Guidance on Dossier and Substance Evaluation

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LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. 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. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This guidance document describes the evaluation tasks to be performed by the Authorities under REACH: evaluation of testing proposals and compliance check by the Agency and substance evaluation by the Member States Competent Authorities. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

The legal reference for the document is the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006)

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1 GENERAL INTRODUCTION

1.1 About this guidance

This document provides technical guidance to the European Chemicals Agency (hereinafter referred to as "the Agency") and Member States involved in evaluation processes under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH). It will be also useful for registrants, downstream users and third parties to understand how the evaluation of registration dossiers and substances will be performed and decisions will be derived.

This document is intended to provide general guidance on how evaluations should be performed. It does not include in-depth guidance on technical issues; this is provided in other RIP guidance documents which are identified in the text.

1.1.1 Structure of the guidance

This introductory chapter provides general information on evaluation processes including a rough characterisation of the various actions. The duties and responsibilities of actors involved in the various steps of evaluation processes are described, and detailed information on the tasks is given in form of tables in the Appendices. A description of the main relations between the three evaluation processes as well as links to other parts/processes under REACH are provided to show how the individual processes fit into the broader context of REACH.

The guidance is made up of separate chapters addressing:

(i) the examination of testing proposals;

(ii) the compliance check of registrations;

(iii) the substance evaluation.

The chapters provide a short description of the processes and provide guidance on how to perform the evaluation tasks. The structure of the chapters is similar; they include information on the selection of dossiers/substances, possibilities for prioritisation as well as information on the applicability and suitability of a potential targeting of the evaluation process. Further flow charts illustrate certain aspects of the processes. At the end of each chapter, guidance on formats for presenting draft decisions is provided. Examples are based on experiences gained under the current legislative system and from projects such as SPORT (Strategic Partnership On REACH Testing). These examples may be theoretical or adapted to better illustrate certain points. As experience is gained under REACH, it may be necessary to add new examples to reflect new issues.

1.1.2 Who is the guidance for?

This guidance is primarily intended for use by staff in the Agency and within Member States competent authorities (MS-CAs) responsible for carrying out the evaluation tasks. It is assumed that suitable experience on chemicals risk assessment and management is available.

This guidance will also be useful for registrants, downstream users and third parties to better understand how the evaluation of registration dossiers and substances will be performed and decisions will be taken. Thus, it gives additional information that can help registrants and downstream user to meet their requirements under REACH.

More detailed information on the obligations of all actors is given in Section 1.4 and in Appendix 1.

1.2 Communication between the actors

Communication under REACH relies on electronic tools. All information will be held in a central REACH-IT database. If information needs to be transferred from registrants/downstream users to the Agency or from the Agency to registrants, competent authorities, etc., this will be done by accessing the REACH-IT system.

Informal discussion may take place between the person in charge of the evaluation and the manufacturer/importer or downstream user. The registrant or downstream user should identify in the registration dossier or the downstream user report the most relevant person (or persons) who should be in contact with the Agency in order to facilitate the discussion and access to the necessary information.

It should be noted that the term 'informal' is used throughout this guidance document to refer to contacts with registrants and in certain circumstances with downstream users aiming at voluntary submission of information. It should not be confused with the formal request for further information or the formal invitation for commenting on requests for further information under Articles 46, 50 and 52. Informal discussions are meant to be made in an unofficial form and should be performed using rapid communication tools like phone, e-mail or fax. No set rules or format apply to informal discussion. The authority performing an evaluation should decide upon the need, the resources and time to be allocated to such activities. In any event, informal communication should be recorded by the evaluator. In the case of telephone conversations, notes prepared by the authority may be shared with the registrant (or downstream user) as appropriate.

Experience from new and existing substance legislation has shown that a phone call or an e-mail can often help to clarify issues very quickly, while a formal procedure according to the legal text generally takes longer to achieve the same result. Such informal communication can contribute to an efficient evaluation of dossiers and substances. It is important that all information exchanged, even that through informal communication, should be documented and traceable. If the informal communication clarifies unclear issues, the outcome should in most cases be documented in an update of the registration dossier. Alternatively, the outcome will be used in the justification of the draft decision prepared by the Agency or the MS-CAs. Although informal communication may be very helpful in solving some issues, it should be kept in mind that a regular and extensive use can become time consuming. If informal communication is appropriate, and if so what kind of informal communication is best will of course depend on the case. Details for each of the three evaluation processes are outlined in Appendix 2 of this guidance.

1.3 Evaluation processes under REACH

The purpose of this section is to give an overview of the evaluation processes under REACH and their relations among and to other REACH processes. Flowschemes of all three evaluation processes as well as for each process individually can be found in the relevant chapters of the guidance document.

Evaluation under REACH (Title VI of the REACH Regulation) defines the assessment of registration dossiers (examination of testing proposals and compliance check of registrations) and substances.

The main objective of the examination of testing proposals is to check that reliable and adequate data are produced and to prevent unnecessary animal testing.

The purpose of checking a registration dossier for compliance is to ensure that the legal requirements of REACH are fulfilled and the quality of the submitted dossiers is sufficient, the safety assessment is suitably documented in a Chemical Safety Report (CSR) as required in the REACH Regulation, the proposed risk management measures are adequate, and that any explanation to opt out from a joint submission of data has an objective basis.

Substance evaluation aims to clarify any grounds for considering that a substance constitutes a risk to human health or the environment. Furthermore Article 49 in Title VI foresees the possibility to request information on on-site isolated intermediates (for which neither dossier nor substance evaluation applies), if certain conditions are fulfilled. A substance evaluation may result in a decision that further information is needed for the registrant to properly assess the safe use of a substance. Any information obtained shall be considered by MS-CAs for its suitability for preparing an Annex XV dossier to propose and justify the identification of a substance of very high concern, to initiate the restriction of the manufacture, placing on the market or use of a substance within the Community, and/or to propose a harmonised classification and labelling. In some cases it may be more appropriate to have follow-up actions under other legislation (see Section 3.5).

1.3.1 Dossier evaluation

Dossier evaluation is performed by the Agency (i) to examine any proposal for testing (Article 40) to ensure that unnecessary animal tests and costs are avoided and test results are relevant for the chemical safety assessment process, and (ii) to check the compliance of a registration dossier with the registration requirements (Article 41). Flow charts and tables in chapter 2 on dossier evaluation (examination of testing proposals and compliance check of registrations) illustrate the process of how to adopt a decision and how much time this will take (Articles 50 and 51).

1.3.1.1 Examination of testing proposals

All proposals for tests specified in Annexes IX and X submitted as part of registrations or downstream user reports **have to** be examined and a decision drafted within certain timelines (Article 43). Detailed information on how to conduct the examination of testing proposals, decide whether a proposed test is justified or adequate, what to do when unnecessary tests are proposed, and how to draft a decision, is provided in Section 2.1 of this guidance document.

1.3.1.2 Compliance check

The Agency may examine any registration dossier in order to check whether the registrants have met their obligations and the dossier complies with the provisions of REACH. Discussion on the selection of dossiers can be found in Section 2.2.2. Additional priority criteria for the selection of registration dossiers will be developed in the Guidance on priority setting for evaluation.

A compliance check examines whether all required information is included in the dossier, and whether this information is adequate. Any part of a registration dossier may be checked, however, it may be efficient in some cases to target a compliance check on certain parts. The circumstances

under which targeting is useful and how a targeted compliance check could be performed are described in Section 2.2.3. The result of a dossier evaluation may be a decision on a request for further information.

1.3.2 Substance evaluation

The general substance evaluation process (see Figure 4), the compilation of the Community rolling action plan (Article 44) and the allocation of substances between the Member States (Article 45 procedure) are described and illustrated in chapter 1.

For the performance of a substance evaluation the Agency relies on MS-CAs. The evaluation aims to clarify a concern that a given substance constitutes a risk to human health or the environment. Therefore, all registration dossiers submitted for the same substance are as far as relevant examined together and any other relevant information available is taken into account. Substance evaluation does not focus only on substances but also on break-down products and takes into account suspicion from structural alerts/similarities to other substances of concern.

The coordination of the evaluation process falls under the responsibility of the Agency. The Agency in cooperation with Member States will develop criteria to select substances using a risk-based approach. The Guidance on priority setting for evaluation will provide the criteria for prioritising which substances should be fed into the substance evaluation process. A targeted approach may be applied, focusing on the relevant issues but taking care to address all grounds for considering that the substance constitutes a risk. Reasons for concern which may lead to a targeted substance evaluation, together with procedures for carrying this out, are outlined in this guidance document (cf. Section 3.2).

Within 12 months of the publication of the Community rolling action plan on the Agency's website (Article 46), a substance evaluation shall be completed. However, if further information is requested formally from the registrant or in certain circumstances the downstream user by a given deadline, the substance evaluation shall finish 12 months after the information was submitted (see Table 8).

Substance evaluation is not a stand alone process. Information obtained from the evaluation process should be considered for identification of substances of very high concern (Article 59(3)), restriction (Article 69(4)) and harmonised classification and labelling (Article 115(1)) procedures. In certain cases it may however be more appropriate to use the information for risk management procedures under other Community legislation (for details see Section 3.3).

1.3.3 Links between evaluation processes

In general, the three evaluation tasks (testing proposal and compliance check within dossier evaluation, and substance evaluation) are to be considered independently. However, certain links are evident, and results and information obtained in the different tasks should be used and linked in an intelligent manner, particularly to avoid any duplication of work between the Agency and MS-CAs. To ensure a good coherence between the evaluation processes it is important to document the information available. Annotations are foreseen in IUCLID 5 giving the authorities concerned with the evaluation processes an opportunity to document their comments on and add their remarks to the information stored in IUCLID. Duplication of work could also be avoided if the report resulting from a substance evaluation is filed to the appropriate part of the REACH-IT to make the information within this report available e.g. to other MS-CAs for future work on the same substance

(cf. Section 3.5.1). At the moment REACH-IT is being developed and the final tools are not available.

1.3.3.1 Examination of testing proposals - compliance check

There is no automatic link between the examination of testing proposals and the compliance check of registrations which are the two parts of the dossier evaluation. In fact examination of testing proposals and compliance check are two separate processes. However, a dossier can be evaluated for testing proposal(s) and also be selected for a compliance check. In addition, the examination of a testing proposal could result in a check on some relevant sections of the CSR or different studies included in the technical report. Hence, all the steps undertaken during the examination of testing proposals should be properly documented in order to avoid any duplication of this work if the dossier is selected for a compliance check.

1.3.3.2 Compliance check - substance evaluation

Compliance check and substance evaluation are processes that can in principle start independently, one after the other, or even in parallel.

Where a compliance check is carried out first, any information obtained as a result of this evaluation process shall be taken into account by MS-CAs in order to conclude whether there is concern that the substance constitutes a risk to human health or the environment. For this reason annotations as proposed in IUCLID 5 should be used. In case of a risk the MS-CA shall highlight the substance to the Agency for addition to the Community rolling action plan for further evaluation. Substance evaluation should be based on valid information in order to ensure the quality of the assessment. Therefore a quality check of the relevant dossier(s) is regarded as being a basis for substance evaluation.

Registration dossiers for substances on the Community rolling action plan are, according to Article 41(5)(c), prioritised for compliance check. The highest priority should be given to those dossiers which fulfil at least one of the criteria mentioned in Article 41(5); further priority criteria for dossier selection can be found in the Guidance on priority setting for evaluation. The deadline for both procedures is 12 months. Therefore, a compliance check (by the Agency) and substance evaluation (by the MS-CA) can run in parallel and the result of the compliance check may not necessarily be available before the substance evaluation begins. In order to promote that the results of a compliance check are available in a suitable timeframe, the Agency should prioritise the relevant dossier(s) for a compliance check as soon as the substance is known to be put on the draft Community rolling action plan.

The MS-CA shall, before formally starting a substance evaluation, get information on the status of the dossier(s) regarding compliance check. Ideally the result of a compliance check should be available during the earliest stage of evaluation and duplication of work should be avoided. The Agency will make available to MS-CA's a list of dossiers for which the compliance check has been started (Article 41(2)). However, it may be useful for a Member State to contact the Agency in order to get information on the future time plan. It should be noted that more than one dossier might be available for one substance. If a compliance check(s) of the dossier(s) for the substance is/are not available, and the MS-CA concludes that a compliance check should be conducted, they should discuss the procedure with the Agency. Where a MS-CA wants to start a substance evaluation and no compliance check is available, the MS-CA needs to perform a quality check of the dossiers itself. A compliance check performed by the Agency is not a precondition for starting a substance evaluation by a MS-CA. Also, in this case the MS-CA and the Agency shall be in dialogue to avoid

duplication of work and to ensure consistency. More details on links of these evaluation tasks are given in compliance check and substance evaluation chapters of this guidance document.

1.3.3.3 Examination of testing proposals – substance evaluation

The same links that can be made between the examination of testing proposal and compliance check can also be identified between testing proposal and substance evaluation. Indeed, during the stage of testing proposal examination, a partial check of relevant parts of the CSR and/or the technical report might be performed. Consequently, to avoid unnecessary duplication of work, it is important that any remark on the quality of parts of the registration dossier made during the evaluation of testing proposal is reported via annotations in IUCLID 5 and is taken into account by the MS-CAs in their substance evaluation.

The Agency has to prepare draft decisions on the testing proposals within certain time periods (Article 43). For non phase-in substances draft decisions shall be prepared within 180 days of receiving a registration or a downstream user report containing a testing proposal. Time periods for phase-in substances are substantially longer (within 2 to 4 years of receiving a registration depending on the volume band). In view of the long time periods, a substance evaluation may start before a decision has been taken regarding a proposed test or before testing results have been submitted. Test result(s) may be crucial for the substance evaluation. Therefore, the MS-CA evaluating a substance needs to contact the Agency to agree on the best way forward.

1.4 Actors and responsibilities

This section gives an overview of the actors involved in evaluation procedures and their duties. Compared to chemicals legislation under NONS and ESR, actors and responsibilities have changed considerably. The new central European Chemicals Agency (cf. Title X of the REACH regulation) in Helsinki is a new actor in the field, with the Member State Committee (MS Committee) taking up part of the tasks of the Technical Committee on New and Existing Chemicals (TC NES), and the Committee for Risk Assessment which shall, amongst others, be responsible for preparing the opinion of the Agency on evaluations, etc. There is a need for all actors to become familiar with their roles and their obligations under REACH.

Under Title VI of the REACH regulation, the actors' obligations for evaluation are summarised as follows.

The European Chemicals Agency

- To examine **testing proposals** submitted for tests contained in Annexes IX and X.
- To **check compliance** of information in selected registration dossiers with the requirements of the Regulation.
- To **draft decision(s)** regarding testing proposals and compliance check.
- To use the information from dossier evaluation for prioritising substances for further evaluation and to add these substances to the **Community rolling action plan.**
- To manage the decision making process, and to coordinate the substance evaluation process and the general information flow between the actors.

Member State competent authorities

- To cooperate with the Agency in order to develop criteria for prioritising substances for evaluation.
- To comment on draft decisions from dossier and substance evaluation.
- To use the information from dossier evaluation for proposing substances to be added to the Community rolling action plan for **substance evaluation** and for preparing an Annex XV dossier for the purpose of **identification of substances of very high concern, restriction, and harmonised classification and labelling.**
- To conduct a **substance evaluation** when a substance is on the Community rolling action plan.
- To **draft decisions** under substance evaluation and contribute to the decision making process on requesting further necessary information to be submitted by registrants and, in rare cases, by downstream users.

Member State Committee

- To come to **agreements** for decisions on evaluation.

Commission

- If necessary, to decide to vary the percentage of dossiers to be selected for compliance check and the criteria for prioritisation
- To adopt implementation measures if appropriate (Article 47(2))
- To take final decisions on dossier and substance evaluation in case of no agreement within the MS Committee

Registrant(s) or downstream user(s)

- To react to (draft) decisions by commenting, clarifying, updating the dossier with new information or corrections, to generate requested information or to cease the manufacture or import, and inform the Agency accordingly.

The **Agency** manages the information exchange between registrant(s) or downstream user(s), MS-CAs, MS Committee and the Commission, and will provide scientific and technical guidance. The evaluation of dossiers (testing proposal and compliance check) is conducted by the Agency.

For dossier evaluation, the Agency selects registration dossiers taking into account criteria for prioritisation as outlined in the Guidance on priority setting for evaluation and any available information submitted by MS-CAs or other third parties. Communication with MS-CAs will be crucial in order to coordinate evaluation tasks allocated between the Agency and Member States. The Agency may draft a decision as a result of a dossier evaluation, and communicate with the registrant, Member States and if necessary with the MS Committee and the Commission in order to come to a final decision on further information needs.

The Agency is also responsible for coordinating the substance evaluation process. In cooperation with the MS-CAs the Agency develops risk-based priority criteria for the selection of substances. The Agency will compile, update and make available a Community rolling action plan and will ensure that each substance on that list will be evaluated by a Member State. The Agency also serves as the interface for communication between registrant(s), downstream user(s) and Member States and, if necessary, the MS Committee and the Commission in order to come to a final decision

regarding a request for further information. Moreover, the Agency will monitor draft decisions to ensure consistency in requests for further information at Community level.

If required, the Agency will designate one registrant or downstream user to perform the required test(s) on behalf of other registrants. The Agency will coordinate any follow up activities such as authorisation or restriction procedures.

Detailed information on the tasks and responsibilities of the Agency is listed in Appendix 1 (Table 9).

Under dossier evaluation, the role of **MS-CAs** is to examine decisions drafted by the Agency and, if appropriate, to propose any amendments. However, if a MS-CA becomes aware that a dossier may not be in compliance, it shall highlight this dossier for priority selection by the Agency for a compliance check.

MS-CAs shall take into account further information obtained from registrants or downstream users as the result of a dossier evaluation when proposing substances for addition to the Community rolling action plan or for the preparation of an Annex XV dossier to propose and justify the identification of a substance of very high concern, to propose a harmonisation of classification and labelling, and/or to propose the restriction of the manufacture, placing on the market or use of a substance within the Community (Article 42).

While the Agency coordinates the substance evaluation process, MS-CAs are responsible for carrying out the evaluation of selected substances from the Community rolling action plan. However, another body can be appointed to act on behalf of the MS-CA, and therefore working under the same conditions as the MS-CA, including the protection of information that has been agreed to be treated as confidential. As a result of a substance evaluation, the MS-CA may draft a decision to request further information taking into account comments from registrant(s), downstream user(s) and other Member States. The MS-CA shall conclude on how to use any information obtained (i.e. follow up activities, for details see chapter 1).

Detailed information on the tasks and responsibilities of MS-CAs are outlined in Appendix 1 (Table 10).

The tasks of the **MS Committee** with respect to evaluation procedures are to form an opinion on the draft Community rolling action plan presented by the Agency (Article 44(2)), to decide on who should be the competent authority in case of disagreement between Member States, and to come to an agreement on any amendments to a draft decision made by MSs as laid down in Articles 51 and 52.

The role of the **Commission** is to take a decision in accordance with the procedure referred to in Article 133(3) when the MS Committee does not reach unanimous agreement. It may also decide to vary the percentage of dossiers selected for compliance check, and amend or include further criteria (Article 133(4)).

Registrants and downstream users have the right to comment on draft decisions related to requests for further information and to cease manufacture or import in response to a (draft) decision, informing the Agency accordingly. When a decision is taken, the registrant or downstream user has to submit the information by the deadline set. In the case of multiple registrants or downstream users, they have to agree who is going to carry out testing on behalf of all registrants and/or downstream users and to share the costs of testing equally. Registrants have the right to appeal against an Agency decision. Whenever relevant new information is available to a registrant, they are obliged to update their registration dossier without delay. Under the evaluation process this includes

information given in the form of draft decisions which may trigger the update of the registration dossier, or even via informal consultation with the Agency or MS-CA. See also Section 1.2 as well as Appendix 2.

Detailed information on the tasks and responsibilities of the MS Committee, Commission, registrants and downstream users are outlined in Appendix 1 (Table 11, Table 12 and Table 13, respectively).

In addition **third parties (**for example **scientists, other institutions, NGOs)** may have a role in providing additional information to be used for evaluation activities.

In all three evaluation processes one possible result is a decision requesting the registrant(s) to submit specified information within a set time. There could also be cases where the registrant would be justified in asking for more time due to circumstances beyond their control. The authorities are asked to take into account the time constraints for the registrant(s) when setting the deadlines for the submission of further information. Informal communication between the evaluating authorities and the registrants should clarify the time needed depending on the information requested.

Nevertheless cases could occur where a registrant simply does not supply the information requested without any acceptable reason. In this case enforcement procedures are addressed by MS-CA(s). A formal extension of the deadline set requires a new decision which has to be taken by the Agency according to the procedure outlined in Articles 51 and 52

1.5 Interactions between different REACH processes

This section explains how evaluation is linked with other REACH processes and gives references to other relevant RIP guidance documents.

The information gained through an evaluation process should be used by registrants and downstream users to manage the risks related to their substances and to update their registration dossiers or downstream user reports. However, this information may also be used for follow up actions, e.g. for the purpose of classification and labelling, the identification of substances of very high concern or the initiation of a restriction procedure as foreseen under REACH or, if more appropriate, risk management procedures under other Community legislation.

1.5.1 Registration – Evaluation

Evaluation relates to registration dossiers. Hence only substances for which a registration dossier exists can be subject to an evaluation.

In accordance with Article 6(1) and 7(1) of the Regulation, any manufacturer or importer of a substance, either on its own or in preparation(s), or in an article if intended to be released and not yet registered for that use, in quantities of 1 tonne or more per year shall submit a registration to the Agency. Manufacturer and importer of isolated intermediates shall also submit a registration. For on-site isolated intermediates used under strictly controlled conditions the information requirements are reduced (Article 17 and 18). And neither dossier nor substance evaluation shall apply. (see also chapter 3.6). When a registration dossier is received, the Agency will do a completeness check which is an automated process and does not constitute any check of quality of the submitted dossier. Dossier evaluation enables a quality check of the complete or certain elements of the registration dossier.

The evaluation may require an update of the registration after additional or more detailed information is submitted. This means that the registrant is obliged to update the registration dossier with the information generated under the evaluation procedure. In case the set deadlines have been exceeded or the requested information has not been provided in acceptable quality by the registrant, adequate enforcement activities may have to be taken.

The amount of information available when starting a substance evaluation process will depend on the status of the substance in REACH. Although all information available shall be taken into account, one of the main information sources for evaluation will be the registration dossiers.

1.5.2 Evaluation – Restriction/Authorisation/harmonised classification and labelling

The results of the evaluation may in principle trigger restriction and/or authorisation procedures as well as proposals for harmonised classification and labelling. Whereas the main idea behind the substance evaluation is to get appropriate further information to clarify an initial concern, and then consider how to use any information obtained for the purpose of restriction, identification of substances of very high concern or harmonised classification and labelling, the compliance check is intended to only check the quality of a dossier. Thus it is stressed that it is not the aim of a compliance check to identify candidates for restriction/authorisation/harmonised classification and labelling, although new information obtained after dossier evaluation may finally be used for that purpose.

The information obtained through evaluation can be used for the preparation of an Annex XV dossier (i) to propose and justify the identification of a substance of very high concern and (ii) to propose the restriction of the manufacture, placing on the market or use of a substance within the Community, and/or (iii) to propose a harmonised classification and labelling. For example, hazard or use and release/exposure information can be used as a way to increase the information available for a restriction dossier (one type of Annex XV dossier). As sufficient information has to be obtained before the formal submission of the Annex XV dossier, substance evaluation is the procedure to obtain the relevant data for that dossier from the registrant. However, there is no obligation to do a substance evaluation before the compilation of an Annex XV dossier. Performing a substance evaluation for substances that are already listed in Annex XIV (list of substances subject to authorisation) will only be useful if there is another concern that was not covered before.

