FR	466/2008/EC
237-410-6 239-148-8	13775-53-6 15096-52-3	Trisodium hexafluoroaluminate	DE	466/2008EC

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