Evaluation, restriction, identification of substances of very high concern and harmonised classification and labelling procedures should be regarded as entirely independent of each other. This means that for example a procedure for a harmonised classification and labelling can be directly initiated without a prior evaluation procedure. During the preparation of an Annex XV dossier, it may be concluded that registration dossier(s) are not in compliance with the registration requirements. The Member State should point this out to the Agency to initiate a compliance check. Substance evaluation could be started if a need for more information is recognised during Annex XV dossier preparation.

Further information on the specific requirements of such follow-up procedures and the preparation of an Annex XV dossier for that purpose is developed in the Guidance on Annex XV for C&L, the Guidance on identification of SVHC and the Guidance on Annex XV for restrictions. Some of that guidance may be particularly useful to carry out parts of the substance evaluation, in terms of justifying a request for further information based on review of the available data and on risk assessment.

1.5.3 Who will perform the test and cost sharing

When a decision under dossier or substance evaluation requires that a test is performed which involves several registrants and downstream users they need to agree on who shall perform the test and how to share the costs. The Agency shall be informed within 90 days about who is to perform the test, otherwise it shall designate one of the registrants or downstream users as responsible for performing the test. Article 53 deals with the sharing of costs and information when no agreement is reached between registrants and downstream users. An arbitration board may be used to decide on claims for remuneration. If agreement cannot be reached on cost sharing then national courts shall enforce the claim. The procedures for cost sharing are beyond the scope of the present guidance document and will be developed in Guidance on data sharing.

2 DOSSIER EVALUATION

2.1 Examination of Testing Proposals

2.1.1 Scope and purpose of testing proposals as foreseen under REACH

The main objective of the examination of testing proposals is to investigate whether the information requirements according to REACH are fulfilled, and if the proposed studies are appropriate and will increase the knowledge of the dangerous properties of chemicals in order to protect human health and the environment, while at the same time preventing unnecessary animal testing and costs.

According to Article 40 all proposals for tests specified in Annexes IX and X submitted as part of registrations or in downstream user reports **have to** be examined and a decision drafted by the Agency.

Testing should only be necessary when information on the dangerous properties is needed for compliance under REACH, i.e. when the registrant considers it necessary to obtain additional information to allow them to assess and document that risks are adequately controlled. Consequently Annex XI, as well as specific adaptation rules in Annexes VII to X, has been developed with a view to keeping animal testing to a minimum.

Two main aspects in relation to examination of testing proposals can be identified.

- Whether the proposal complies with the standard testing requirements.
- Whether reasons for proposing additional testing for endpoints beyond the standard testing requirements are appropriate.

Depending on the outcome of the examination of the testing proposal the Agency shall draft one of the following decisions (Article 40(3)):

(a) *a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;*

(b) *a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;*

(c) *a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;*

(d) *a decision rejecting the testing proposal;*

(e) *a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.*

For non phase-in substances a decision shall be drafted within 180 days of receiving a registration or downstream user report containing a testing proposal. For phase-in substances the deadlines are substantially longer. The Agency shall draft a decision within 5.5, 9 and 15 years for those dossiers which have been submitted within 3.5, 6 and 11 years respectively after entry into force of REACH.

All testing proposals have to be examined and decisions drafted within the above deadlines. Priority will be given to substances which have or may have persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), sensitising, and/or carcinogenity, mutagenicity and toxicity for reproduction (CMR) properties, or substances produced and/or imported in quantities above 100 tonnes per year, classified as dangerous and with uses resulting in widespread and diffuse exposure (Article 40(1)).

The final decision will be taken in accordance with the procedure laid down in Articles 50 and 51 (see Figure 1) and will take at least 30 days to allow for any comments by the registrant or downstream user. The procedure can take up to more than 6 months in cases where MS-CAs propose to amend the decision drafted by the Agency. The Commission will take the final decision if the MS Committee fails to reach unanimous agreement within 60 days of the referral. For this procedure no fixed deadline is set (see Table 1). A flow chart illustrates the process in detail (see Figure 2).

The Agency decision should take into account an appropriate time frame when setting deadlines. The registrant should be pro-active and inform the Agency in time if he cannot meet the deadline set. If the test requested by the final decision is not submitted within the specified deadline, the Agency has to decide whether a new decision should be taken or the enforcement authorities will be informed to consider possible further action.

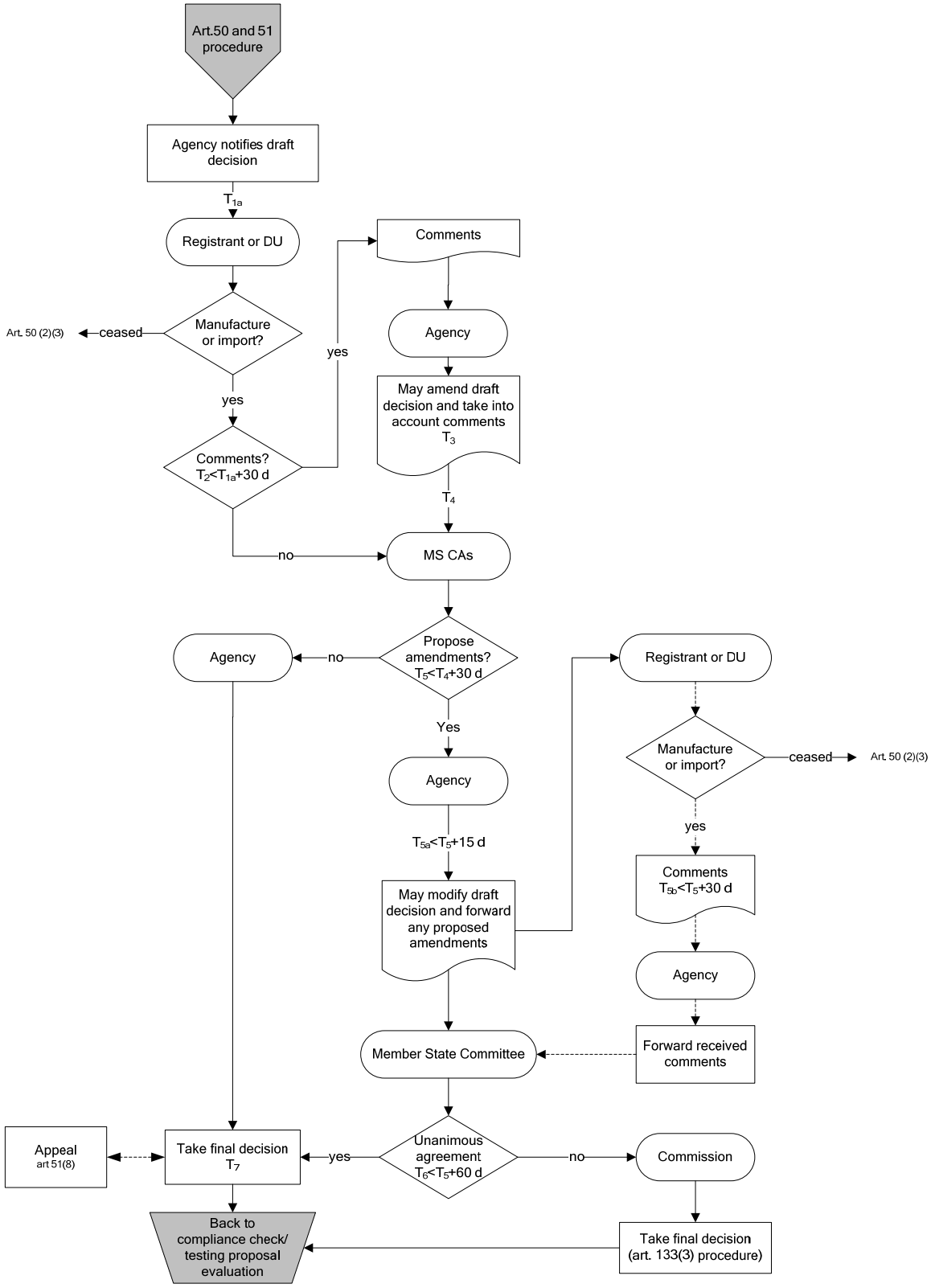

Figure 1 Article 50 and 51 procedure.

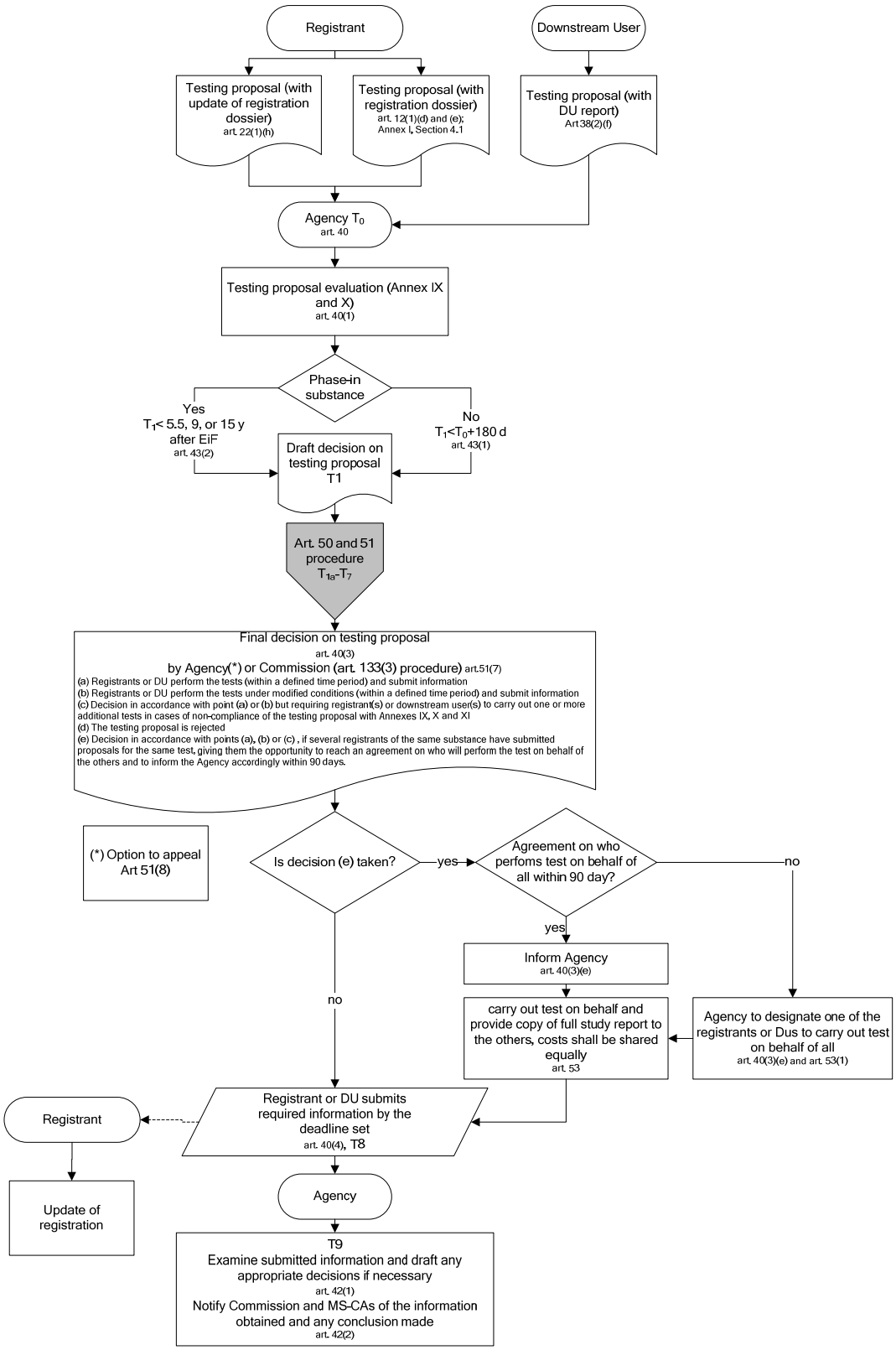

Figure 2 Examination of testing proposals.

Table 1 Time periods for examination of testing proposals

Time	Process	Actor	Period
T0	Receive registration dossier including the testing proposal	Agency	
T1	1. Ranking of substances to be evaluated with priority for CMR, PBT, vPvB etc (Article 40(1)) 2. Examination of testing proposals 3. Draft a decision (Article 40(3))	Agency	Non phase-in substances: within 180 days after receipt Article 43(1) Phase-in substances: within 5.5, 9, or 15 years after entry into force (EiF), depending on volume band. Article 43(2)
T2	Comment on draft decision (Article 50(1))	Registrant/DU	30 days
T3	May amend draft decision and take into account comments (Article 50(1))	Agency	Not specified
T4	Notify draft decision together with any comments to MS-CAs (Article 51(1))	Agency	Not specified
T5	Propose amendments (Article 51(2))	MS-CAs	30 days
T5a	May modify draft decision and forward any proposed amendments to MS Committee (Article 51(4))	Agency	15 days
T5b	Comment (Article 51(5))	Registrant	30 days
T6	Conclusion (Article 51(6))	MS Committee	60 days
T7	Take final decision acc. to Article 51(6) and 52(2) or Article 133(3) procedure (Article 51(7))	Agency/ Commission	Not specified
T8	Submit the information required to the Agency by the deadline set (Article 40(4))	Registrant	Within adequate time period to be set
T9	Notify Commission and MS-CAs of the information obtained and any conclusion made (Article 42(2))	Agency	Not specified

2.1.2 Prioritisation of examination of testing proposals

According to Article 40(1), the Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which:

– have or may have PBT, vPvB, sensitising and/or CMR properties, or

– substances classified as dangerous according to Directive 67/548/EEC produced or imported above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

When evaluating the testing proposals submitted, the Agency should also give priority to substances subject to substance evaluation.

Prioritisation of dossiers is dealt with in the Guidance on priority setting for evaluation.

2.1.3 Guidance when several testing proposals are submitted on the same substance

Aim: The objective is to explain how the Agency will examine testing proposals received on the same substance by several registrants or downstream users.

Task: The Agency will have to carry out the following actions.

- Gather the different registration dossiers.
- Check if substances are the same
- Check the justification for separate submission in the different registration dossiers.
- Examine the submitted testing proposals.
- Agree on the best way forward and decide with the registrants and downstream users who will be in charge of the test performance.

As there may be more than one registration dossier for the same substance (as defined in the Guidance on substance identification) it is also possible to have several testing proposals for the same substance. This will be particularly true in cases where different registrants of the same substance are not part of a consortium, or when a downstream user notifies its use separately. There may be cases where substances appear to be the same but show different hazard profiles. Testing has to be carried out individually for these substances if this is relevant for the endpoint.

Where separate submissions have been made, they may propose the same or different tests in order to fill the information gaps. Therefore, for certain chemicals the number of testing proposals could be relatively high and not all of them may be needed, as the result of one test may render other testing unnecessary. In order to limit testing and to be consistent in the evaluation of the different testing proposals, the Agency has to be very careful when looking at different testing proposals for the same substance in order to determine the best testing strategy. The possibility of applying a conclusion according to Article 40(3)(e) should be checked (see also section 2.1.6.5).

It is highly recommended that, where possible, all testing proposals submitted for the same substance should be examined at the same time (see the Guidance on data sharing).

2.1.3.1 Checking if substances are the same

Whether or not the substances from different registrants or downstream user can be regarded as the same is essential when deciding on testing proposals. Even if the substance appears to be the same, different types and/or concentrations of impurities can lead to a significant difference in the hazard profiles that it is required to carry out testing for all substances. Rules and guidance on this issue is given in the Guidance on substance identification.

2.1.3.2 Clarification of the need for separate submission

Firstly the Agency has to decide if only a single test needs to be performed by one registrant on behalf of the others, or if all registrants should carry out the tests they have proposed. Therefore, the Agency has to check if the justification for separate submission is justified. In most cases, it might be more appropriate to evaluate the justification for separate submission at the same time when examining the testing proposals.

Several registrants

In the case of several registrants, who have provided all the information required in Article 10 of the REACH Regulation separately, the Agency has to check if the explanation given for separate submission in the registration dossier is in agreement with Article 11(3).

If, based on the justification given by the registrants for separate submission, it is acceptable for the Agency not to request agreement for one testing proposal, then the Agency will have to examine all testing proposals and the tests will have to be performed separately.

Nevertheless it may also be possible, where separate submission of dossiers has taken place, for the Agency to take the decision that only one test needs to be performed. In this situation, the Agency has to inform all registrants that they should agree on the best way to perform the testing proposal and encourage them to agree on who will perform the test. It is recommended to first examine the different testing proposals received in order to facilitate the discussion with the registrants. Depending on the cases, the different testing proposals submitted could be similar or very different which will lead to informal discussion between the Agency and the several registrants before drafting a formal decision.

Downstream users

When the Agency receives the same testing proposal for the same substance from a downstream user and also from the main registrant, the Agency has to proceed in a similar way as is recommended in the case of several registrants. Usually, downstream users will be part of a consortium, the exception being when they have decided to notify their use separately. In this case, according to Article 38(2)(f), the information reported by a downstream user will include a proposal for additional testing on vertebrate animals where this is considered necessary to complete their chemical safety assessment.

It is nevertheless possible that this testing proposal is the same as the one submitted by the main registrant, in which case seeking agreement between the two is highly recommended.

2.1.3.3 Examination of testing proposals

Examination of testing proposals shall follow the guidance developed under Section 2.1.6.

2.1.3.4 Agreement between registrants and downstream users

Once the testing strategy is clarified internally at the Agency, informal discussion with the different registrants and downstream users should take place in order to try to reach an agreement between them on the strategy, on who will perform the different tests and how the costs will be shared. In order to facilitate the exchanges with the registrants or downstream users, the Guidance on data sharing should be consulted.

If agreement is not reached, the Agency shall designate one of the registrants or downstream users to perform the test on behalf of all of them.

2.1.4 Guidance when testing proposal(s) are submitted as part of a joint submission

The Agency has to check the justifications for the joint submission focussing on the substance identity. In addition the applicability and adequacy of a read across or category approach have to be checked. There may be cases where the substance identity is the same but the hazard profile is different due to a variable composition or impurities. Therefore guidance on data sharing should be considered as well. The critical point to check is that the data in the lead dossier are relevant to the related dossier, i.e. that the substance as defined in the related dossier is similar enough to that in the lead dossier for any differences in composition not to affect the relevance of the data.

If the substances are not identical and a joint submission is not justified, this is in fact a compliance issue. The dossiers shall be highlighted for a future compliance check. Testing has to be carried out for all substances that are not considered to be the same and draft decisions prepared accordingly.

2.1.5 Endpoint specific information for a testing proposal

2.1.5.1 Physicochemical information suggested in a testing proposal

Information on physicochemical properties is often essential in understanding the fate of the substance in the environment or the most probable exposure route for humans. It is expected that in most cases these data will already be available in the registration dossier or that there will be submission of a testing proposal.

The information required under Annex IX (NB: Annex X does not require any additional physicochemical information) is:

- Stability in organic solvents and identity of relevant degradation products (Annex IX, 7.15);
- Dissociation constant (Annex IX, 7.16); and
- Viscosity (Annex IX, 7.17).

From experience it is considered very unlikely that a testing proposal for physicochemical information would be rejected as in most cases this information will be needed in order to improve the knowledge of the chemical and to focus on the most relevant and specific higher level studies for both the environment and human health. Therefore the decision of Article 40(3)(d) should not be a conclusion in such situations. However there might be cases where this decision applies, particularly when the specific rules for adaptations in column 2 of Annex IX have not been taken into account by the registrant or the downstream user.

The sections of the registration dossier and CSR that might be considered in the evaluation of a testing proposal for a physicochemical endpoint are listed in Table 2.

Table 2 Registration/Technical dossier and CSR sections relevant for physicochemical endpoints

Topic	Sections in Technical dossier	Sections in CSR
Identification of substance	Section 2 (chapter 1)	Part B, Section 1
Physicochemical properties	Section 7 (chapter 2)	Part B, Section 1

2.1.5.2 Human health toxicity information suggested in a testing proposal

Requirements for toxicological information can be divided into four main information types:

- Repeated dose toxicity (Annex IX and X, 8.6): short-term toxicity, sub-chronic toxicity, long-term repeated dose toxicity.
- Reproductive toxicity (Annex IX, 8.7 and Annex X 8.7): (pre-natal) developmental toxicity, two-generation reproductive toxicity study.
- Carcinogenicity study (Annex X, 8.9.1).
- Additional studies regarding genotoxicity, toxicity of a particular concern if available evidence is inadequate for toxicological evaluation and/or risk characterisation (e.g. immunotoxicity, neurotoxicity) – (Annex X).

In the majority of cases a testing proposal will be submitted in order to fulfil the requirements of REACH when the tonnage of a substance produced or imported in Europe reaches the trigger for Annexes IX or X requirements. A testing proposal might also be submitted in order to gain more information on the toxicity of the substance in different cases, as in the following examples.

- The available information on an endpoint is inconclusive on the hazard.
- Further testing is triggered by structural alerts.
- The chemicals safety assessment (CSA) indicates that there is a risk and therefore the Derived No-Effect Level (DNEL) needs to be refined.
- There is a need to identify or refine the assessment of a certain hazardous property and this could have an impact on the classification and labelling of the substance.

Testing strategies have been developed in the Guidance on information requirements for these different situations and the Agency should refer to this guidance in order to evaluate whether there is a need for more information on the toxicity of the substance based on the data already available in the registration dossier.

The different sections of the registration dossier and CSR that might be considered in the examination of a testing proposal for human health information are listed in Table 3.

Table 3 Registration/Technical dossier and CSR sections relevant for human health endpoints

Topic	Sections in Technical dossier	Sections in CSR
Identification of substance	Section 2 (chapter 1)	Part B, Section 1
Physicochemical properties	Section 7 (chapter 2)	Part B, Section 1
Classification and labelling	Section 4 (chapter 1)	Part B, Section 3
Toxicological information	Section 8 (chapter 5)	Part B, Section 5
Exposure assessment for humans	Section 3 (chapter 1)	Part B, Section 9
Risk characterisation for human health	(chapter 10)	Part B, Section 10

Specific examples have been developed following the checklist available in Section 2.1.6.3 in order to illustrate the different steps needed in the evaluation of a testing proposal related to human health information. These examples are available in Appendix 3.

2.1.5.3 Environmental information suggested in a testing proposal

Requirements for environmental information can be divided in two main information types.

- Ecotoxicity information: long term aquatic toxicity (invertebrates, fish - Annex IX, 9.1.5 and 9.1.6), short-term or long-term toxicity on terrestrial organisms (Annex IX and X, 9.4), long-term toxicity on sediment organisms (Annex X, 9.5.1), long-term or reproductive toxicity to birds (Annex X, 9.6.1).

- Environmental fate and pathways: biotic degradation (simulation testing - Annex IX, 9.2.1 and Annex X, 9.2 and 9.3.4), information on degradation products (Annex IX, 9.2.3 and Annex X, 9.3), bioaccumulation (Annex IX, 9.3.2), adsorption-desorption (Annex IX, 9.3.3).

Testing proposal on ecotoxicity information

A testing proposal might be submitted in order to gain more information on the ecotoxicity of the substance in different cases.

- The available information on an endpoint is inconclusive.

- Further testing is triggered by suspicion based on structural similarities with substances of concern.

- The CSR indicates that there is a risk and therefore the predicted no-effect concentration (PNEC) needs to be refined.

- The classification and labelling of the substance needs to be refined.

- There is a need to improve the PBT/vPvB assessment.

A testing proposal might be submitted in order to gain more information on the fate and pathways in the environment of the substance in different cases.

- The CSR indicates that there is a risk and therefore the predicted effect concentration (PEC) needs to be refined.

- The classification and labelling of the substance needs to be refined.

- There is a need to improve the PBT/vPvB assessment.

Testing strategies have been developed in the Guidance on information requirements for these situations and the Agency should refer to this guidance in order to evaluate whether there is a need for more information on ecotoxicity or on fate and pathways in the environment based on the data already available in the registration dossier.

Specific examples have been developed in Appendix 3.

The different sections of the registration dossier and CSR that might be considered in the evaluation of a testing proposal for an environmental endpoint are listed in Table 4.

Table 4 Registration/Technical dossier and CSR sections **relevant** for environmental endpoints

Topic	**Sections in Technical dossier**	**Sections in CSR**
Identification of substance	Section 2 (chapter 1)	Part B, Section 1
Physico-chemical properties	Section 7 (chapter 2)	Part B, Section 1
Classification and labelling	Section 4 (chapter 1)	Part B, Section 3
Ecotoxicological information (+ fate and pathways)	Section 9 (chapter 3 and 4)	Part B, Section 4 and 7
Exposure assessment for environment	Section 3 (chapter 1)	Part B, Section 9
Risk characterisation for the environment	-	Part B, Section 10

2.1.6 General tasks for examination of testing proposals

Aim: The objective is to explain how the Agency should evaluate the testing proposals received from a manufacturer/importer or a downstream user. For that purpose, the following main tasks are identified that should guide the Agency in the evaluation (see also introductions to Annexes IX and X of the REACH regulation):

Tasks: The Agency has to:

- examine if the testing proposal is justified for the compliance of the dossier; and

- examine if the testing proposal is adequate.

The role of the Agency is to assess whether the testing proposals received are justified for the purpose of bringing the dossier into compliance (i.e. if the testing proposal received is needed as regards the REACH requirements). This can be done by looking at the relevant sections of the technical dossiers and CSR when available. Information requirements under Annexes IX and X include data on the physicochemical properties, toxicological properties (mammalian toxicity), and environmental properties (ecotoxicological properties and environmental fate).

In the course of the evaluation it should also be clarified whether the testing proposal is adequate, i.e. reliable and relevant, or if modifications of the proposed test, or additional tests, are justified.

For these tasks, the Agency should consider the Annexes IX to XI which provide the following information.

- Column 1 on Annexes IX and X states the standard information required depending on the tonnage of the substance.

- Column 2 of Annexes IX and X lists specific rules according to which the requirement of standard information may be modified.

- Annex XI gives general rules for adaptation of the standard testing regime set out in Annexes VII to X.

The Guidance on information requirements (Integrated Testing Strategies (ITS)) and the Guidance on the Chemical Safety Report should be consulted when performing the examination of the testing proposals.

The outcome of the complete testing proposal examination by the Agency is one of the decisions of Article 40(3)(a) to (e) (see Section 2.1.7).

2.1.6.1 Is the testing proposal justified?

Aim: The objective is to check whether the testing proposal submitted is justified for the compliance of the dossier as regards the information available in the technical dossier and the CSR (including risk management measures (RMM)) when available. The outcome will be the rejection of the testing proposal (decision of Article 40(3)(d)) or its acceptance (decisions of Article 40(3)(a), (b), (c) or (e)).

Tasks: The Agency has to carry out the following actions.

- Check whether the information is necessary for the clarification of a suspected hazard (e.g. DNEL/PNEC determinations, bioaccumulation properties, setting of classification and labelling, assessment of PBT and vPvB properties) or to refine the risk assessment (e.g. refinement of the exposure assessment with new data on environmental fate), or, depending on the manufacture/import tonnage, whether it is required in Annexes IX or X (see the Guidance on information requirements and theGuidance on the Chemical Safety Report).

- Verify if waiving of the test is possible by the use of alternative data or due to low exposure according to specific rules in column 2 of Annexes IX and X and general rules of Annex XI.

To check whether new information on hazards will be useful for the chemical safety assessment, exposure information should be assessed, by evaluation of relevant sections on exposure available in the technical dossier, but also by looking at specific parts of the CSR (including RMM) when available. This does not mean that a complete quality check of the CSR including exposure scenarios and RMMs has to be performed, as this is part of the compliance check of the dossier. The assessment of the relevancy of the testing proposal should include a check of specific information in the CSR that could be used to confirm the need to conduct a test.

In order to accomplish its tasks, the Agency should also check the information in other registration dossiers available for the same substance.

2.1.6.2 Is the testing proposal submitted adequate?

Aim: The objective is to assess the adequacy of the testing proposal for filling the data gap identified by the registrant in cases where the Agency has already concluded that information is missing and will choose between the decisions of Article 40(3)(a) to (c)).

Tasks: The Agency will have to carry out the following actions.

- Examine if the testing proposal submitted is adequate (reliable and relevant) using the Guidance on information requirements and the Guidance on the Chemical Safety Report.
- Identify if modifications of the testing proposals are needed.
- Identify if additional testing is needed.

2.1.6.3 Examination of testing proposal: checklist

A standard checklist is available in Table 5, which may help the assessor during the examination of testing proposals. Depending on the specific case, some items of the checklist may not be relevant, or other items may need to be considered.

Table 5 Standard checklist for evaluating a testing proposal

Is the testing proposal justified?	
Source of information	*Checklist*
Annexes IX, X	According to the tonnage, is the information in column 1 required?
Technical dossier and The Guidance on information requirements	What information is available? • No information available. • Invalid standard information available. • Valid standard information already available allowing or not allowing a classification and labelling of the substance. • Valid standard information already available allowing or not allowing a derivation of a DNEL or a PNEC. • Valid standard information already available allowing or not allowing the assessment of PBT/vPvB properties.
CSR and the Guidance on the Chemical Safety Report	Has a risk or no risk been identified?
	Has the classification and labelling been correctly identified? Can it be improved?
	Has the PBT/vPvB assessment to be improved?
Rules for adaptation (column 2 in Annexes IX and X and the Guidance on information requirements	Does the study need to be conducted on the basis of the specific rules in column 2 of Annexes IX and X?
Rules for adaptation (Annex XI and the Guidance on information requirements	Is the use of alternative methods or approaches (weight of evidence, QSARs, read across, *in vitro*, category approach) possible?
Is the testing proposal adequate?	
Technical dossier and the Guidance on information requirements	Is there a need to modify the test conditions (e.g. on the basis of physicochemical propeties)?
Guidance on information requirements	Is the testing proposal in agreement with the strategies described in the guidance?
Rules for adaptation (column 2 Annexes IX and X) and the Guidance on information requirements	Does the test need to be adapted based on the specific rules in column 2 of Annexes IX and X?
	Are modified studies and/or additional testing needed?
CSR	Based on exposure considerations, is the the choice of tests appropriate?
Test method (Article 13)	Does the proposed test follow methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article 133(3) or other international test methods recognised by the Commission or the Agency as appropriate (Article 13(2))?
	Will the proposed testing be carried out in compliance with the principles of Good Laboratory Practice (GLP)?

2.1.7 Draft decisions

Aim: The objective is to explain how the Agency should document its draft decision after the examination of the testing proposal.

Task: The Agency should document its decision in a reporting format and notify it to the registrant(s) and downstream user(s).

Once the Agency has examined the testing proposal, an informal discussion (see Section 1.2 and Appendix 2) with the registrant or downstream user is recommended initially in order to clarify any potential misunderstanding. Whether or not this informal discussion leads to an agreement between the parties, the Agency will then draft a formal decision, documented in a reporting format (see Appendix 4).

Once a decision has been taken, different elements should be taken into account for the setting of a deadline for the registrant or downstream user to submit the required information, e.g. availability of labs, discussions on the protocol.

2.1.7.1 Decision of Article 40(3)(a): the testing proposal is accepted

As described in Section 2.1.6, when a testing proposal is justified and adequate, it should be accepted by the Agency.

It should be noted that if a testing proposal is submitted for an endpoint not listed in Annexes IX and X, it can nevertheless be accepted by the Agency if it is a higher level study which is necessary for the identification of a suspected hazard or to refine the risk assessment. There might also be cases where tests would highlight the potential of a substance to exert endocrine disrupting effects or other very high concern effects. If such cases occur it is recommended to examine the testing proposal in greater depth as the higher level tests listed in Annexes IX and X are not exhaustive.

In the same way, even though the information required under Annexes IX and X is intended to be required for chemicals produced at more than 100 t/y, such information might be also needed at lower tonnages. As a consequence, a tonnage level below 100 t/y should not be the sole reason for rejecting the testing proposal.

To reach a conclusion on the necessity for a test, the Agency should check that it is not possible to waive the test. The Guidance on information requirements should be consulted. Basically a test may be waived under the following conditions.

- The conditions in column 2 of Annexes IX and X for a specific endpoint are fulfilled.
- Testing does not appear scientifically necessary because it is possible to use alternative methods including weight of evidence (Annex XI(1)).
- Testing is technically not possible (Annex XI(2)).
- An adequate justification based on an exposure assessment is available (Annex XI(3)).

The potentially relevant sections that might be checked when considering exposure-based waiving are shown in Table 6.

Table 6 Technical dossier and CSR sections relevant in case of the assessment of exposure-based waiving

Topic	Sections in technical dossier	Sections in CSR
Information on manufacture and use	Section 3 (chapter 1)	Part B, Section 2
Guidance on safe use (parts of safety data sheet (SDS))	Section 5	
Exposure information for substances with quantities between 1 and 10 t/a: use categories, routes of exposure, pattern of exposure	Section 6	
Exposure assessment, including exposure scenarios and exposure estimation (for humans and the environment)		Part B, Section 9
Risk characterisation (for human health and the environment)	(chapter 10)	Part B, Section 10

When a testing proposal submitted by a registrant or a downstream user is accepted by the Agency the latter has to notify the registrant or downstream user concerned to carry out the proposed test. This should be done through a formal communication, using the format provided in Appendix 4.

2.1.7.2 Decision of Article 40(3)(b): the testing proposal is accepted but under modified conditions

As described in Section 2.1.6 and in the previous sub-section, when a testing proposal is justified and adequate it should be accepted by the Agency. However, there can be cases where the testing proposal is justified, but in order to be adequate it needs to be modified.

The Guidance on information requirements on the recommended testing methods (standardised or not) should be consulted to conclude if the testing proposal can be accepted as such (Article 40(3)(a)) or if the conditions under which the proposed test is to be carried out need to be modified (Article 40(3)(b)). To be accepted, the testing proposal should follow the general requirements for generation of information on the intrinsic properties of substances as mentioned in Article 13.

- Test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article 133(3) or other international test methods recognised by the Commission or the Agency as appropriate (Article 13(2)).

- Tests and analyses shall be carried out in compliance with the principles of Good Laboratory Practices (GLP) provided for in Directive 2004/10/EC, or other international standards recognised as being equivalent by the Commission or the Agency, and with the provisions of Directive 86/609/EEC, if applicable (Article 13(3)).

The modifications proposed by the Agency may relate specifically to the test proposed but may also depend on the information available on the substance in the technical dossier (e.g. results of previous testing). This information may be directly linked to the physicochemical properties of the substance which may influence the choice of protocol used to perform the test. Therefore, standard protocols for environmental and toxicological endpoints might need to be modified in order to be applicable to certain chemicals.

If modified conditions are requested, the draft decision should contain a concise phrase that clearly states the modified conditions expected and why such modifications are needed. This should be done through a formal communication, using the format provided in Appendix 4.

2.1.7.3 Decision of Article 40(3)(c): the testing proposal is accepted or rejected or the conditons of the test are modified and the registrant or downstream user is required to carry out one or more additional tests

When looking at the adequacy of the testing proposal submitted, the Agency may also recommend that complementary tests need to be performed in addition to or instead of the testing proposal received. The Agency may also ask for another test before examining further what has been proposed by the registrant or downstream user.

Such decisions should be based on a check on whether the testing proposal is in compliance with Annexes IX, X and XI. Several situations can be foreseen. A few examples are given here, that may be expanded on the basis of experience.

- The registrant or downstream user proposes BCF testing with fish. The water solubility provided is determined using non appropriate methods for that purpose and therefore not accurate enough to decide whether a standard BCF test is feasible or a fish dietary study would be advised. The Agency drafts a decision requesting the registrant or downstream user to carry out first additional testing on water solubility (e.g. with radiolabeled material) and on the basis of the results either accepts the testing proposal on BCF testing, suggests modified conditions, or rejects this proposal and requires instead a dietary fish study. (N.B. the full testing strategy shall be included in the formal decision)

  Studies proposed in the registration dossier (or downstream user report) for information required in the Annexes IX and X and for which a testing proposal is available are not considered as reliable and relevant (see Section 2.2 and the Guidance on information requirements). For example, the registrant or downstream user proposes a short-term repeated dose toxicity study (28 days) whereas the Agency concludes that a sub-chronic repeated dose study (90 days) should have been proposed. Consequently, the testing proposal is rejected and the additional test is required to be carried out. This type of evaluation is the one that is required within a compliance check. Therefore, in the frame of the examination of the testing proposal, it is recommended to check if the data provided in the technical dossier according to the requirements of Annexes IX and X, and which are related to the testing proposal, are considered reliable.

There may be situations where the justifications for adaptations of the standard information requirements do not comply with the specific rules in column 2 of Annexes IX and X and the general rules in Annex XI. In this case it should be determined which information requirements of Annexes IX and X have been waived. The waiving statements should be checked for their relevance to the testing proposal and those that could be relevant should then be looked at in more detail. The level of detail needed may vary and should in practice be determined on a case-by-case basis, depending on the content of the waiving statement and the relation of the waiving statement with the testing proposal. Wherever it is clear from the context or from other relevant information that the waiving statement is in line with the specific rules of the Annexes IX, X and the general rules in Annex XI, more detailed checking is unnecessary.

In all cases the choice of the additional tests needs to be made in accordance with the Guidance on information requirements.

When one or more additional tests are requested, the Agency has to notify the registrant or downstream user concerned. The reason for such requirement and the nature of the additional test(s) should be clearly identified. This should be done through a formal communication, using the format provided in Appendix 4.

Four cases can be anticipated:

- The testing proposal is accepted but one or more additional tests need to be performed simultaneously to fulfil the REACH requirements.

- The testing proposal is accepted but, depending on the result of this test, one or more additional tests may be needed to fulfil the REACH requirements.

- The testing proposal is rejected and one or more additional tests need to be performed to fulfil the REACH requirements.

- The testing proposal is accepted but under modified conditions and one or more additional tests need to be performed to fulfil the REACH requirements

See Appendix 4 for the description of the format for these cases.

2.1.7.4 Decision of Article 40(3)(d): the testing proposal is rejected

The responsibility for assessing the risks and hazards of substances lies with natural or legal persons that manufacture or import substances, produce or import articles, or use it as downstream user in case the use is not covered by the exposure scenario(s). Therefore the Agency should **reject** a testing proposal from a registrant or downstream user only in the following two cases.

- The registrant or downstream user does not provide an acceptable justification and the Agency considers that the information is not necessary in order for them to manage the risks of the substance appropriately.

- Relevant information on the endpoint is already available or should have been made available since it was a requirement of REACH, Annexes VII and VIII.

If a testing proposal is submitted for information which appears in Annexes VII or VIII, the dossier is not in compliance with the requirement of the REACH Regulation. Therefore, the Agency should inform the manufacturer/importer or the downstream user of this fact. Furthermore, the MS-CAs, responsible for considering enforcement as appropriate, will be informed and the dossier may be prioritised for compliance check.

The second case above could also arise when a registration dossier or downstream user report contains information considered as not reliable by the registrant or downstream user, respectively, but considered reliable by the Agency. When the testing proposal is rejected, the Agency has to notify the registrant or downstream user concerned of the reason for such rejection. This should be done through a formal communication, using the format provided in Appendix 4.

The registrant or downstream user can bring an appeal against Agency decisions.

2.1.7.5 Decision of Article 40(3)(e): several registrants or downstream users of the same substance have submitted proposals for the same test

Following the evaluation of the testing proposals submitted separately (see Section 2.1.3), the Agency should take a decision in accordance with Section 2.1.7.1, Section 2.1.7.2, Section 2.1.7.3 or Section 2.1.7.4. This decision should deal with the requirement for one or more tests.

The following cases are possible.

- All of the testing proposals submitted for the same substance concern different endpoints.

  In this case, a draft decision according to Section 2.1.7.1, Section 2.1.7.2, Section 2.1.7.3 or Section 2.1.7.4 will be developed, depending on the conclusion of the examination of the testing proposals. The Agency has to notify each registrant or downstream user concerned of the reason for the decision. This should be done through a formal communication, using the format provided in Appendix 4.

- The testing proposals submitted for the same substance refer to the same endpoint but different tests are proposed.

  In this case, the Agency will have to decide on the most relevant test(s) for fulfilling the requirements for that endpoint. Each registrant or downstream user will receive a draft decision according to Section 2.1.7.1, Section 2.1.7.2, Section 2.1.7.3 or Section 2.1.7.4, depending on the conclusion of the evaluation of the testing proposals. The Agency has to notify each registrant or downstream user concerned of the reason for the decision and should ask who will perform the test on behalf of the others. This should be done through a formal communication, using the format provided in Appendix 4.

- The testing proposals submitted for the same substance concern the same test.

  In this case, each registrant or downstream user will receive a draft decision according to Section 2.1.7.1, Section 2.1.7.2, Section 2.1.7.3 or Section 2.1.7.4, depending on the conclusion of the examination of the testing proposals. If the test proposed and/or additional test(s) should be carried out, the Agency has to notify each registrant or downstream user concerned of the reason for the decision and should ask who will perform the test on behalf of the others. This should be done through a formal communication, using the format provided in Appendix 4.

Further guidance will be developed by the Agency for the choice of the registrant or downstream user who will perform the test on behalf of others and on how the costs will be shared.

2.1.7.6 Reporting format for drafting decisions

See Appendix 4 (Reporting format for the examination of testing proposals).

2.2 Compliance check of registrations

2.2.1 Scope and Purpose of compliance check

The main purpose of a compliance check is to evaluate **whether a registrant is meeting his obligations**. It is a means by which the Agency may request further information from registrants in case the information submitted does not comply with the requirements of REACH.

According to *Article 41(1) the Agency may examine any registration in order to verify any of the following:*

a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12, and 13 and with Annexes III and VI to X;

b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;

d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.

The compliance check differs from the completeness check that is carried out by the Agency under Article 20(2). Within the compliance check the Agency has to determine whether the information submitted in the technical dossier or in the CSR is adequate and corresponds to the requirements of REACH, by taking into account the tonnage and rules for adaptations of standard information requirements. In contrast, the completeness check is an automated process that does not include an assessment of the quality or the adequacy of any data or justifications submitted.

If the dossier does not comply the Agency shall prepare a draft decision (see 2.2.5) requiring the registrant to submit any information necessary to bring the dossier into compliance with the requirements. It can therefore be regarded as a control tool to ensure the **quality** of the registration dossiers.

In the context of Article 41(1)(a) to (c) the Agency should check the adequacy and the interpretation of the information presented in the registration dossier(s).

In the context of Article 41(1)(d) the Agency should check if the explanation(s) for separate submission of information have an objective basis. According to *Article 11(3) or Article 19(2), the manufacturer or importer may submit information separately if:*

a) it would be disproportionately costly for him to submit this information jointly; or

b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

c) he disagrees with the lead registrant on the selection of this information

It should be borne in mind that the results obtained from the compliance check shall be used when carrying out other activities, i.e. by MS-CAs for the purposes of substance evaluation

(Articles 45(5)), identification of substances of very high concern (Article 59(3)) and restriction (Article 69(4)) and by the Agency for the purpose of developing criteria for substance evaluation (Article 44) (cf. Article 42(2)).

The Agency may select any registration dossier for a compliance check. Within 12 months from the start of a compliance check, the Agency may prepare a draft decision requiring the registrant to submit further information within adequate time limits. When a decision is taken and the information required is submitted, the procedure ends. If there are reasons to check the dossier again at a later date, the dossier can be selected for another compliance check. However, multiple decisions on one and the same dossier shall be avoided where possible.

A flow chart illustrates the process in detail (see Figure 1 and Figure 3).

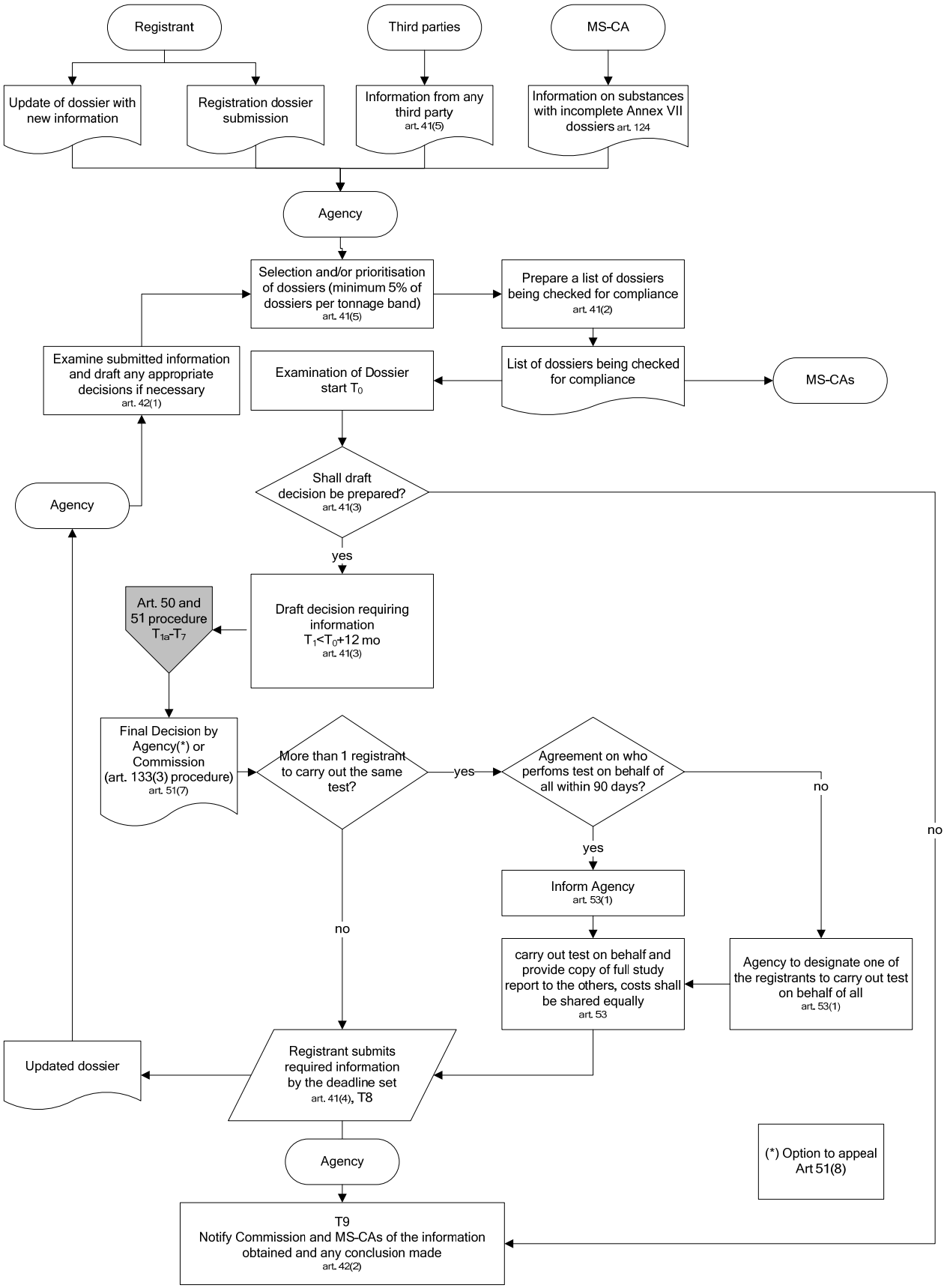

Figure 3 Compliance check of registrations.

Table 7 Time periods for compliance check

Time	Process	Actor	Period
T0	Selection/prioritisation of dossiers (5% per tonnage band (Artilce 40(5)). Make available the list of dossiers being checked for compliance (Article 41(2)).	Agency	
T1	Prepare draft decision (Article 41(3)).	Agency	12 months
T2	Comment on draft decision (Article 50(1)).	Registrant/DU	30 days
T3	May amend draft decision and take into account comments (Article 50(1)).	Agency	Not specified
T4	Notify draft decision together with any comments to MS-CAs (Article 51(1)).	Agency	Not specified
T5	Propose amendments (Article 51(2)).	MS-CAs	30 days
T5a	May modify draft decision and forward any proposed amendments to MS Committee (Article 51(4)).	Agency	15 days
T5b	Comment (Article 51(5)).	Registrant	30 days
T6	Conclusion (Article 51(6)).	MS Committee	60 days
T7	Take final decision acc. to Article 51(6) and 52(2) or Article 133(3) procedure (Article 51(7)).	Agency/ Commission	Not specified
T8	Submit the information required to the Agency by the deadline set Article 41(4).	Registrant	Within adequate time period to be set
T9	Notify Commission and MS-CAs of the information obtained and any conclusion made Article 42(2).	Agency	Not specified

2.2.2 Selection of Dossiers

Aim: To provide guidance for the Agency on how to select dossiers for a compliance check.

Task: The task of the Agency with regard to selecting dossiers for compliance checking will be to:

- apply specified criteria (Article 41(5)) and random selection; and
- define new criteria from the experience gained.

To ensure that the registration dossiers comply with the Regulation, the Agency shall select a percentage of these dossiers for compliance checking, not lower than 5% of the total received by the Agency for each tonnage band. Prioritisation criteria for the compliance check of registrations will be further developed in the Guidance on priority setting for evaluation and the following sections may have to be revised accordingly.

2.2.2.1 Random selection

It is highly recommended that, besides the criteria for dossier selection under Article 41(5), dossiers be selected mainly at random in the first years after entering into force of REACH in order to be able to identify the main reasons for non-compliance. Such an analysis could help improve guidance for the registrants, to develop criteria for selection of dossiers for a non-random compliance check (see Section 2.2.2.2), and eventually also to target the compliance check (see Section 2.2.3). This procedure may also ensure that the quality of the submitted dossiers increases over time. After some time the number of dossiers randomly selected can be reduced either by a combination of dossiers randomly selected and dossiers selected on the basis of criteria, or by dossiers selected via selection criteria only. The Agency should develop new criteria to select certain kinds of problematic dossiers. It is highly recommended to have enough flexibility to vary the selection criteria from time to time, so that particular problems can be focused on for short, intensive periods.

Irrespective of whether criteria or random based selection are used, the overall benefit of a compliance check should be an increase in the quality of the dossiers as well as an increased confidence that industry is meeting its obligations. Applying selection criteria gives the Agency the opportunity to set priorities in its work.

2.2.2.2 Non-random selection

Where registration dossiers are to be selected for a compliance check in a non-random manner, the Regulation specifies some criteria for dossier selection. Article 41(5) explicitly states that priority for compliance check shall be given to dossiers meeting at least one of the following criteria. However, these priority criteria are not exclusive.

a) Information in the technical dossier on the following parts was submitted separately in case of a joint submission:

- classification and labelling, Article 10(a)(iv);
- study summaries, Article 10(a)(vi); and/or
- robust study summaries, Article 10(a)(vii).

b) The dossier for a substance (phase-in and non-phase-in) manufactured or imported in volumes above 1 tonne per year does not meet the full requirements of Annex VII.

For phase-in substances that are manufactured or imported in volumes between 1 and 10 tonnes per year not meeting the criteria of Annex III, the registrant is not obliged to fulfil all the requirements of Annex VII and is allowed to submit only the physicochemical properties mentioned in Annex VII.

c) The dossier is for a substance listed in the Community rolling action plan.

Duplication of work should be avoided as much as possible and ideally the results of the compliance check(s) should be available prior to or in the first stage of substance evaluation. It is highly recommended that the Agency performs the compliance check(s) of the registration dossier(s) relating to a substance on the Community rolling action plan as soon as the substance is known to be on the Community rolling action plan. Further links between compliance check and other evaluation processes are discussed in the introductory chapter, Section 1.3.3.

Additionally, information submitted by third parties shall be considered when selecting dossiers for a compliance check (Article 41(6)).

Besides the criteria for dossier selection mentioned in the Regulation and cited above, a compliance check may be performed on dossiers selected by using one or a combination of trigger criteria listed below. Some of these criteria could be used as a trigger for a targeted compliance check as well (see Section 2.2.3). Guidance on selection criteria for a compliance check is given in the Guidance on priority setting for evaluation. The following list shows examples for such selection criteria.

- Dossiers containing waiving statements.
- If a testing proposal is submitted for a test quoted in Annexes VII or VIII.
- The information submitted by third parties as suggested in Article 41(6) is contradictory to information in the dossier. In any case, the adequacy of the information received from third parties needs to be checked first.
- Dossiers highlighted by Member States (e.g. during preparation of an Annex XV dossier) or the Agency itself (e.g. during examination of testing proposals or preparation of an Annex XV dossier), identifying poor quality or gaps in registration requirements.
- The dossier has been flagged because of non-compliance of data used in a category or read across approach (see Section 2.2.4.4).
- Specific physicochemical properties of the substance which make testing difficult may require an in-depth quality check (e.g. substances of low solubility, volatile substances).

2.2.3 Targeting a compliance check

Aim: To provide guidance on how to target a compliance check.

Task: In order to save time and reduce the workload a compliance check might be performed only on specific parts (e.g. human health endpoints) of the dossier. The Agency may target the compliance check by checking specific sections of the registration dossier. This involves:

- targeting specific parts of the technical dossier and CSR; and
- identifying new criteria for targeting the compliance check

Whenever targeting a compliance check, a stepwise approach is considered useful. Thereby part of the dossier will be checked for compliance, and if this is found to be non-compliant then checks on further parts of the dossier may be carried out.

2.2.3.1 Legal basis for targeting

The REACH text provides the legal basis for targeting a compliance check (Article 41(1)).

When targeting a compliance check it should always be kept in mind that although the dossier or parts of it may be checked for compliance again later, multiple draft decisions on the same part of the dossier, e.g. the same endpoint, shall preferably be avoided. Therefore in the absence of a specific concern about the quality of a given part of the dossier, it is reasonable as a general rule to perform the whole task of a compliance check regarding the technical dossier (Article 41(1)(a)(b)) including the explanations in case of separate submission (Article 41(1)(d)) at the same time. The

compliance check of CSRs and the adequateness of RMMs (Article 41(1)(c)) however can be limited and targeted at specific issues as a means of managing the workload.

If a compliance check has been targeted, it must be recorded in the IUCLID file, stating which parts of the dossier have been checked.

There are several parts of the registration dossier of which the evaluator should be aware in any case, such as general information like the registrant's name, the identity and purity of the substance. The tonnage band with its implications for information requirements is also important.

2.2.3.2 Reasons for targeting

The Agency may have concerns about compliance in a certain area of the **technical dossier**, and therefore may consider paying specific attention to that area within a targeted compliance check. Some of the situations that might be encountered are listed below; however this list should not be considered exhaustive and will be updated once more experience has been gathered.

- Where the dossier was selected for a particular reason (non-random), the reasons for choosing the dossier might direct the targeting, e.g. if dossiers are selected because of waiving statements, the compliance check can be targeted in order to check if these statements comply with the general and specific rules set out in Annexes VII to XI.

- If a Member State or the Agency identifies poor quality or gaps in registration requirements with regard to certain endpoints, the compliance check can be targeted at those areas where such gaps have been identified.

  Example 1: an Annex XV dossier for a potential vPvB substance is being prepared by a Member State and inadequacies in the registration dossier have been identified. In this case the evaluating Member State could inform the Agency who in turn may decide to perform a targeted compliance check and focus on the persistence and bioaccumulation data in the technical dossier and in the CSR.

  Example 2: the examination of a testing proposal by the Agency may result in a targeted compliance check of the relevant sections of the CSR or the technical dossier.

- The registration dossier does not meet the obligations for a joint submission as one of the manufacturers or importers disagrees with the "lead registrant" or other registrants on the selection of certain information. If the separately submitted information is adequate, but contradictory to that in the lead dossier, the relevant section of the dossiers may be checked by a targeted approach (e.g. human health part and/or environmental part).

- For some situations, e.g. if inconsistencies in the environmental classification and labelling have been found, it might be relevant to target the compliance check e.g. at environmental issues. In these cases the compliance check will be targeted at the relevant endpoints in the technical dossier and CSR.

- If adequate information submitted by third parties is contradictory to other information received, the compliance check may be targeted at the relevant section(s) (e.g. classification and labelling).

Reasons for targeting the compliance check at specific issues of the CSR (Article 41(1)(c)) might arise when the Agency first focuses on items of the technical dossier (Article 41(1)(a)(b)), and finds inconsistencies. For example, in the case of non-compliance of classification and labelling, the

hazard assessment may need to be revised as well. Furthermore, MS-CAs or the Agency may point out inconsistencies in the CSR while working on restriction/authorisation/testing proposals. As this might also concern parts of the technical dossier, it is described in more detail under the second bullet point above.

It should be mentioned that any list of selection criteria provided may be only temporary as new problems might arise which could be dealt with in a targeted compliance check. Therefore the Agency should develop new selection criteria in order to select certain problematic dossiers for a targeted compliance check.

2.2.4 Tasks involved in checking compliance

Aim: To provide guidance on how to check the quality of the submitted information.

Task: The Agency will have to evaluate the quality of the submitted information. For this purpose, the completeness and adequacy of the information supplied should be checked.

According to Article 20, the Agency performs an automated completeness check on each registration. Nevertheless, the Agency should start with checking whether the required information is in fact available. Additionally, the purpose of a quality assessment within a compliance check is to check the adequacy of the information submitted, which can be defined by its reliability and relevance.

Reliability relates to the inherent quality of the submitted data regarding the test or methodology used. This includes the test performance and the description and presentation of the results. These data may include, depending on the situation, reports on tests performed according to recognised and approved test methods and in compliance with the principles of GLP; reports on tests performed prior to these standards; reports on the results obtained when applying alternative methods (e.g. *in vitro* data, (Q)SARs); and exposure and/or monitoring data.

Relevance covers the extent to which data, tests and/or methodology are appropriate for a particular hazard or risk assessment.

For a more detailed definition of the reliability and relevance of submitted data, the Guidance on information requirements needs to be consulted.

When performing a compliance check any of the following may be checked for adequacy: the technical dossier, the chemical safety report, and explanations for separate registrations of the same substance. Each of these aspects will be described in detail in the following sections.

2.2.4.1 Compliance check of the technical dossier

Aim: To provide guidance on how to check compliance of the technical dossier.

Task: The compliance check of the technical dossier requires qualitative checking of the adequacy of information, as well as a justification for adaptation of the standard information requirements. The Agency may examine any registration in order to verify that

- the information in the technical dossier(s) complies with the requirements of Articles 10, 12 and 13 and with Annexes III, VI to X (Article 41(1)(a)), and

- the adaptations of the standard information requirements and the related justifications comply with the rules set out in Annexes VII to X and the general rules in Annex XI (Article 41(1)(b)).

The checklist in Appendix 5 for the technical dossier can be used as a guide by the Agency's staff when evaluating the compliance of a specific endpoint. Guidance on preparing the technical dossier for registration is available in the Guidance on registration, and this guidance should be used by the Agency as well. All the registration dossiers will be provided in IUCLID. As a consequence, guidance that will be developed on IUCLID 5 will also be helpful when performing a compliance check.

In general, if only a small amount of additional information or minor clarification is needed to bring the dossier into compliance, the Agency may consider informal contact with the registrant. The advantage could be that the formal procedure of drafting a decision under Article 41 might thus be avoided and efficiency could be increased. Additionally, inconsistencies between the different parts (e.g. technical dossier and CSR) and sections (e.g. "information on the manufacture and use(s) of the substance" and "guidance on safe use") of the registration dossier may be clarified first by informal consultation. The same may apply to negligible errors (e.g. typo mistakes). However, if this informal consultation between the Agency and the registrant does not lead to satisfactory results, a decision should be drafted requiring the registrant to submit the requested information.

Several parts of the technical dossier are linked to part B of the CSR and therefore the draft decision may also result in an update of the CSR by the registrant.

When carrying out a compliance check on the technical dossier, the Agency may consider concentrating on five main areas which are outlined below.

Identification of the substance

The Agency should use guidance and criteria given in Guidance on substance identification to check if the substance is defined and identified according to the REACH requirements. Identification of the substance is especially important if one dossier is referring to another (e.g. read across and category approach). Also, in the case of a joint submission it is critical to look at the composition of the substance in the lead dossier and related dossiers, to check if there are any differences in composition which may affect the relevance of the data. The Guidance on data sharing should also be consulted.

Endpoint specific information

For the different endpoints, the evaluating person(s) should first assess if the choice of the key studies that will be used in the chemical safety assessment is relevant. This will mostly concern registration dossiers of **phase-in substances**, where more than one study on an endpoint may be available. If there are several studies addressing the same endpoint, the adequate study or studies giving rise to the highest concern shall be used. The registrant should submit robust study summaries for the key study(ies) of each endpoint and for any other study showing higher concern, but not considered to be the key study, if the substance is manufactured or imported in quantities above 10 tonnes. Guidance on this issue is developed under Guidance on the Chemical Safety Report. The availability of the robust study summaries should be checked in the compliance check. In order to fully assess the selection, the study summaries for all available data providing the information necessary to identify the relevant key studies should be used as a basis, together with the Guidance on information requirements.

Concerning **non-phase-in substances** the choice of the key study is of minor interest as in most cases only one study per endpoint will be available. This study will therefore be the key study and a robust study summary has to be provided if the substance is manufactured or imported in quantities above 10 tonnes.

The correct choice of the key study is also important for the CSR (e.g. classification and labelling, PNEC-calculation, etc.). If the choice of the key study is wrong but has a minor impact on the whole assessment (e.g. if the classification would be the same, just minor changes in the CSR because of another NOAEL and therefore a new DNEL derivation, however the order of magnitude is the same, etc.), it is recommended that this should be clarified in a first step by informal discussion with the registrant. However, if the change of the key study leads to different conclusions in the assessment, a decision should be drafted requiring the registrant to modify the key study as recommended by the Agency and to revise the whole dossier accordingly within a set deadline. The right of the concerned registrant to comment the draft decision (Article 50(1)) could be of specific importance here.

Example 1 Possible consequence of the c**hange of the key study in the technical dossier**

Selecting a different key study concerning chronic toxicity leads to a classification as harmful (Xn) with R48. The substance is therefore also considered PBT (persistent, bioaccumulative and toxic) as the toxicity criterion is fulfilled (Annex XIII). Regarding the compliance of the dossier a complete revision within the CSR is requested; this request is supported by details of why different conclusions (e.g. key studies) have been drawn by the Agency.

It is noted that a draft decision concerning major changes in the technical dossier and the CSR could lead to a request of information under the REACH Annexes IX and X.

In addition to the selection of the key study, reliability and relevance of the information submitted should be checked. Guidance on integrated testing strategies (ITS) for all endpoints developed in the Guidance on information requirements and the Guidance on IUCLID containing detailed information on all the fields will be helpful for this assessment. Information provided under "indication as to which of the information submitted has been reviewed" may also be regarded as a quality statement of the information submitted, depending on the independence and quality of the assessor.

It is noted that the objective of study summaries and robust study summaries is to provide sufficient information to allow independent assessment by a technically qualified person without having to access to the full report. In specific cases, however, original study reports may be requested by the Agency for clarification, referring to Article 36.

Adaptations to standard information requirements

Guidance on how to adapt standard information either according to column 2 of Annexes VII to X for each endpoint or according to the general rules contained in Annex XI is given in the Guidance on information requirements and the Guidance on the Chemical Safety Report. During the compliance check it should be checked whether reported adaptations follow this guidance. If adaptations for a defined endpoint are not in accordance with the guidance, these adaptations have to be evaluated for their applicability on a case-by-case basis.

Classification and labelling

It should be checked if the classification given is in line with the information provided in study summaries and robust study summaries.

If the information given in study summaries and robust study summaries requires a different classification than the one submitted, a draft decision should be prepared by the Agency.

Under the auspices of the United Nations, a Globally Harmonised System of classification and labelling of chemicals (GHS) is being developed and will be implemented in Community legislation. GHS will substitute currently valid criteria for classification and labelling. The Guidance on Classification, Labelling and Packaging will be of use.

Request for information not to be made available on the internet

The Agency shall check the justification(s) for requests for information not to be made available on the internet of every registration before making the information available on the internet in accordance with Article 119. This check is therefore not part of the compliance check and independent from the fact whether a dossier is selected for compliance checking. As the data to be published does not include any technical information related to production processes a clear reason has to be given why publication could be problematic for the commercial interests of the registrant or any other part concerned. Justifications have to be evaluated on a case-by-case basis.

2.2.4.2 Compliance check of the CSR and the adequateness of RMMs

Aim: The objective is to provide guidance on how to check whether the CSR (including the RMMs) is in compliance with the requirements set in Annex I of REACH.

Task: The Agency has to carry out the following tasks.

- Check that the CSR has been submitted as required.
- Check that any required CSR complies with the requirements of Annex I.
- Check that the proposed RMMs are adequate.

A CSR is required to accompany the technical dossier for substances produced or imported in quantities above 10 tonnes.

A checklist for going through the CSR can be found in Appendix 6.

Within the compliance check of the CSR the information should be checked for quality and the adequacy of the RMMs should be evaluated. However a compliance check does not mean that a "new" CSR should be produced by re-evaluating the data.

All sections within a CSR should be checked for availability when performing a compliance check of the CSR because the automated completeness check will record only if a CSR is part of the registration dossier or not.

Part A of the CSR should include the following:

- a summary of risk management measures;
- a declaration that risk management measures are implemented; and
- a declaration that risk management measures are communicated.

Part B of the CSR should include the risk assessment and document how the substance can be manufactured and used safely, i.e. that risks are adequately controlled:

- substance identity, manufacture and uses, classification and labelling, as well as environmental fate properties;
- human health hazard assessment including derivation of DNEL(s), and environmental hazard assessment including derivation of PNEC(s);
- human health hazard assessment of physicochemical properties; and
- PBT and vPvB assessment.

In addition it should include, in cases where the hazard assessment shows that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC, or the substance is assessed to be a PBT or vPvB (Article 14(4)):

- exposure assessment (including exposure scenario(s) and exposure estimation);
- risk characterisation for human health and environment.

RMMs are a part of the exposure scenario(s) and checking the adequacy of RMMs is an integral part of checking part B of the CSR. It is recommended that the compliance check should start with part B, and come back to part A afterwards, because part A contains only a summary of the RMMs. A compliance check of part A only needs to check that the RMMs are adequately summarised from part B.

If any of the information required is missing in the CSR, a decision should be drafted requiring the registrant to submit the respective information.

Information contained in the various parts of the CSR should be in line with the technical dossier (e.g. hazard information). In addition, information contained in the CSR has to be consistent, as for example the registrant has to include the DNEL/PNEC values in several parts of the CSR (e.g. part B: hazard assessment and risk characterisation). A **cross-check** with the relevant sections in the technical dossier and within the CSR should be made.

Similar to the compliance check on the technical dossier, the Agency may prepare a draft decision requiring the registrant to submit any information needed to bring the registration into compliance if the information submitted is found to be inadequate. Again, if the information needed is just a small addition, informal contact with the registrant may be considered, as the procedure of drafting a decision might thus be avoided.

Generally, it should be checked whether the CSR is prepared in accordance with the principles set out in Annex I. The Guidance on the Chemical Safety Report can be used as a state-of-the-art description of Annex I principles and as a reference when checking compliance with Annex I. Where the registrant has used another methodology than described in the respective guidance, the alternative methodology used needs to be explained and justified. If parts of the CSR are not in accordance with this guidance they should be evaluated on a case-by-case basis, with special attention being paid to any justification given for using other approaches.

Hazard assessment, PBT/vPvB assessment, exposure assessment and risk characterisation

Guidance on the **derivation of DNEL/PNEC** values is provided in the Guidance on the Chemical Safety Report. During a compliance check, a cross-check should determine whether:

- the selection of the key studies on which the derivation of DNEL/PNEC values is based is appropriate (see above);

- the assessment factors for deriving DNEL/PNEC values were applied correctly;
- the justifications given for the selection of applied assessment factors are plausible; and
- in addition the DNEL/PNECs should be recalculated to detect miscalculations.

If the derivation of the DNEL/PNEC is not in accordance with the guidance, the approach taken to calculate the DNEL/PNEC and the related justification have to be evaluated for their suitability on a case-by-case basis. If the derived DNEL/PNEC value is regarded as inadequate because of a calculation error, a clarification by informal discussion with the registrant is highly recommended. However, if the derived DNEL/PNEC value is regarded as inadequate due to other reasons which cannot be clarified by informal consultation between the Agency and the registrant within an appropriate period of time, a decision should be drafted requiring the registrant to revise the CSR within a set deadline.

For a **PBT and vPvB assessment,** the registrant has to provide an assessment of whether a substance fulfils the criteria given in Annex XIII. Comparison with these criteria and other evidence (if the available data are not sufficient to allow a decision as to whether the substance fulfils these criteria) should be clearly presented in the CSR. The guidance for the production of the CSR contains detailed principles on the interpretation of studies in relation to the individual criteria set out in Annex XIII of the Regulation. Additionally where substances are considered as PBTs or vPvBs, an emission characterisation has to be performed and included in part B, section 8 of the CSR (Annex I, 4.0.2 and 4.2). This should also be checked during a compliance check.

Where only information required in Annexes VII and VIII is available, the registrant needs to consider the information relevant for screening against the PBT criteria and to decide on whether further information is needed for the purpose of the PBT/vPvB assessment. The Agency should check that this is done in accordance with Annex I, section 4.

If the PBT and vPvB assessment performed by the registrant is regarded as inadequate, a decision should be drafted requiring the registrant to bring the PBT/vPvB assessment into compliance. Here again the right of the concerned registrant to comment on the draft decision (Article 50(1)), or to appeal against it once it has been adopted (Article 51(8)) could be of specific importance here. When the interpretation of information indicates that follow up action is necessary, the Agency might also consider developing an Annex XV dossier. Guidance on this issue is given in the Guidance on Annex XV for C&L, the Guidance on identification of SVHC and the Guidance on Annex XV for restrictions.

In cases where the hazard assessment shows that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC, or the substance is assessed to be a PBT or vPvB, the registrant has to provide an **exposure assessment** and perform a **risk characterisation**.

Guidance on developing exposure scenarios, estimating emissions and exposure, as well as for performing a risk characterisation, is being given in the Guidance on the Chemical Safety Report for individual registrants, describing the basic approaches.

The Agency should check if all stages in the life-cycle of a substance, resulting from the manufacture and identified uses and any exposure that may relate to the hazards identified in hazard and PBT/vPvB assessment, have been considered by the registrant in the development of **exposure scenarios**. The exposure scenarios should define the RMMs and Operational Conditions in a way that allows exposure estimation (e.g. the efficiency of the RMMs is recorded). In order to **evaluate** whether the recommended **RMMs** are adequate, the exposure has to be known first (e.g. what kind of process, use, handling procedure, etc.). The credibility of the efficiency figure and other

characteristics of the type of RMM recommended should be checked when evaluating the adequacy of RMMs.

A registrant may submit a testing proposal for further tests considered necessary for preparing their chemical safety report. According to Annex I, section 0.5, the implementation of interim RMMs may be necessary whilst waiting for the results of further testing. When performing a compliance check on the CSR, proper recording of these interim RMMs shall be checked as well.

The exposure estimations are based on exposure scenarios, where RMMs and Operational Conditions defined in these scenarios are used to calculate the exposure. Where monitoring data are used, they should reflect the situation where these elements of the exposure scenario are implemented, and the compliance check should make sure that this is the case. The Agency should also check if the exposure estimation has been done for all relevant environmental compartments and all human health exposure routes.

If the exposure scenarios or the exposure estimations are inadequate, a decision should be drafted requiring the registrant to revise the CSR to bring the dossier into compliance. The right of the concerned registrant to comment on the draft decision (Article 50(1) or to appeal against it once it has been adopted (Article 51(8)) might be of specific importance here.

A **risk characterisation** considering the human population and environmental spheres shall be carried out for each exposure scenario. The risk characterisation should be done in accordance with Annex I and demonstrate that, if the exposure scenario (including the suitable RMMs and Operational Conditions) is implemented, the risks will be adequately controlled. The respective RMMs shall be summarised in Part A. Any update of the effect and exposure assessment in the technical dossier and/or the CSR will therefore influence this section and require an update of the risk characterisation. Furthermore, if during the compliance check of the CSR the RMMs are not considered adequate and the registrant is required to update the relevant section, this will also affect the section on risk characterisation.

2.2.4.3 Separate submission of certain data

Aim: To provide guidance on how to reach a conclusion on the separate submission of certain data.

Tasks: The Agency has to check if the explanation(s) for the separate submission of certain data has/have an objective basis. The Guidance on data sharing should be used for this evaluation.

When a substance is manufactured by two or more manufacturers and/or imported by two or more importers the following information for the technical dossier has to be submitted jointly (Articles 11 and 19):

- classification and labelling;
- study summaries;
- robust study summaries;
- any indication about data being reviewed; and
- testing proposals.

However in justified situations the manufacturer(s)/importer(s) may decide to submit such information separately. According to Article 41(1)(d), the Agency may check whether the explanation(s) received from those registrants who submitted parts of the registration dossier separately (instead of jointly with the other registrants of the same substance) has/have an objective basis.

The reasons for separate submission are set out in Article 11(3) and/or Article 19(2).

- Disproportionally high costs of joint submissions, linked to the cost of generating data compared to the cost of data sharing (assessing validity, negotiating compensation, etc.).
- Disclosure of commercially sensitive information which would cause the registrant substantial commercial detriment. Generally, the information which is to be submitted jointly should be the same for one substance (e.g. classification and labelling). Nevertheless, information contained in robust study summaries (e.g. information on test substance composition) may give hints on production processes (e.g. through the nature of impurities), representing commercially sensitive information.
- A registrant disagrees with the lead registrant. In case the manufacturer or importer disagrees with the lead registrant on the selection of certain information, the respective section of the dossier should be checked carefully for adequacy. However if separately submitted data are reliable and relevant, the contradictory data submitted by the "lead registrant" should be checked (possibly by a targeted approach) in a second step. See Section 2.2.4.4 and the procedure similar to a "normal" joint submission.

The Guidance on data sharing should be used for checking the objective basis of explanations for the separate submission of certain data.

In cases where the given explanation(s) is/are not regarded to have an objective basis a decision should be drafted requiring the registrant to submit the respective information jointly. Guidance regarding the information of the other registrants of the respective joint submission will be developed later.

If the explanation(s) for separate submission has/have an objective basis, the compliance check should be continued on the dossier selected.

2.2.4.4 Dossier selection and draft decision in cases of joint submission, read across and/or category approach

Aim: The objective is to provide guidance for the Agency on how to check the compliance of a dossier which was submitted jointly, or for which a read across or a category approach was used.

Task: The Agency has to check the justifications for the joint submission focussing on the substance identity. In addition the applicability and adequacy of a read across or category approach have to be checked. In case of non-compliance, the Agency has to draft decisions which should be addressed to the lead registrant and the consortium in case of a joint submission, or to the registrant of the selected dossier in case of a read across or category approach.

Joint submission

According to Article 11(1) the following information shall be submitted **jointly**:

- classification and labelling;
- study summaries;
- robust study summaries;
- an indication as to which of the submitted information on classification and labelling, study summaries and robust study summaries has been reviewed by an assessor; and
- proposals for testing.

A lead registrant will submit this joint part of the dossier on behalf of the other registrants with the agreement of the consortium.

Additionally each registrant shall submit **separately:**

- the identity of the manufacturer or importer;
- the identity of the substance;
- information on the manufacture and use(s);
- exposure information for substances in quantities of 1 to 10 tonnes; and
- an indication as to which of the submitted information on manufacture and use has been reviewed by an assessor.

The registrants may decide to submit the following information **jointly or separately:**

- guidance on safe use of the substance;
- CSR when required under Article 14; and
- an indication as to which of the submitted information on the CSR has been reviewed by an assessor.

If a dossier is selected and found to be part of a joint submission, the Agency would have to select all the other related dossiers to check the availability and adequacy of the voluntarily jointly submitted parts, e.g. in case of a joint CSR. When performing a compliance check regarding a joint submission, the Agency should **as a first step** check whether the joint submission is justified. Thereby it should be evaluated if the substance identity in all the dossiers submitted jointly is the same. Guidance on how to record the identity of substances correctly and how to assess whether it is the same substance is available in the Guidance on substance identification.

However, there may be cases where the substance identity is the same but the hazard profile is different due to a variable composition or impurities. Therefore the Guidance on data sharing should be considered as well. The critical point to check is that the data in the lead dossier are relevant to the related dossier, i.e. that the substance as defined in the related dossier is close enough to that in the lead dossier for any differences in composition not to affect the relevance of the data.

If the substances are not identical and a joint submission is not justified, a decision should be drafted to all registrants specifying which dossier(s) should be submitted separately or as part of another joint submission.

As a **second step** the Agency should check whether the information provided is in compliance with the REACH provisions (see Section 2.2.4.1).

In the case of non-compliance of the information provided jointly the whole consortium is concerned. The draft decision should be sent to the lead registrant as well as all members of the consortium. If this regards information which is submitted voluntarily jointly, only part of the consortium might be concerned and a draft decision should then be sent to the respective consortium members.

In the case of non-compliance of the information provided separately, the respective registrant of the selected dossier is responsible and the draft decision should be directed to this registrant only.

Read across and category approach

A definition of read across and category approaches is provided in the Guidance on information requirements as well as guidance on how to establish and present such a category and criteria on how to use read across.

When using data from other substances either for read across or category approach the registrant has to make sure that all required information is available in their registration dossier. In particular an appropriate justification for the read across or category approach should be included. In the dossier it has to be stated clearly which substance(s) is (are) the other members of the category or, in the case of read across from an analogue, which substance was used as the analogue.

As a first step when a dossier in which a category or read across approach is used is selected for a compliance check, the Agency should check whether the justification of the approach is acceptable.

In the case of a category approach this justification check should cover all members within the category. In the case of a read across approach this check should focus on the respective endpoints for which the read across approach was used.

If the justification for a read across or category approach is not in compliance the draft decision should focus on the data gaps which result from the use of information from substances not justified as members of a category approach or used for read across. The draft decision should be addressed to the registrant of the selected dossier (see also Example 2).

If the justification for the use of a read across or category approach is accepted, the Agency should as a **second step** check whether the data submitted are in compliance with the REACH provisions (see Section 2.2.4.1).

In case the data used are not in compliance, the draft decision should be directed to the registrant of the selected dossier. The dossiers of the substances which were used for read across or category approach should be flagged.

This flag should be used as a selection trigger for a possible future compliance check.

Example 2 Compliance check regarding a category approach

A group of chemicals consists of the four substances **A**, **B**, **C** and **D**. A dossier of substance **A** is selected for a compliance check. Therefore as a **first step** it should be checked if the justification for the category approach is acceptable. **Possible result**: category approach can be accepted for the substances **A**, **B** and **C** but not for substance **D** **Consequence**: The Agency should prepare a draft decision requiring the registrants to revise their registration dossiers accordingly. If the registrants decide to use the category nevertheless, they can only build it on substances A, B and C. . **The dossiers B, C and D can be flagged for a possible future compliance check if parts are suspected to be not in compliance.**

2.2.5 Draft Decision on Request for further information

Aim: Formats for drafting a decision as a result of the compliance check are provided in this section.

Task: The Agency may prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration dossier(s) into compliance, specifying adequate time limits for the submission of further information.

This draft decision will follow an adoption process, Article 50/51 procedure (see Figure 1), to ensure that the registrant and downstream user, as well as the MS-CA and the members of the MS Committee, can comment and agree on the proposal.

When a decision is taken, the registrant has to submit the information required by the set deadline. In cases of multiple registrants, they have to agree on who will carry out the tests on behalf of the other registrants and on sharing the costs of testing equally.

The format for a draft decision on compliance check can be found in Appendix 7 of this guidance.

2.2.6 Reporting

The Agency should report the work done in the course of a compliance check. Annotations, which are foreseen under IUCLID 5, should be used for that purpose, whereby different types will be provided either for a compliance check, examination of a testing proposal or a substance evaluation. Annotations will be further differentiated depending on the kind of information, i.e. for general information (available for each sub-chapter, e.g. annotations for classification and labelling) or for a (robust) study summary (available for each study report).

The Agency should document any observation made regarding the reliability and relevance of the data submitted, i.e. in the free text field for a (robust) study summary, when performing a compliance check. Thereby the authorities will be able to read the annotations, which will however not be made accessible for the registrants. It is possible that several authorities will include annotations on the same study, which might be relevant when performing a compliance check, e.g. if annotations are available prior to a compliance check that would require an update of the dossier, it could be evaluated within a compliance check if the respective changes have been done adequately.

Furthermore, the Agency should comply with its obligation under Article 54, i.e. to make recommendations to potential registrants to improve the quality of the dossiers in the report on the progress made over the previous calendar year on its website.

3 SUBSTANCE EVALUATION

3.1 Introduction

Aim: The objective of substance evaluation is to clarify an initial concern for human health or the environment. This section provides a general introduction to the substance evaluation process.

Tasks: Following the identification of an initial concern, the MS-CA has the possibility to perform a substance evaluation to clarify the initial concern, to assess if additional information is required, and to judge on the most appropriate follow-up to address the concern.

After a description of the aim and objectives of substance evaluation, the process of drafting the Community rolling action plan is described in the remainder of section 3.1. The inclusion of a given substance in the Community rolling action plan is a prerequisite for performing an evaluation of that substance. The possibilities for targeting a substance evaluation and the methodology for the evaluation are described in section 3.2 and 3.3, respectively. Section 3.4 elaborates on some considerations for the (draft) decision on a request for further information as well as the procedures for adopting the decisions. The possible outcomes of the substance evaluation process, including a format for reporting, are worked out in detail in section 3.5. Finally, the evaluation of on-site isolated intermediates within the Member States is described in section 3.6.

3.1.1 Aim and objective of substance evaluation

Substance evaluation aims at the clarification of a concern for human health or the environment. The substance evaluation process provides a mechanism for MS-CA, where necessary, to require (the) registrant(s) to obtain and submit additional information to address the initial concern. The outcome of a substance evaluation shall be to decide whether sufficient information is available to clarify the concern and, where further information is required, results in a formal decision that is drafted by the MS-CA and finally taken by the Agency. Following substance evaluation, the MS-CA may come to the conclusion that action should be taken under the authorisation, restriction or classification and labelling procedures in REACH, that information should be passed to other authorities responsible for relevant legislation, or that no further action is needed. The common feature of these regulatory activities is that they are based on reliable data. The substance evaluation process will ensure that such data are provided by (the) registrant(s) and made available to the relevant bodies by the Agency. Last but not least, the registrant(s) should update their registrations, including chemical safety reports, with any additional information obtained.

Although a compliance check is not mandatory for substance evaluation, substances listed in the Community rolling action plan should be given priority for compliance check because it will facilitate the substance evaluation. Guidance for performing the compliance check is provided in section 2.2. If the dossier has not yet undergone a compliance check, the MS-CA conducting the substance evaluation should check the reliability and relevance of the data used within the substance evaluation, before commencing with the substance evaluation. However, this situation can be avoided by giving priority in compliance checking to substances proposed for inclusion in the Community rolling action plan (see the Guidance on priority setting for evaluation).

The flow chart in Figure 4 illustrates the general substance evaluation process. Each of the steps is described in detail in the following sections and the reader is referred to these for the details of the process. The time indications of Figure 4 (e.g. T_0 etc) can also be found in Table 8.

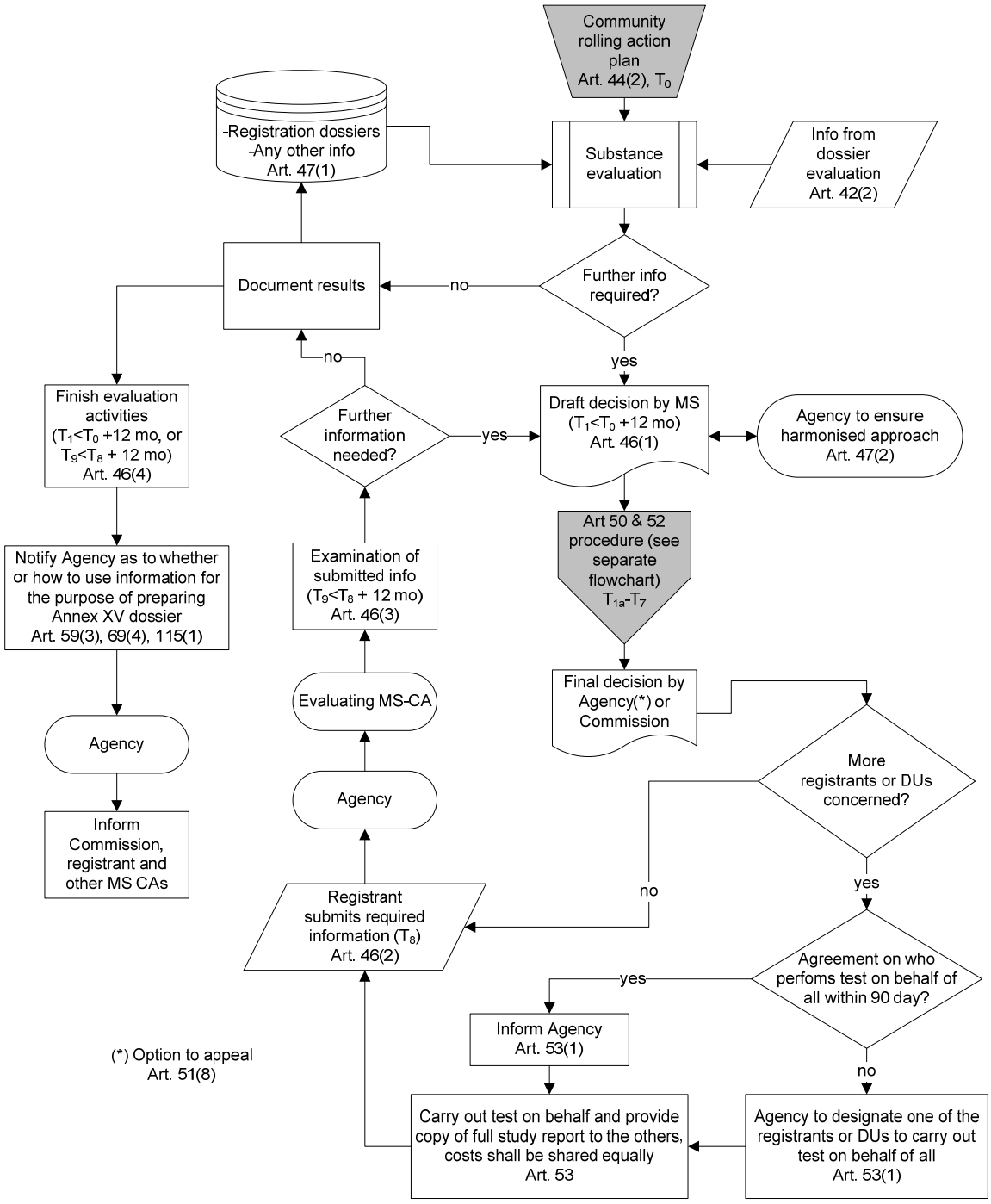

Figure 4 General overview of the substance evaluation process.

Substance evaluation in the REACH context

Substance evaluation is one step in a, possibly iterative, process of data collection and data review, starting with an initial concern and ending with a decision on how to address this initial concern, if appropriate.

The normal procedure after the identification of an initial concern would be that the readily available sources such as registration dossiers are obtained and reviewed. This review includes a full evaluation of the data including its use in the assessment. Following the review of these sources it may be that there are gaps in the information available. This can then lead to a request for further information, which may include further testing, as a result of substance evaluation. Other possibilities could include more specific searching for information, or consideration of other substances for read-across (for guidance on read-across see chapter 6.2.2 in the Guidance on information requirements). In some cases an iterative process between information gathering and review may be useful, when e.g. results of a first test will indicate whether further testing would be needed. The aim is to ensure that, once the substance evaluation process is complete, there is sufficient information available to clarify, and possibly address, the initial concern. This basic process is set out in Figure 6.

Substance evaluation is a key element in REACH, because it is at this stage that new information can be requested from (the) registrant(s), including any information not required in Annexes VII to X. The information generated following a substance evaluation, and the results of the evaluation itself, shall feed into the most appropriate follow-up process to address the concern (see Section 3.5), and into the REACH-IT system.

3.1.2 Community rolling action plan

3.1.2.1 Inclusion of substances in the Community rolling action plan

Aim: The objective is to provide guidance for the Agency and/or MS-CA on the process of drafting the Community rolling action plan, adding substances for subsequent evaluation.

Tasks: The Agency and/or MS-CA have to take into account the prioritisation criteria in identifying substances for inclusion in the Community rolling action plan.

In order to provide a harmonised approach, criteria for prioritising substances for inclusion in the (draft) Community rolling action plan shall be developed by the Agency in co-operation with the Member States. Article 44(1) of REACH indicates the considerations for criteria for prioritising substances for inclusion in the (draft) Community rolling action plan. The present document provides a list of possible reasons for concern that may prompt the inclusion of a substance in the (draft) Community rolling action plan (see Section 3.2), without an indication for prioritisation.

Only substances that have been registered and appear on the Community rolling action plan will be subject to the process of substance evaluation by an MS-CA.

The only exception would be when read across has been applied. Article 47(1) states that if information on the intrinsic properties has been developed with reference to related substances, then these related substances may form part of the evaluation. This means that if a registrant has derived some of the data on e.g. substance A by read across from others (e.g. substance B and C), then these others (B and C) can also be the subject of the evaluation, although substances B and C are not

included in the Community rolling action plan and possibly not registered themselves. If the MS-CA thinks that further information on yet another substance (e.g. substance D) would help to resolve the uncertainties, then they would have to include this substance D on the Community rolling action plan (provided substance D has been registered) if this substance is not already used in the registration for the main substance. The latter could for instance apply where the registrant had used read-across but with other substances than the one the MS-CA wishes to use or where the MS-CA considers that the alternative substance will act by the same mode of action, and might be easier to test than the main substance and other alternatives used in the registration by virtue of its properties.

The process of the compilation of the Community rolling action plan by the Agency is visualised in the flow chart in Figure 5.

3.1.2.2 Timing of the proposal by MS-CA to include substances in the Community rolling action plan

Aim: The objective is to provide guidance for MS-CA to aid their decision on when to propose a substance for inclusion in the Community rolling action plan. Several elements are listed that may be considered by the MS-CA who has a concern for a given substance.

Tasks: The MS-CA has to decide when to propose a substance for inclusion in the Community rolling action plan prior to the substance evaluation process.

There are two possibilities for a Member State to propose a substance for addition to the Community rolling action plan to allow for a substance evaluation to be conducted. The first is during the process of drafting the Community rolling action plan. The Member State should describe the grounds for considering that the substance constitutes a risk to human health or the environment and argue why (in line with the criteria of Article 44) the substance should be prioritised for addition to the draft Community rolling action plan (Article 44(2)). Alternatively, a Member State may notify (see Article 45(5)) the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is of priority for evaluation. The formal expression of concern to the Agency can be done at any point in time, i.e. after an initial concern has been identified (Figure 6, arrow A), after a first look at the available data, or after a comprehensive data review (Figure 6, arrow B). The timing of this action is important and the following aspects need to be considered by the Member State.

- How to express the concern to the Agency?
- What is the duration of the procedure to come to inclusion of a substance in the Community rolling action plan? Note that the Community rolling action plan is updated annually and submitted to the Member States by 28 February each year.
- What is the urgency and magnitude of the concern?
- When should the relevant information be available?
- What certainty does the Member State want to have that their request for further information addresses all relevant missing information? Note that any subsequent draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge (Article 47). In other words, it is not possible to ask for further information again and again if the circumstances have not changed. However, a

further request can be made after a review of the new information if it did not resolve the issue.

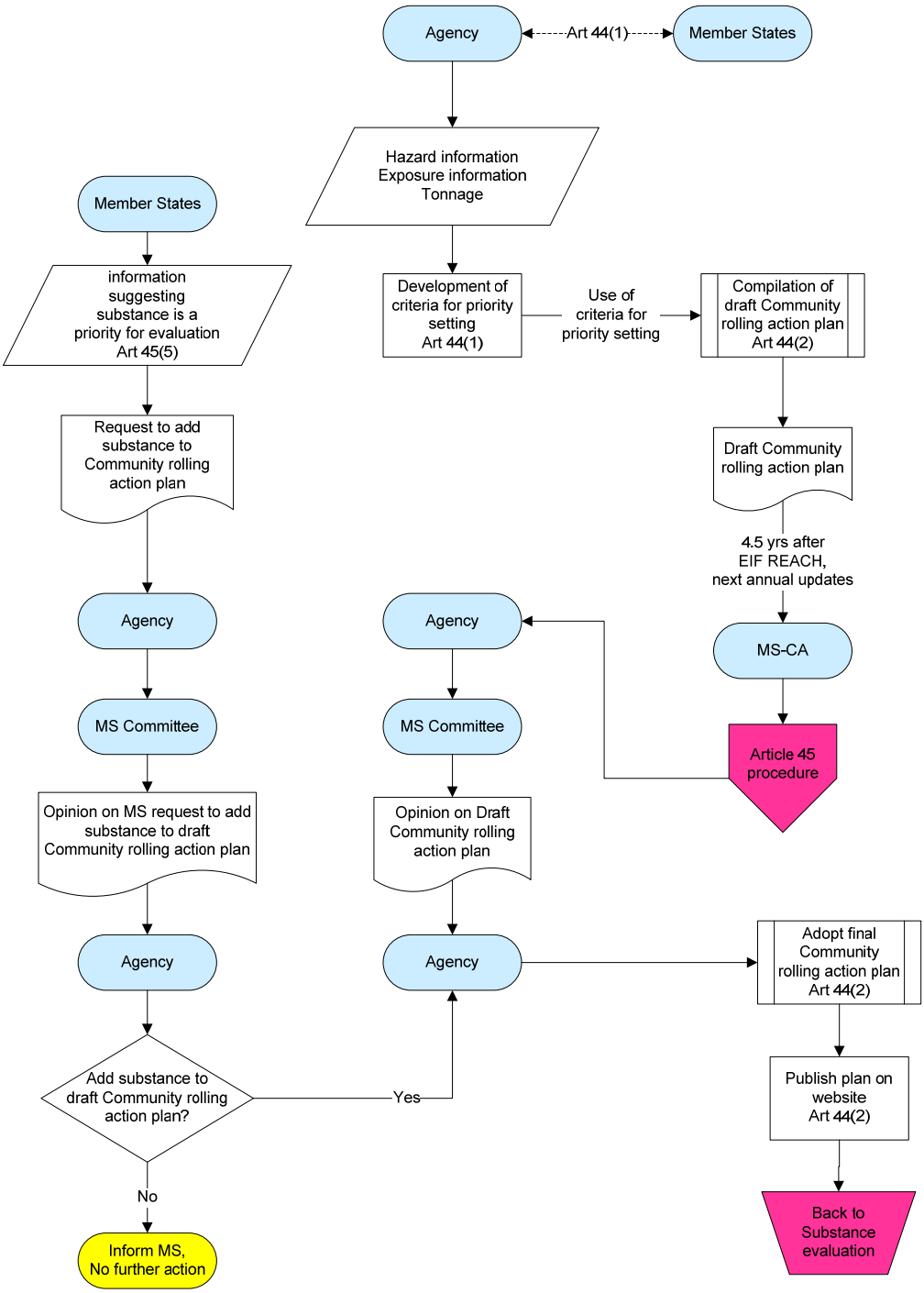

Figure 5 Compilation of the Community rolling action plan.

- Is it possible to do the substance evaluation within 12 months after publication of the Community rolling action plan? For example, are sufficient resources available?

- Has testing been proposed by the registrant(s) or is testing underway? Have the testing plans been reviewed? It may be the case that the substance is undergoing testing, for example as proposed in the Technical Dossier. Any such testing should be considered in case it might be of relevance to the evaluation. If the testing is relevant, then it should be considered very carefully whether to proceed or whether to await the result of the testing. If the information on the substance includes testing proposals which have not yet been implemented, these proposals should be examined to determine whether they would be able to address the initial concern identified in the review.

There is no best practice in these cases as the timing is dependent on the specific case. For example, if a Member State has a great concern over a substance and wants to address this urgently, it may be worthwhile to do a first or targeted review of the available data and propose addition of the substance to the Community rolling action plan as early as possible. On the other hand, if the urgency is less, there are numerous and complex dossiers for a given substance and the Member State is not convinced that it will succeed in getting a clear picture of the need for additional information within twelve months, it may be better to propose addition of the substance to the Community rolling action plan only after a comprehensive review of the available data. A consequence of this may be that the draft request for information can be developed in less than twelve months.

There may be cases where the Member State begins work on an Annex XV dossier expecting that all of the required information is available, but then finds that further information is needed to resolve a particular issue. They would then want to have the substance included in the Community rolling action plan as quickly as possible. To reduce the possibility of such a delay, the MS-CA could request the inclusion of the substance in the plan when they begin the Annex XV dossier work in case further information is needed. If there was no need for further information, then at the end of the 12 months they would report this.

3.1.3 Proposal for inclusion of substances in the Community rolling action plan

Aim: The objective is to provide guidance to MS-CA in the drafting of a proposal for inclusion of a substance in the Community rolling action plan.

Tasks: The MS-CA has to inform the Agency of its concern for human health or the environment and his intentions for a substance evaluation. The MS-CA proposal should be directed to the Agency.

The MS-CA proposing a substance for inclusion in the Community rolling action plan should prepare a short document to substantiate their proposal. The proposal should address the following issues.

- The **substance**, including chemical name, EC number, and CAS number.

- The **registration dossiers** that will be included, identified by **registration number** and **registration date**, as assigned by the Agency under Article 20(3).

- A **description of the grounds for considering a risk** for human health or the environment with reference to the prioritisation criteria developed in the Guidance on priority setting for evaluation. This description can be less detailed than the justification for a request for

further information (see Section 3.4.4). The proposal does not need to demonstrate any risk, just that there are grounds for considering that the substance constitutes a risk for health or the environment, based on any appropriate information.

- An indication of the (eco)toxicological **endpoints and/or parts of the dossiers that will be covered**. The MS-CA may wish to do a targeted substance evaluation, i.e. focus on only specified parts (see Section 3.2), or choose to do a comprehensive evaluation of the substance. NB Where several grounds for concern have been identified for the same substance by different Member States, all such grounds have to be evaluated in view of Article 47(1).

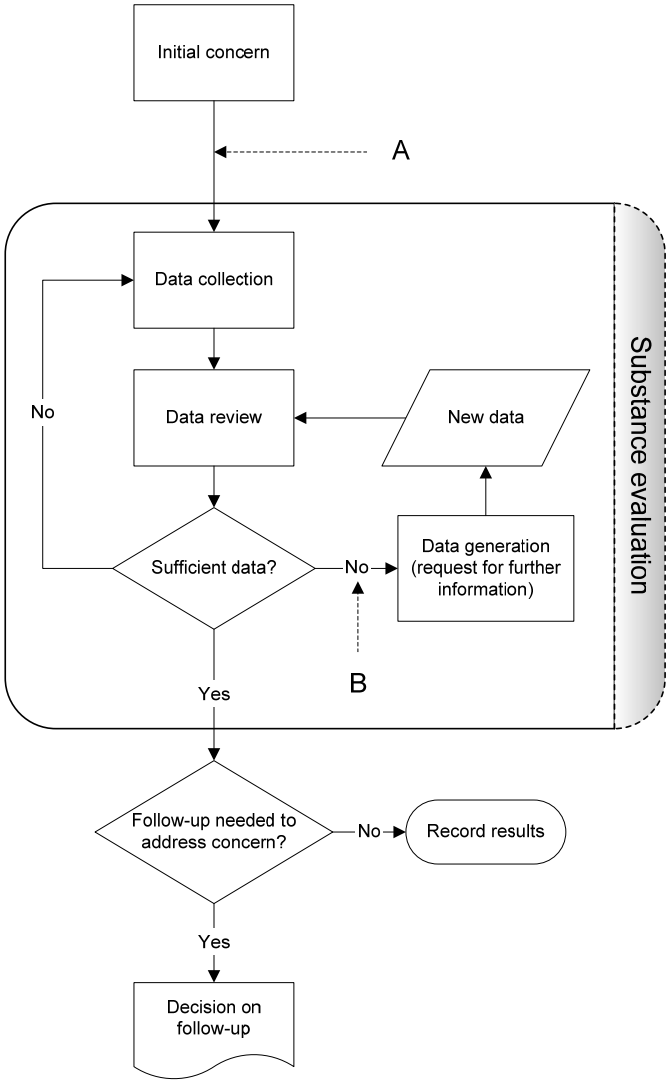

Figure 6 Basic process of data collection and data review.
(The arrows with A and B refer to the timing of inclusion of substances in the Community rolling action plan (see Section 3.1.2.2)).

Importantly, the proposal only expresses intentions based on the current state of knowledge. The experience gained during the substance evaluation process may change the view of the MS-CA e.g. leading to the coverage of other endpoints or inclusion of other registration dossiers.

The indication of the endpoints that will be covered is very important for an efficient use of resources within MS-CA. If, for example, two MS-CA have expressed an interest in the same substance, but have a different concern, they can agree to work together on the substance under the responsibility of the MS-CA that is identified as the responsible MS-CA on the Community rolling action plan (see Section 3.1.4).

MS-CA should be aware that it is not possible to withdraw substances from the Community rolling action plan once it is published.

3.1.4 Allocation of substances to Member States

Aim: The objective is to ensure that each substance on the draft Community rolling action plan is allocated to one MS-CA. The final Community rolling action plan will list the substances to be evaluated each year together with the MS-CA responsible for the evaluation of the respective substances.

Tasks: The Agency has to ensure that each substance on the draft Community rolling action plan is allocated to one MS-CA.

The procedure for the allocation of substances on the draft Community rolling action plan to the Member States is described in Article 45 and is visualised in the flow chart in Figure 7. A Member State may choose (a) substance(s) from the draft Community rolling action plan (Article 45(2)), with the aim of becoming the competent authority for the purposes of Articles 46 to 48. If a substance from the draft Community rolling action plan is not chosen by any Member State, the Agency shall ensure that the substance is evaluated by appointing a MS-CA to carry out the substance evaluation. Guidance for this procedure may be developed in due time by the Agency based on experience. In practice, however, such a situation could be avoided via an informal consultation of the Member States by the Agency in the process of drafting the Community rolling action plan.

It is also possible that two or more Member States express an interest via REACH-IT in evaluating the same substance. If this is the case and these Member States cannot agree who should be the competent authority for the purposes of Articles 46 to 48, the Agency shall refer the matter to the MS Committee in order to agree which authority shall be the competent authority, taking into account the Member State in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a Member State and the expertise available.

If, within 60 days of the referral, the MS Committee reaches unanimous agreement, the Member States concerned shall adopt substances for evaluation accordingly.

If, however, the MS Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 133(3), and the Member States concerned shall adopt substances for evaluation accordingly.

If a substance is added to the Community rolling action plan following a notification by an MS under Article 45(5), the proposing Member State, or another Member State who agrees, shall evaluate that substance.

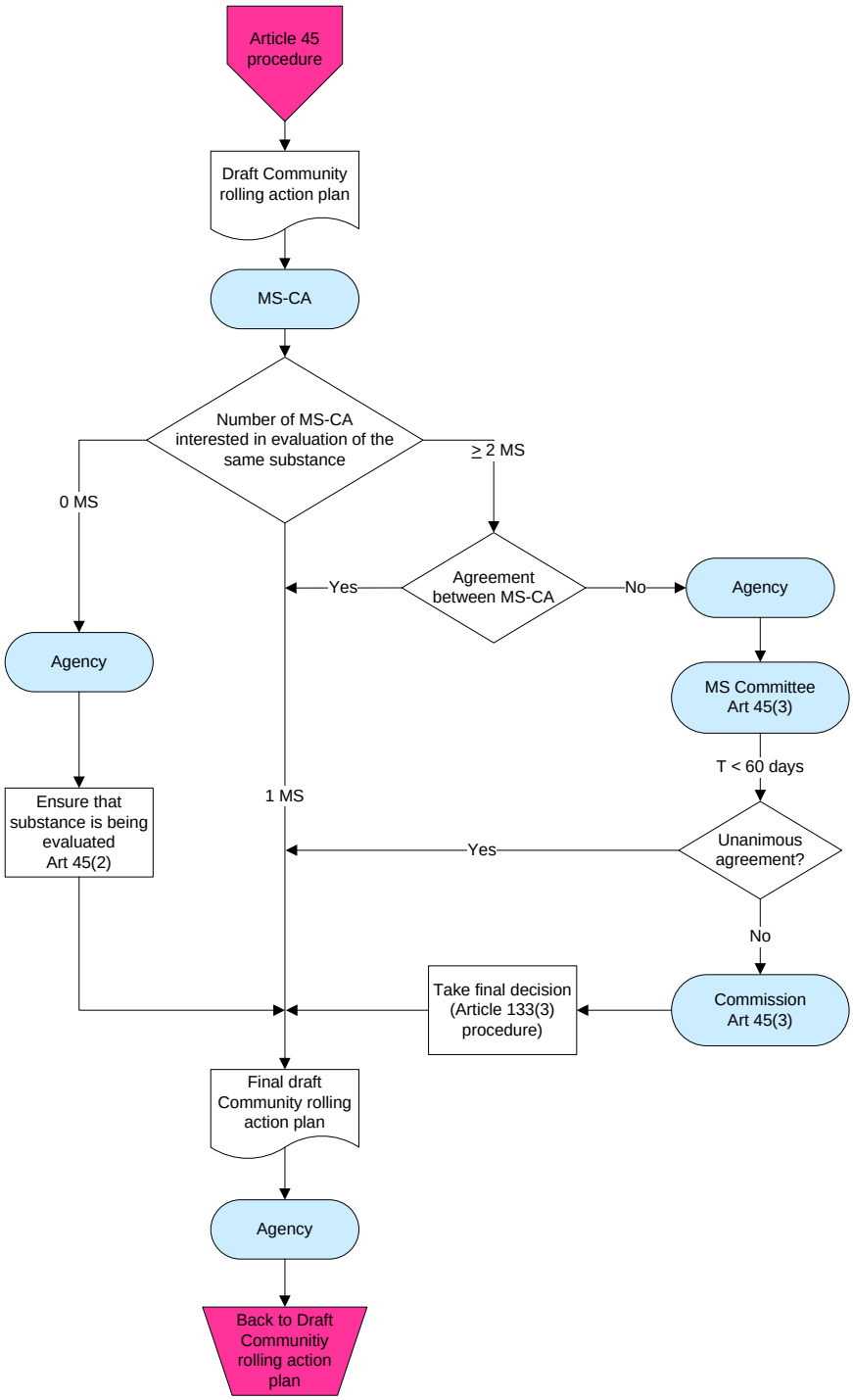

Figure 7 Allocation of substances on the draft Community rolling action plan to Member States (Article 45 procedure).

Finally, the Community rolling action plan is adopted by the Agency on the basis of an opinion from the MS Committee. The final Community rolling action plan covers a period of three years, specifies substances to be evaluated each year and identifies the MS-CA who will carry out the evaluation of the substances listed therein. The final Community rolling action plan will be put on

the Agency website. The Agency is responsible for co-ordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, the Agency relies on the competent authorities of the Member States as they are responsible for carrying out the evaluation of the substances allocated to them on the Community action rolling plan (Article 45(4)). In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf on the condition that the same rules that have to be taken into account by MSCA's including those with regard to the protection of confidential business information are applied

3.2 Targeting a substance evaluation

Aim: The objective of this section is to describe how work within substance evaluation can be targeted to the most relevant parts of the registration dossier. Starting from the different grounds for considering that a substance constitutes a risk to human health or the environment (Article 44), the possibilities for targeting are described and dependencies between these reasons for concern are discussed.

Task: The MS-CA has to decide whether to target the evaluation, and on which parts of the available information the substance evaluation should focus.

When considering the targeting of a substance evaluation, it should be kept in mind that the substance evaluation should address all grounds that have been identified for considering a risk to human health and/or the environment (see also Section 3.1.3).

3.2.1 Principles for targeting substance evaluation

For effective use of resources a substance evaluation may be targeted, i.e. work may concentrate on the information that is relevant for the objective of the individual evaluation. Targeting will, in particular, depend on the reasons for concern that led to the inclusion of the substance in the Community rolling action plan. It should nevertheless be kept in mind that all grounds for concern need to be addressed. The issues involved with those grounds of concern will define the limits of the targeting. Normally, the MS does not need to look at issues unrelated to the grounds for concern, but it may chose to do so in case it is worried in general about the quality of assessments and exposure scenarios for the substance. A balance needs to be found between a straight forward and efficient procedure and the goal to cover of all grounds for concern.

In cases where a decision on a substance evaluation has previously been taken in accordance with Article 52, then according to Article 47(1) a request for further information (in the frame of a second substance evaluation) may be justified only by a change of circumstances or acquired knowledge. Therefore the MS-CA, when considering targeting of a substance evaluation, should aim at including all grounds for considering that the substance constitutes a risk, which are identifiable based on available information. Another MS-CA willing to reopen a substance evaluation is not to be considered as a change of circumstances.

There are dependencies between issues which have to be taken into account. For example, if the reason for concern is that aggregated tonnages from several registrants are considerably higher than individual registrants' tonnages, then this information may have an impact on both environmental exposure assessment and human exposure via the environment and consequently on the assessment of both environmental and human health risks. Or, if a change in classification and labelling leads to a classification as reproductive toxicant, category 3, this might initiate a revision of the PBT/vPvB

assessment, according to the criteria in Annex XIII of REACH. These dependencies will be elaborated below. But as not all possible cases can be anticipated here, expert knowledge should generally be applied to all substance evaluations in order to check the implications of specific data for other parts of the registration dossier. This refers for example to situations where new data result in adaptations of information requirements or on the fulfilment of the criteria for substances with tonnages below 10 t/a according to Annex III of REACH.

In principle, all available relevant information should be considered during substance evaluation. This includes information in the technical dossier, in the chemical safety report (available for substances with tonnages > 10 t/a) and any relevant additional information.

There are several parts of the registration dossier, which the evaluator should be aware of in any case. General information like the registrant's name, the identity and purity of the substance, the tonnage band with its implications for information requirements are important for all evaluations. When it comes to requests for further information, testing proposals submitted to the Agency and the data expected to emerge from these tests should also be taken into account.

Targeting a substance evaluation means focusing - but not limiting - efforts on the most important information. Experience from the existing substance evaluation process shows that major endpoints of concern are not always anticipated when starting a risk assessment (Bodar et al., 2002). Evaluators are therefore encouraged to take a wider perspective on the substance evaluation process.

3.2.2 Targeting based on ground for concern

Targeting of a substance evaluation depends on the grounds for considering that a substance constitutes a risk. The examples given in the following sections are not meant to be exhaustive. More reasons together with criteria for prioritising substances for evaluation are provided in the Guidance on priority setting for evaluation.

Note that some of these examples are relevant to more than one type of concern, and so appear under a number of headings.

3.2.2.1 Grounds for concern relating to health or environmental risks

The identification of risk clearly involves consideration of both exposure and hazards. However, a concern is likely to be triggered by either information on hazard(s) or information on exposure. Therefore, hazard and exposure information are addressed separately in this section.

Concern for health effects

- New more severe classification for physicochemical and/or human health hazards.
- Suspicion of hazard based on structural similarities with substances of concern (not recognised or not considered in the registration dossier) or based on the outcome of evaluation of similar substances.
- New hazard data, e.g.:
  - from published literature data
  - observations made by poison control centres
  - data on vulnerable groups

  - occupational health information (example: report on respiratory sensitisation at the workplace).

The focus of the assessment is on human health hazard information and its consequences for risk characterisation. In most cases, the concern will focus on specific health endpoints. However, since different health effects may be mechanistically connected and in order to establish a comprehensive profile of the toxic properties of a substance, a good working practice would be to look at a wider range of endpoints.

There is a strong link between hazard and risk assessment and classification and labelling. The outcome of discussions on classification and labelling may influence the approach to risk assessment. For example, if a substance is classified as a carcinogen, category 2, for which a direct genotoxic mechanism cannot be excluded, a non-threshold model for risk assessment will be applied. Conversely, if a concern for a specific health effect (e.g. respiratory sensitisation) is substantiated during substance evaluation, this may lead to a harmonised classification proposal. A change in the classification might consequently also lead to changes in the PBT assessment.

Exposure data and risk management measures (RMM) (human)

- Aggregated tonnage from all registrants is significantly higher than the tonnage per registrant and raises concern with respect to high exposure on a local and/or regional scale (in case of long-range-transport-pollutants, even global exposure may be of importance).
- Combined exposure from various exposure pathways (e.g. consumers exposed via different routes through using consumer products belonging to supply chains of several registrants) is anticipated to be substantially higher than assumed in individual registrants' registration dossiers.
- New exposure data (e.g. surveys reveal substance in food or in consumer products).
- New information indicates uses in addition to those covered by the registration or suspicion that there are unknown uses (e.g. uses noted in national product registers for substances of low tonnage or non-classified substances).
- Registrant(s)' dossier(s) indicate complex exposure situations, involving multiple human exposures from various pathways (e.g. inhalation, dermal and oral exposure) or wide dispersive use of a substance.

The substance evaluation can be targeted on the human exposure and risk characterisation parts of the registration dossier. It should take into account available information on manufacturing and uses. Also, if indirect exposure via the environment is an issue, information on environmental fate properties given in the technical dossier might be relevant. Physicochemical properties may be important to understand conditions of use and the suitability of RMM.

Concern for environmental effects

- New classification for environmental hazards
- Suspicion for hazard based on structural similarities with substances of concern (not recognised or not considered in the registration dossier) or based on the outcome of evaluation of similar substances
- New hazard data
  - from published literature data

– other reports

The assessment will generally target all parts of the registration dossier containing environmental (fate and toxicity) information as well as the risk characterisation part. For conclusions on risk characterisation the environmental exposure assessment has also to be considered.

The risk assessment process is also linked with classification for environmental effects. For example, new data on aquatic toxicity may trigger a reassessment of environmental risks as well as a change of the environmental hazard classification. New data on long-term aquatic toxicity may also influence the PBT assessment.

Exposure data and RMM (environment)

- Aggregated tonnage from all registrants is significantly higher than the tonnage per registrant and raises concern with respect to high exposure on a local and/or regional scale (in case of long-range-transport-pollutants, even global exposure may be of importance).
- Aggregated exposure from similar acting substances.
- Dossiers from several registrants of the same substance indicate exposure concentrations (PECs) close to the PNEC values.
- New exposure data (e.g. biomonitoring data; surveys reveal high concentrations in environmental media or in biological organisms; new data suggest importance of pathways not covered in registration dossier, e.g. plant exposure via air).
- New information indicates uses additional to those covered by the registration.
- Different RMM are proposed by several registrants.

The substance evaluation will focus on those parts of the technical dossier which provide relevant data for releases to the environment (e.g. use pattern) as well as for characterising the behaviour of the substance in the environment, i.e. physicochemical data and environmental fate and pathway information, and on the environmental part of the chapters on exposure assessment and risk characterisation of the CSR.

If as a result of new information on environmental concentrations the substance is suspected of being bioaccumulative, the possible consequences for PBT/vPvB assessment should be kept in mind.

3.2.2.2 Grounds for concern relating to classification and labelling

- New hazard data.
- Diverging classifications proposed by several registrants.
- Proposed classification is not in accordance with existing classification in Annex I of Directive 67/548/EEC.
- Opinion of MS-CA deviates from registrant's proposal (e.g. for substances classified by registrant in CMR category 3).
- Additional or diverging assessments of information relevant for classification by other (national or international) organisations.

- Structural similarities with other substances (based on structure-activity relationships), outcome of evaluation of similar substances (not recognised or not considered in the registration dossier).

Classification deals with the assessment of physicochemical hazards, human health hazards, and/or environmental hazards. Within these subjects, not all endpoints and data may be of concern, but discussion will focus on specific properties of substances. For example, if there is concern for mutagenicity, only data related to this endpoint need be assessed. This may need to include additional data, e.g. from toxicokinetic studies, in order to interpret correctly the outcome of studies pivotal for classification.

For harmonized classification and labelling, work focuses on those parts of the registration dossier, which contain the classification as proposed by the registrant(s).

3.2.2.3 Grounds for concern relating to substances of very high concern

CMR category 1 and 2 substances

No specific reasons for CMR category 1 and 2 substances are included here as they are covered in Section 3.2.2.2.

PBT and vPvB assessment

- Structural similarities with other PBT/vPvB substances (not recognised or not considered in the registration dossier).
- Opinion of MS-CA (on data contained in the dossier) deviates from registrant's proposal.
- Additional or diverging assessments of other (national or international) organisations, e.g. by OECD or Member States.
- New (field / monitoring) data on degradation/accumulation.
- New data on chronic aquatic toxicity (NOEC < 10 µg/l).
- New/revised classification (CM Cat 1 or 2, R Cat 1, 2 or 3, R48).

According to the criteria laid down in Annex XIII of REACH, information on persistence and bioaccumulation, as well as chronic aquatic toxicity and classification of the substance are important in this context. The assessment will therefore focus on those parts containing data on physico-chemical properties and on environmental behaviour.

Several interdependencies with other parts of the registration dossier exist. As the toxicity criteria for PBT properties include classification according to Directive 67/548/EEC as well as long-term aquatic toxicity, changes in classification may alter the PBT evaluation. Similarly, the environmental hazard data (PBT criterion: aquatic toxicity data; long term no-observed effect concentration (NOEC) < 10 µg/l) may also influence the outcome of the PBT assessment. Conversely, new data on degradation or accumulation may be of importance for the environmental risk assessment, even for substances which are assessed as not being PBT compounds.

The evaluator should also be aware of the relevant exposure information in the CSR when evaluating a substance. If information on exposure is not available to the MS-CA, and this information is considered useful for priority setting for inclusion in Annex XIV (Guidance on Annex XIV inclusion), then this exposure information could be requested.

Assessment of equivalent levels of concern

- Structural similarities with PBT/vPvB substances.
- Substance which narrowly misses one (or more) of the PBT criteria, for which there is supporting or alternative information related to the missed criteria.
- Information indicating endocrine disruption potential.
- Information indicating potential for long-range transport.
- Other aspects identified and considered at a case-by-case basis.

According to Article 57(f) of REACH, in addition to CMR and PBT/vPvB substances, substances may be included in Annex XIV for which there is scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern. These substances are to be identified on a case-by-case basis. Various types of effects on humans and/or the environment (e.g. endocrine disrupting properties) may lead to the consideration that a substance constitutes a risk. In addition, new effects may raise concern in the future and may be dealt with under Article 57(f) of REACH.

Which information should be considered relevant for an evaluation of a substance of equivalent concern will depend on the type of effect under discussion and may differ from case to case. Therefore no general guidance on how to target the substance evaluation can be given. For substances with an equivalent level of concern in relation to PBT or vPvB properties targeting may be in analogy to the above section. For further information reference is made to the guidance documents on production of an Annex XV dossier (Guidance on Annex XV for C&L, Guidance on identification of SVHC and Guidance on Annex XV for restrictions).

The paragraph on exposure information in the PBT section above is also relevant here.

3.3 Methodology for substance evaluation

Aim: This section is intended to provide guidance on how to clarify the concern which has led to the evaluation of the substance.

Tasks: In order to clarify the concern, the MS-CA has to carry out an assessment. This involves the collection of information relating to the area of concern, the review of this information and reaching a conclusion on whether there is sufficient information to assess the concern.

The approaches to be followed in these areas are generally the same as those to be followed in producing a registration dossier or an Annex XV dossier and the main technical guidance for these is included in the Guidance on the Chemical Safety Report.

Information sources

The main source of information under REACH will be the registration dossier(s) for the substance. Results from dossier evaluation (if available), or any previous substance evaluation should also be used (these may/should have been incorporated into revised registration dossiers). Any decision on targeting (see Section 3.2) may help in determining what information needs to be collected. The Annex XV guidance (Guidance on Annex XV for C&L, Guidance on identification of SVHC, and Guidance on Annex XV for restrictions) includes a section (Section 1.2.2) on what information is

available under different situations within REACH. Other possible sources of information in addition to those within REACH include:

- scientific publications;
- assessments by (inter)national bodies, e.g. assessments by OECD, WHO;
- environmental surveys, e.g. by NGOs or national authorities;
- consumer product information, e.g. by Product Registries or NGOs;
- observations made by poison centres;
- occupational health reports;
- information on exposure and RMM compliance/suitability down the supply chain, including reports on national enforcement activities, e.g. through the Forum.

The amount of effort needed to locate information will vary on a case-by-case basis. The MS-CA will need to have sufficient information to make a definite decision on the area of concern, or to show that there is insufficient information to make such a decision. Guidance on information requirements will provide guidance on how to find information and on what is considered 'adequate' for different endpoints.

General remarks on information review

The available information should be reviewed against the criteria for validity and relevance developed in the Guidance on information requirements and in the Guidance on the Chemical Safety Report. The particular aim here is to decide whether the information is sufficient for a decision to be made on whether criteria (e.g. for classification and labelling, or for PBT) are met or the information is suitable for the required purpose.

The studies which are considered by the registrant to be the key ones for each endpoint should have been identified and Robust Study Summaries should be included in the registration dossiers. Where studies are interpreted in a different way by the MS-CA, it will be important to develop explanations for these differing views to form part of any justification for requesting further information.

There may be additional registration dossiers to that submitted by the lead registrant, which may contain other results or different interpretations of data. Where these are relevant for the endpoints being considered, the justifications provided in the additional registration dossiers for not using the lead registrant data or interpretation should be examined, evaluated and the overall conclusions reviewed. Guidance on information requirements will provide guidance on comparing studies and ranking these to identify the most appropriate, both in general terms and for specific endpoints.

Registration may involve the substance as part of a category – so data on all category members are considered together and the chemical safety report deals with the category rather than an individual substance. In case of a category registration, each category member has to be registered separately. The MS-CA will need to consider whether their concern relates to a specific member of the category or to all members. One aspect of concern may be the degree to which the specific substance fits the category. Data on other members of the category will most likely need to be considered in the evaluation even if only one substance is being evaluated.

A registration may also use data on other substances without the formal creation of a category, for the purpose of read-across to fill data gaps. The MS-CA will need to consider whether the read-

across is justified. This may be the reason for concern, i.e. the substance of interest is similar to another, and shows similar effects, but there is uncertainty over how close the similarity is.

The MS-CA may themselves make use of data on other substances, whether or not the registration has used such data. When making use of information on related substances, the MS-CA will need to explain how these relate to the substance being assessed, and how this justifies the use of the information. The amount of information needed for related substances used to support the proposal is likely to vary case-by-case. For example, where there is an agreed classification for a similar substance (on Annex I of Directive 67/548/EEC) this could be used directly without referring to any supporting information, i.e. there is no need to present the data which lead to the agreed classification. Guidance on the use of a category approach and read-across will be part of the Guidance on information requirements and this can be used in each of the different circumstances above.

Information on other related substances and other supporting information should be reviewed in a similar way using the relevant sections of the CSA guidance as appropriate, whether it is included in the registration or is information that the MS-CA considers is relevant.

The following sections provide further guidance on the information review step of the evaluation process. All of the technical guidance required for this step is to be found in the guidance documents for the CSR or Annex XV production (Guidance on the Chemical Safety Report, Guidance on Annex XV for C&L, Guidance on identification of SVHC and Guidance on Annex XV for restrictions)

3.3.1 Methodology for substance evaluation relating to health or environmental risks

A substance evaluation related to health or environmental risks may address any aspect of the risk assessment of the substance. This section considers three parts. The first two parts are hazard (effects) related and exposure related. Each part assumes that the concern relates to that part. Any particular evaluation may only need to consider one of these parts in terms of reviewing the information, but the hazard and exposure will need to be combined to decide whether or not the suspected risk can be confirmed. Hence the third part of this section considers this risk characterisation step. The technical guidance needed to carry out these steps is included in other parts of the REACH guidance (Guidance on CSR/Guidance on Annex XV for C&L, Guidance on identification of SVHC, and Guidance on Annex XV for restrictions).

3.3.1.1 Hazard related

PNEC and DNEL

In most cases the starting point will be a review of the DNEL and PNEC values in the registration dossier(s). Criteria for the validity and relevance of studies are included in the Guidance on the Chemical Safety Report and this guidance should be used. In many cases there will be just one data set as submitted by the lead registrant. In cases where the registrants did not share data in compiling their registrations, the reasons provided for this should be examined. There may be a broader data base available when the different submissions are combined and after having considered other data sources than registration dossiers, and this could allow the revision of the PNECS and/or DNELs.

Outcomes

There are two possible outcomes from this review.

1. The PNECs and DNEL values are found to be suitable.

2. The MS-CA does not agree with the derived values. In this case the MS-CA will need to decide whether the available information is sufficient to allow new PNEC or DNEL values to be derived, based on the revised interpretation of studies or on new data, using the methods in the CSA guidance. There are two possible results from this decision.

    a. The data are sufficient. The MS-CA should derive the new values for use in the risk characterisation step.

    b. The data are insufficient. The MS-CA should consider whether the provision of further information would allow the required values to be derived (Section 3.4).

In the situation where there are no CSRs available for the substance, the MS-CA will need to develop their own PNEC and DNEL values using the Guidance on the Chemical Safety Report. This process will result in the same situation as the second outcome above.

The MS-CA should consider whether the outcome of their review of the PNEC/DNEL values has any consequences for the exposure estimates required to perform the risk characterisation.

Related to classification of substances

A proposal for a harmonised classification to be added to Annex I of Directive 67/548/EEC can be made for any classification provided a justification of the need for action at Community level is made. Classification as CMR category 1, 2 or 3 or as a respiratory sensitiser is sufficient justification in itself. Guidance on possible justifications for other endpoints is included in the guidance for Annex XV dossiers, and this aspect is not discussed here.

The specific types of test data needed for the classification and labelling of a given endpoint are outlined in Directive 67/548/EEC, which will be subject to future adaptations to technical progress, and will be amended to implement GHS. In addition, non-test information may be considered suitable for Classification & Labelling purposes under REACH as described in Annex XI. Guidance on the evaluation of the various studies is (will be) included in the Guidance on information requirements. Guidance on Classification & Labelling under GHS will be further developed in the Guidance on Classification, Labelling and Packaging. The current guidance therefore does not discuss technical issues.

Outcomes

1. The information is not sufficient for the MS-CA to decide whether the substance meets the relevant Classification and Labelling criteria. Move on to Section 3.4 in this guidance.

2. The information available is sufficient for the MS-CA to decide whether the substance meets the relevant criteria. If so:

    a. If the substance meets the criteria, proceed with the development of the Annex XV dossier or other appropriate follow-up (see Section 3.5).

    b. If the substance does not meet the criteria, the MS-CA should notify the Agency that the evaluation is completed. The work done and the conclusions should be documented so that others can benefit from this (see Section 3.5.1).

Related to substances of very high concern

How to identify substances of very high concern is discussed in the Guidance on identification of SVHC. The identification of CMR category 1 and 2 substances is covered in the Guidance on information requirements. The guidance for the production of the Guidance on the Chemical Safety Report will contain detailed guidance on the interpretation of studies in relation to the individual criteria set out in Annex XIII of the Regulation. The current guidance therefore does not discuss technical issues in relation to such studies or issues.

Outcomes

1. The information is not sufficient for the MS-CA to decide whether the substance meets the criteria in Article 57 of REACH. Move on to Section 3.4 in this guidance.

2. The information available is sufficient for the MS-CA to decide whether the substance meets the relevant criteria. If so:

    a. If the substance meets the criteria of Article 57, proceed with the development of the Annex XV dossier or other appropriate follow-up (see Section 3.5).

    b. If the substance does not meet the criteria of Article 57, the MS-CA should notify the Agency that the evaluation is completed. The work done and the conclusions should be documented so that others can benefit from this (see Section 3.5.1).

3.3.1.2 Exposure related

There are two parts to the estimation of exposure: estimates or measurements of emissions and exposure on the one hand, and substance data which affect the calculation of exposure concentrations on the other. Either may be the specific target for the evaluation.

Guidance on estimating emissions and exposure is included in the Guidance on the Chemical Safety Report for individual registrants, and this describes the basic approaches. The guidance for Annex XV dossiers adds to this consideration of the combination of emissions from multiple registrants, and of the inclusion of emissions from other sources.

The implemented risk management measures identified in the CSRs are an integral part of the exposure assessment. Guidance on reviewing the effectiveness of these measures is included in the Guidance on Annex XV for restrictions.

Information on the physicochemical properties of the substance and those which govern its environmental fate and distribution is needed to move from the emission estimates to exposure concentrations. If the MS-CA considers that there is uncertainty in one or more of these properties which would (significantly) affect the calculated exposure concentrations then they should use the CSA guidance to review the available information on the property or properties.

Outcomes:

1. The MS-CA considers that a suitable value cannot be derived from the available information – go to Section 3.4.

2. The MS-CA confirms there is uncertainty in the value. It should select the most reliable value from the data and use this, then consider the effect of the uncertainty on the results in Section 3.3.1.3. The CSA guidance includes a chapter on uncertainty analysis which should be consulted.

3. The MS-CA considers a suitable value can be derived – this should be used in the exposure calculations.

Where the emissions or the property values are revised from those in the CSRs, the MS-CA will need to calculate new exposure estimates, using the methods described in the CSA guidance.

The reason for evaluating the substance may be the availability of monitoring data, information on measured levels, or reported values of releases from point sources, e.g. from environmental release registers. These could relate to worker or consumer exposure, or to levels in the environment. Such data should be reviewed for validity and relevance, as described in the CSA guidance.

3.3.1.3 Risk characterisation related

The risk characterisation involves the comparison of exposure estimates and PNECs/DNELs as described in the guidance developed in the Guidance on the Chemical Safety Report. The MS-CA should use whichever of these have been changed as a result of the information review, in combination with the values from the CSR(s). This may be limited to specific parts of the overall assessment depending on the degree of targeting involved. Where relevant, the influence of uncertainty in property values or in the estimated exposure levels should be considered.

Outcomes

1. Risks are identified. Consider whether the effect values (PNECs, DNELs) could be refined through further information and whether this could have a significant effect on the conclusions (i.e. could result in no risk). Consider whether the exposure levels could be refined through further information (again so that the risk could be removed). If further refinement of the risk characterisation along these lines is considered possible then go to Section 3.4. If refinement is not considered possible, proceed with Annex XV dossier or other appropriate follow-up (see Section 3.5).

   As an example of the possible considerations, the case of aggregated emissions for a substance shows a risk for aquatic organisms. The PNEC is derived from acute studies, and the risk characterisation ratio (RCR) is <10. There is a good chance that chronic testing could result in a higher PNEC and demonstrate that the risks are in fact controlled.

2. No risks are identified, even when uncertainty in property or emission values is considered. The MS-CA should notify the Agency that the evaluation is completed. The work done and the conclusions should be documented so that others can benefit from this (see Section 3.5.1).

3.4 Requests for further information

3.4.1 Introduction

Aim: The objective is to provide guidance to the MS-CA on the process of obtaining further information to judge on the initial concern. This section provides a general introduction.

Tasks: The MS-CA has to draft a request for further information where this information is essential for a conclusion on the initial concern.

After the identification of missing information (see Section 3.3), the MS-CA shall decide whether this missing information is necessary for the MS-CA to conclude on its concern. If this information is considered essential, the MS-CA shall prepare a draft decision with a request for further information. According to the REACH text, the MS-CA shall consider how to use the information obtained from the substance evaluation (including the additional information submitted in response to a request for further information) for the purposes of identification of substances of very high concern (Article 59(3)), restriction (Article 69(4)) or harmonised classification and labelling (Article 115(1)). This does however not limit the possible consequences of a substance evaluation to the preparation of an Annex XV dossier (see Section 3.5).

Any information, if justifiable, can be requested under Article 46. This includes information that is not part of the registration requirements under REACH, e.g. information outside the tonnage band of the evaluated registrations.

3.4.2 Considerations regarding requests for further information

Aim: The objective is to provide guidance to MS-CA on the type of information that can be requested in different situations.

Tasks: The MS-CA has to decide which information is most appropriate to address his concern.

If the MS-CA concludes that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision. Any information can be requested, if justifiable, and the further information requested may address general aspects, intrinsic properties of the substance and exposure characteristics. It may also be that more than one type of information is requested to clarify the concern, e.g. in the case of a significant risk a request for further information may address hazard as well as exposure information.

Where a group of substances is evaluated, further information may be requested for one or more representative members of the group, with the results to be used for the group as a whole. As an example, in order to determine whether a group of substances is very bioaccumulative (vB), further bioaccumulation testing could be proposed for two representative members of the group, with the results of this testing to be used for the group as a whole.

3.4.2.1 Information on intrinsic properties of substances

The general requirements for generation of information on intrinsic properties of substances by registrant(s) or downstream user(s) are laid down in Article 13 of REACH. These requirements are relevant for the evaluating MS-CA as well. It is important to note that information on intrinsic properties of substances may be generated by means other than tests (Article 13(1)), in particular through the use of qualitative or quantitative structure-activity relationship models or from information on structurally related substances (grouping or read-across), provided that the conditions set out in Annex XI are met. Guidance on the application and regulatory acceptability of alternative methods is being developed in the Guidance on information requirements and this guidance should be used.

Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article 133(3), which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or other international test methods recognised by the Commission or the Agency as appropriate (Article 13(2)). However,

information on intrinsic properties of substances may also be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

3.4.2.2 Information on exposure

Identification of substances of very high concern or to classification and labelling are based on the intrinsic properties of substances. Exposure information may be useful in the priority setting for inclusion of substances of very high concern in Annex XIV (Article 58(3)). The actual information needed for the prioritisation process is still to be decided (Guidance on Annex XIV inclusion).

If there is a concern that a substance poses a risk to human health or the environment, a request for further information could very well be directed to information on exposure since the level of exposure, together with the intrinsic properties of the substance, determines the risk.

For registered substances, exposure information may be obtained from CSRs; alternatively, the technical dossier(s) will identify the main uses of the substance, and also possibly sources of emission. In principle, only registrants have the obligation to submit information following a request from an evaluating MS-CA. However, where all registration dossiers for a substance have not yet been received (e.g. because a substance is manufactured in a lower tonnage band), the MS-CA may consider entering into a dialogue with potential registrants in order to retrieve more information on exposure for the substance under evaluation. The amount of effort expended to obtain this information will be dependent to a large extent on the MS-CA's concern for the substance.

It is likely that the most important information will be identification of the main uses of the substances and sources of, or potential for, emissions or exposure of humans.

3.4.3 Process description

Aim: The objective is to provide guidance to the MS-CA on the process of obtaining further information to judge on their initial concern.

Tasks: The MS-CA has to decide on the most efficient way to obtain the information required.

The workflow between the different actors involved in the process of requesting and generating further information is not influenced by the type of information that can be requested. Therefore, the workflow as described below and depicted in Figure 8 is the same for all requests for further information.

If the evaluating MS-CA has come to the conclusion that, following the data review, the available information is not sufficient to decide whether an initial concern over the risk can be substantiated, they could consider engaging in an informal consultation with the registrant(s) to obtain additional information. This informal and voluntary process (see Section 1.2) may be an efficient way to obtain the missing information. If the MS-CA considers that it is better, for whatever reason, not to engage in informal consultation, or if the voluntarily submitted information is still not sufficient to conclude on the concern, the MS-CA may proceed with the drafting of a formal request for further information under Article 46. The draft request for further information shall be submitted by the evaluating MS-CA to the Agency within 12 months of publication of the Community rolling action plan on the Agency's website. After submission to the Agency the procedures described in Article 50 and 52 shall be followed (see Section 3.4.5). Ultimately, a final decision shall be taken by the Agency or the Commission and sent to the registrant(s).

After the registrant(s) has/have performed the testing or gathered the information, the information shall be sent to the Agency by the set deadline. The evaluating MS-CA shall, after receipt of the submitted information from the Agency, examine any information submitted.

The MS-CA should then decide whether the available data are now sufficient to conclude on the concern. If the information is still not sufficient, or the circumstances have changed, e.g. as a result of the newly submitted data, it shall draft any appropriate decision within 12 months of the information being submitted. If however the data are considered to be sufficient to conclude on the concern, the conclusion may be that there still is concern or that the submitted information has removed the concern. If concern remains, the MS-CA shall inform the Agency on the follow-up of the substance evaluation (see Section 3.5). If the concern has been removed, the results of the evaluation shall be documented in the appropriate format (see Section 3.5) and added to the relevant part of REACH-IT.

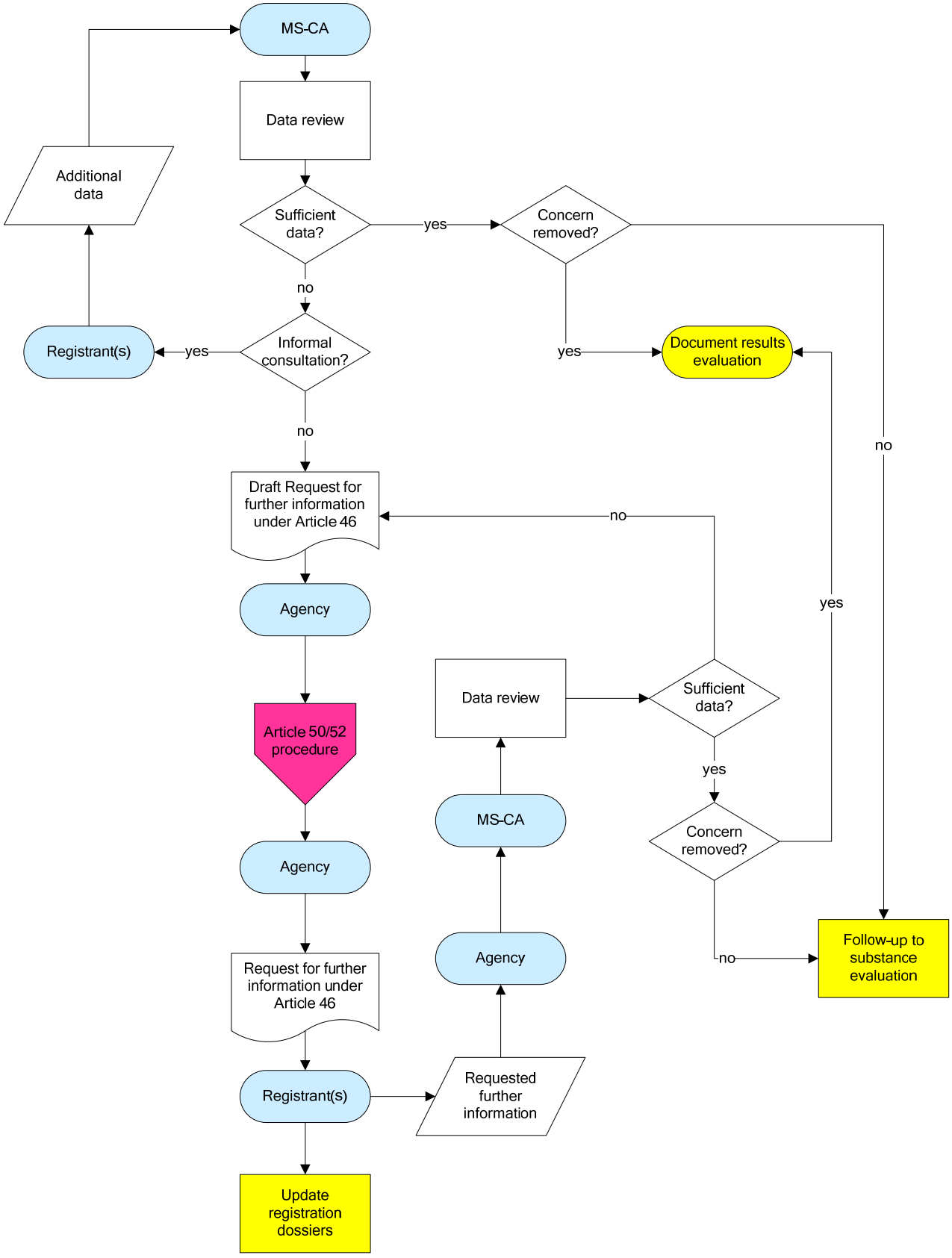

Figure 8 Workflow between different actors related to requests for further information.

3.4.4 The (draft) decision

Aim: The objective of this section is to provide guidance on the drafting of a decision to request further information.

Tasks: The MS-CA has to prepare a clear and unequivocal draft decision on his request for further information. The final decision will be taken by the Agency via the procedure described in Article 50/52.

If it is considered that further information is required, a draft decision shall be prepared by the MS-CA, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year (Article 46).

The request for further information can include a request for several tests to be performed consecutively, where the need for each test after the first depends on the result of the preceding test. The conditions and test sequence should be clearly indicated in the request for further information. There is also the possibility to request further data once the new data have been received and evaluated.

The following issues need to be addressed in the (draft) decision:

- The **substance**, including chemical name, EC number, and CAS number.
- The **registration number(s)** and **registration date(s)**, as assigned by the Agency under Article 20(3), and the **registrant(s)** to whom the request is directed. The MS-CA should justify the selection of registrant(s) to receive the request. A request for further information is not necessarily directed to all registrants of a substance, e.g. in the case of different impurities that have implications for classification and labelling only some registrants may need to be contacted.
- A **justification**. The reason(s) why further information is considered necessary should be clearly stated. It is important to consider whether a decision on an evaluation has been previously taken in accordance with Article 52. In that case, any draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge, e.g. new data (Article 47). The justification would not only need to show that the information could confirm or remove the concern, but also the reasonableness of the request. In the justification, the MS-CA could consider issues like substance identity (purity, impurities), tonnage, and/or the specific concern.
- The **information requested**, including critical details e.g. on test material, test conditions and methodology, if known. For example, for Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) where the composition is unknown, then the PBT or vPvB assessment may be based on the properties of the substance as whole. However, in cases where the composition of the substance is well defined, or the major constituents are defined, it may be necessary to consider the PBT or vPvB properties of the constituents of the substance. This should be clearly indicated.

  The level of detail required in the draft decision will depend on the type of information requested. In any case, the critical test conditions, if known, should be specified.

  - Information through standard tests – for tests included in the standard information requirements as described in Annex VII to X, it may be sufficient to specify the relevant

test material and test conditions and refer to the respective test guideline for methodological aspects.

- Information through non-standard tests – for non-standard tests, in addition to the relevant test material and test conditions, methodological details may also need to be specified. In these cases, the draft decision should properly address the endpoints concerned. It could be that in some cases a detailed test protocol is needed enabling the registrant to carry out the test.
- Information through non-test methods – for non-test methods, e.g. qualitative or quantitative structure-activity relationship models or information from structurally related substances (grouping or read-across), the draft decision should at least specify the models or the structurally related substances. In these cases, the conditions set out in Annex XI should be met. Guidance on the application and regulatory acceptability of alternative methods is being developed in the Guidance on information requirements.
- Information on exposure – for exposure measurements or monitoring, the request should specify the conditions, sites, methods, etc. applicable and relevant for an accurate and representative set of measurements.

Where a group of substances is evaluated, further information may be required for one or more representative members of the group. In these cases, it should be clearly specified which members of the group are included.

- An indication of the level of **quality assurance**, e.g. whether the information should be generated in compliance with the principles of GLP.
- A **deadline** for submission of the requested information, taking into account the time constraints for registrants.

While drafting a decision, the MS-CA should take care not to disclose commercially confidential information as described in Article 118(2).

Criteria and priorities shall be developed by the Agency (Article 47) in order to ensure a harmonised approach to requests for further information, based on monitoring by the Agency of draft decisions under Article 46. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 133(3).

The legal status of the (draft) decision

There can be three types of decisions in accordance with Article 51 and 52.

1. The MS-CA draft decision, which is circulated by the Agency to the registrant(s) (or downstream user(s)) concerned. This decision is not made public.
2. The Agency decision (which will not be made public).
   - The MS-CA shall circulate its draft decision, together with any comments by the registrant(s) or downstream user(s), to the Agency and to the other MS-CA's. If the Agency does not receive any proposal for amendments, the Agency adopts the decision and notifies it to the MS-CA's and to the registrant(s) (not to the downstream user concerned, as Article 46 only talks about registrants – downstream user comment on the draft but do not have to comply with the obligation to provide additional information).

- If the Agency receives a proposal for amendment, it may modify the decision and shall refer the decision, together with the amendments proposed to the MS Committee, and communicate any proposal for amendment to the registrant(s) and/or downstream user(s). If the MS Committee reaches unanimous agreement on the draft decision, the Agency shall take the decision accordingly and inform the MS-CAs and the registrant(s).

3. The Commission decision.

If the MS Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in the Regulatory Committee according to Article 133(3). The Article 46 decision of the Agency or the Commission is addressed to registrant(s) and does not need publication in the Official Journal (OJ) in order to enter into force. The prerequisite for entry into force is notification of the relevant parties. This does not mean that they will not be published in the OJ. However, the information on the substance (in accordance with Article 119) may need to be updated as a result of the decision. The decision itself would be subject to Article 118 and interested parties could use the information provided under Article 77(2)(f) to ask for decisions on a particular substance. The merits of each case as regards confidentiality will then have to be considered.

The format of the (draft) decision

The (draft) decision requesting further information (Article 46) that has been prepared by the evaluating MS-CA, shall be sent to the Agency. An example of the format developed for this is given in Appendix 9. The format addresses all the issues mentioned in the above section together with a reference to the relevant legal text, as well as some additional considerations. In more complex cases, where more detail is needed, one can use an Annex to the (draft) decision.

3.4.5 Adoption of decisions

The final decision under Article 46 is taken by the Agency or the Commission as described in Article 50, 51 and 52 of REACH. The procedure for commenting and adopting decisions is depicted in Figure 9. The relevant time periods are indicated in Table 8.

Comments to draft decisions

Registrants or downstream users potentially affected by an evaluation decision have the right to comment on the draft decisions being prepared by the MS-CA and to have those comments taken into account (Article 50). Also, Member States have the possibility to comment on (draft) decisions prepared by other MS-CA's (Article 51/52). Member States may propose amendments to a draft decision via the Agency and may comment on the (modified) draft decision via the MS Committee.

There is no possibility for other stakeholders to comment on (draft) decisions under Article 46.

Stopping of manufacture or import, or the production or import of an article, or the downstream use

Under normal circumstances a registrant shall not be responsible for producing the additional information required by evaluation if they have either already stopped the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, or if they decide to stop it in light of the additional information requirements needed as a result of evaluation, and have, in either case, informed the Agency (Article 50(2,3)). Only if there is a potential long-term risk to man or the environment and the registrant or downstream user in question is responsible for contributing significantly to the exposure of that substance, shall the registrant be responsible for providing the additional information (Article 50(4)). This is to avoid registrants being retrospectively liable in all but the most extreme cases.

Figure 9 Adoption of decisions (Article 50/52 procedure).

Table 8 Time periods for substance evaluation

Time	Process	Actor	Period
	Draft Community rolling action plan (Article 44(2))	Agency	First draft within 4.5 years of entry into force of REACH
	Substances allocated between MS-CA's (Article 45)	Agency/MS-CAs	
	If more then one MS wants to become CA, MS Committee shall reach agreement, if not, COM decides acc. to Article 133(3) procedure (Article 45(3))	MS Committee/COM	MS Committee: 60 days; (Article 133(3)) procedure: not specified
T0	Publication of a substance on the Community rolling action plan (Article 46(1))	Agency	
T1	Evaluation of substance and drafting of a decision (Article 46(1)(2))	MS-CA	12 months
T2	Comment on draft decision (Article 50(1))	Registrant(s)/DU(s)	30 days
	Forward comments to evaluating MS-CA	Agency	Without delay
T3	May amend draft decision and take into account comments (Article 50(1))	MS-CA	Not specified
T4	Notify draft decision together with any comments to Agency and other MS-CAs (Article 52(1))	MS-CA	Not specified
T5	Propose amendments (Article 51(2))	MS-CAs	30 days
T5a	May modify draft decision and forward any proposed amendments to MS Committee (Article 51(4))	Agency	15 days
T5b	Comment (Article 51(5))	Registrant(s)/DU(s)	30 days
T6	Conclusion (Article 51(6))	MS Committee	60 days
T7	Take final decision acc. to Article 51(6) and 52(2) or Article 133(3) procedure (Article 51(7))	Agency/ Commission	Not specified
T8	Submit the information required to the Agency by the deadline set (Article 46(2))	Registrant(s)	Within adequate time period to be set
T9	Examine any information submitted and draft any appropriate decisions (Article 46(3))	MS-CA	12 months
T9	Notify Agency (Article 46(4))	MS-CA	Not specified

3.5 Outcome of the substance evaluation process

Aim: The objective of this section is to list the possible outcomes of the substance evaluation process.

Tasks: The MS-CA has to decide on an appropriate follow-up of the substance evaluation.

An initial concern is addressed by a review of available registration dossiers and any other information (Figure 10). The outcome of this data review process can be threefold:

1. Initial concern has been removed. If the MS-CA considers that its initial concern has been removed after review of the available data, there is no need to proceed with a request for further information or other follow-up. The results of the data review and the conclusions shall be documented (see section 3.5.1) so that others can benefit from the work done.

   If, in these cases, new information has been found that is not of sufficient weight to carry on with the substance evaluation process, but is considered relevant for the registrant(s) (e.g. because it affects the validity of their risk assessment(s)), the evaluating MS-CA should consider bringing this information to the attention of the registrant(s) with an encouragement to update the registration dossier(s).

2. A request for further information. The request for further information is one outcome of the process of substance evaluation. If the MS-CA considers that further information is required, including, if appropriate, information not listed in Annexes VII to X of REACH, it shall prepare a draft decision, with contents as outlined in Section 3.4.4. The procedures for commenting and adoption have been described in Section 3.4.5.

   The Agency is given responsibility for assuring the consistency of decisions at the draft stage (Article 47).

3. A follow-up to substance evaluation and/or data review. Once the substance evaluation has been completed, the MS-CA shall consider whether there is a need how to use the information obtained for the purposes of identifying substances of very high concern (Article 59(3)), restriction (Article 69(4)) or harmonised classification and labelling (Article 115(1)). This does not, however, limit the follow-up to the preparation of an Annex XV dossier. The following options are identified to address the concern.

   – Annex XV Dossier for harmonised classification and labelling for CMRs and respiratory sensitisers or for other effects, if the need for action on the Community level is demonstrated.

   – Annex XV Dossier for the identification of a substance of very high concern (SVHC, e.g PBT, vPvB or a substance of equivalent level of concern).

   – Annex XV Dossier for restrictions proposal.

   – Actions outside the scope of REACH (e.g., other EU legislation like the Water Framework Directive or national regulations).

   – Voluntary actions by registrant(s) and/or downstream user(s), e.g. adjustment of proposed Risk Reduction Measures.

   The first three options are considered in the guidance developed in the Guidance on Annex XV for C&L, the Guidance on identification of SVHC and the Guidance on Annex XV for

restrictions. With regard to the voluntary action, a written commitment from the Industry is needed before a decision will be taken.

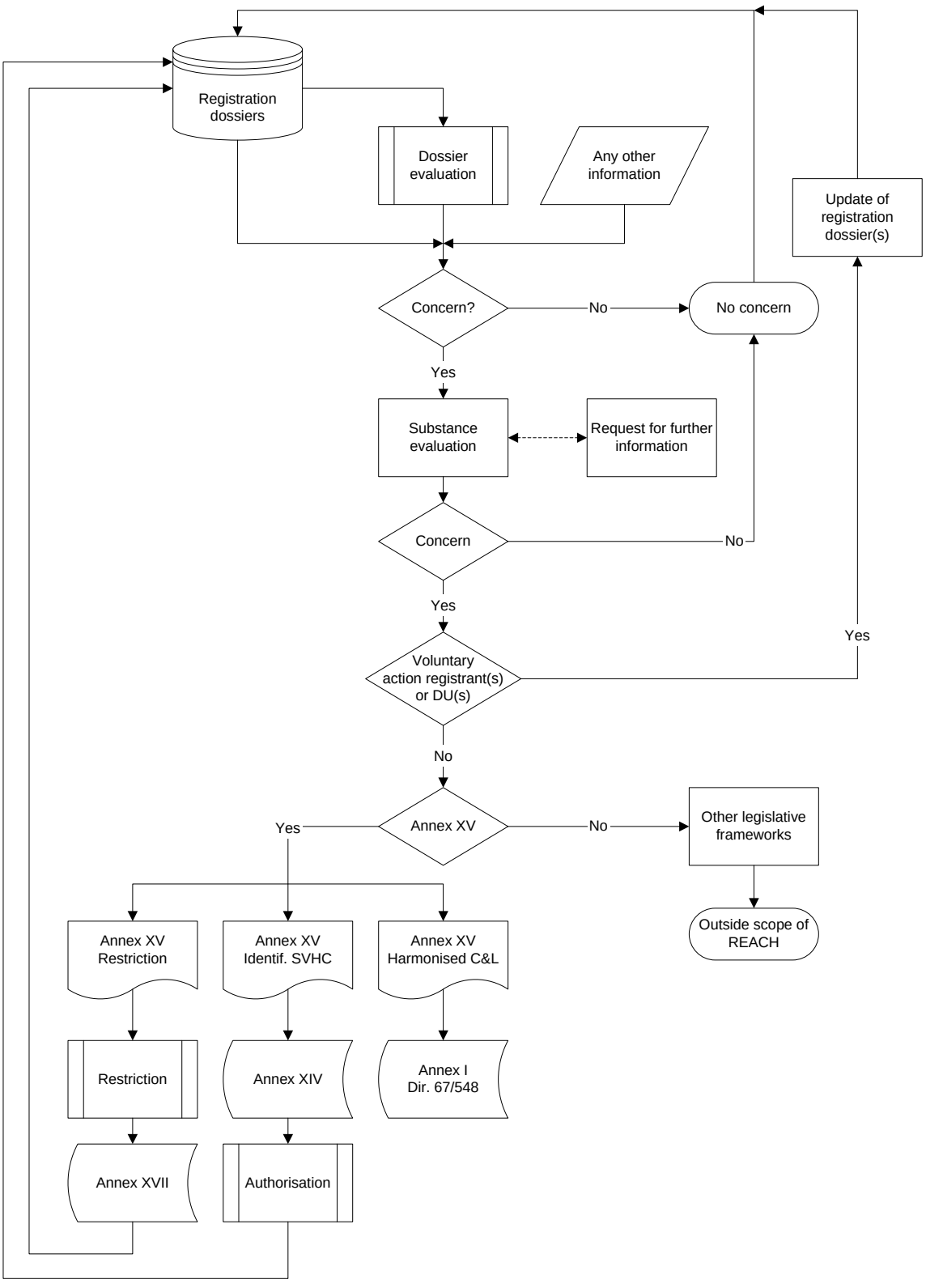

Figure 10 Relationship of substance evaluation with other REACH processes.

In any case, according to Article 48, the MS-CA '*shall inform the Agency of its conclusions as to whether or how to use the information obtained. The Agency shall in turn inform the Commission, the registrant and the competent authorities of the other Member States.'*

Update of the registration dossier

An additional follow-up is the update of the registration without undue delay with relevant new information and the submission of the updated dossier to the Agency. This responsibility for the registrant(s) is laid down in Article 22 of REACH and can be foreseen e.g. when new information is submitted by registrants in response to a request for further information under Article 46, or an adaptation of RMM has been carried through.

Where there has been only an informal consultation of registrants by the evaluating MS-CA, there still might be a need for an update of the registration dossier(s) with the new information that became available.

3.5.1 Format for reporting of work done under substance evaluation

A format for for reporting of the work done under the substance evaluation process is presented in Appendix 8. This format is consistent with the format for Annex XV dossier and with the format of the CSR.

After submission to the Agency, the report shall be filed in the appropriate part of REACH-IT and be accessible to (other) MS-CA for future work on the same substance. Importantly, when the initial concern has been removed after the substance evaluation, the work done has to be properly documented to avoid duplicate work.

3.6 Further information on on-site isolated intermediates

Aim: The objective of this section is to provide guidance to the MS-CA for evaluation of on-site isolated intermediates under Article 49.

Tasks: The MS-CA has the possibility to evaluate on-site isolated intermediates if the intermediate is used at a site located in his territory.

With respect to intermediates, the REACH text discriminates between non-isolated intermediates, on-site isolated intermediates, and transported isolated intermediates (Article 3). The REACH Regulation does not apply to non-isolated intermediates (Article 2), whereas for on-site isolated intermediates and transported isolated intermediates specific registration and information requirements are laid down in Articles 17 and 18 respectively of the REACH text.

Transported isolated intermediates are subject to Title VI of REACH. In contrast, neither dossier nor substance evaluation apply for on-site isolated intermediates that are used in strictly controlled conditions (Article 49). However, Member States may ask for additional information and take necessary action on such a substance, if they can demonstrate that its use gives rise to a risk equivalent to the level of concern arising from the use of substances subject to authorisation, i.e. substances meeting the criteria in Article 57. The procedure provided for in Article 49 may be undertaken only by the MS-CA in whose territory the site is located. The inclusion of the concerning substance on the Community rolling action plan is not a prerequisite for this evaluation procedure.

It is important to note that if the MS-CA decides to ask for further information, then it should be directly related to the risk identified. This request shall be accompanied by a written justification. The format developed for the request for further information under Article 46 (see Appendix 9) can be used for this type of request.

Upon receipt of the information, the MS-CA may examine this and, if necessary, recommend appropriate risk reduction measures to address the risks identified in relation to the site in question. The methodology for evaluation of on-site isolated intermediates is identical to that for evaluation of other substances and is described in section 3.3 of this guidance.

The competent authority shall inform the Agency of the results of such an evaluation, which shall then inform the competent authorities of other Member States and make the results available to them.

4 REFERENCES

AMAP (2001). Guidelines for the AMAP Phase 2 Assessments. Arctic Monitoring and Assessment Programme. AMAP Report 2001:1 (available from http://www.amap.no/).

Bodar, C. W. M.; Berthault, F.; de Bruijn, J. H. M.; van Leeuwen, C. J.; Pronk, M. E. J.; Vermeire, T. G., 2002 Evaluation of EU Risk Assessment Existing Chemicals (EC Regulation 793/93). RIVM Report 601504002/2002 RIVM, Rijksinstituut voor Volksgezondheid en Milieu, Bilthoven, Netherlands, 2002.

APPENDIX 1 TASKS AND RESPONSIBILITIES REGARDING EVALUATION

The following tables provide an overview of the actions within the evaluation processes in dependence on the responsible actor.

Table 9 Tasks and responsibilities of the Agency

Responsibility Agency	REACH text
Dossier Evaluation	
Examination of testing proposals.	Art. 40 (1)
Considering information submitted by MS-CAs or any other party for selection and examination of dossiers for compliance check.	Art. 41 (6)
Selection of registration dossiers for compliance check.	Art. 41 (5)
Make available a list of dossiers being checked for compliance.	Art. 41 (2)
Examination of registration dossiers for compliance check.	Art. 41 (1)
Drafting decisions (dossier evaluation and testing proposals).	Art. 40 (3); Art. 41 (3)
Setting deadlines for submission of required information.	Art. 41 (3)
Notify draft decision under Art. 40 or 41 to registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt.	Art. 50 (1)
Receipt of comments on draft decision under Art. 40 or 41 from registrant(s) or downstream user(s).	Art. 50 (1)
Receipt from registrant or downstream user of former cessation of manufacture or import for a substance, or the production or import of an article, or the downstream use subject to a draft decision under Art. 46.	Art. 50 (2)
Put registered volume to zero upon receipt of notification of former cessation of manufacture or import or the production or import of an article, or the downstream user's use for a substance subject to a draft decision under Art. 40 and 41.	Art. 50 (2)
Withdraw draft decision upon receipt of notification of former cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 40 or 41.	Art. 50 (2)
Inform MS-CA of former cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 40 or 41.	Art. 50 (2)
Receipt from registrant or downstream user of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 40 or 41 in response to this (draft) decision.	Art. 50 (3)
Label registration as no longer valid upon receipt of notification of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 46.	Art. 50(3)
Inform MS-CA of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 40 or 41 in response to this (draft) decision.	Art. 50 (3)
Withdraw draft decision upon receipt of notification of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 40 or 41, in response to this (draft) decision.	Art. 50 (3)

Responsibility Agency	REACH text
Receipt of proposals for amendments to draft decisions from Member States.	Art. 51 (2)
Take decision as proposed in draft decision on request for further information, if no proposals for amendments are received.	Art. 51 (3)
Modification of draft decision, if instigated by proposed amendments.	Art. 51 (4)
Refer draft decision, together with any amendments proposed, to MS Committee within 15 days of the end of the 30-day period after circulation of draft decision by evaluating Member State.	Art. 51 (4)
Communicate forthwith any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days.	Art. 51 (5)
Receipt of comments from registrant(s) or downstream user(s) on proposal for amendment. Forward comments to MS Committee.	Art. 51 (5)
Take decision accordingly if MS Committee reaches a unanimous agreement on the draft decision, within 60 days of referral.	Art. 51 (6)
Inform Commission if no unanimous agreement is reached by MS Committee within 60 days of referral. Commission shall prepare a draft decision in accordance with procedure referred to in Art. 133(3).	Art. 51 (7)
Receipt of agreement between registrants who will perform testing upon decision under Art. 40 or 41	Art. 53 (1)
Designation of one registrant or downstream user to perform the required test(s) on behalf of other registrants, if not informed about an agreement between registrants within 90 days after decision,	Art. 53 (1)
Publication of information on evaluation,	Art. 54
Substance Evaluation	
Development of criteria for prioritising substances with a view to further evaluation, in co-operation with the Member States.	Art. 44 (1)
Compilation of a draft Community rolling action plan - first draft to Member States within 4.4 years after EiF REACH - annual update to Member States before 28 February each year	Art. 44 (2)
Submission of draft Community rolling action plan to Member States,	Art. 44(2)
Adoption of final Community rolling action plan on the basis of an opinion from the MS Committee, including identification of evaluating Member States.	Art. 44 (2)
Publication of Community rolling action plan (website),	Art. 44 (2)
Co-ordination of the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated.	Art. 45 (1)
Ensure that substances from the Community rolling action plan not being chosen by any Member State, are evaluated.	Art. 45 (2)
Refer matter to the MS Committee in cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority.	Art. 45 (3)
Refer matter to the Commission in cases where the MS Committee failed to reach a unanimous decision on who should be the competent authority where two or more Member States have expressed an interest in evaluating the same substance and they themselves previously could not agree who should be the competent authority.	Art. 45 (3)
Decision whether to add substance (as proposed by Member States) to the Community rolling action plan on the basis of an opinion from the MS Committee.	Art. 45 (5)

Responsibility Agency	REACH text
Start Art. 50/52 procedure after receipt of draft decision from Member State	Art. 46 (1)
Notify draft decision under Art. 46 to registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt.	Art. 50 (1)
Receipt of comments on draft decision under Art. 46 from registrant(s) or downstream user(s).	Art. 50 (1)
Inform Member State of receipt of registrant's or downstream user's comments without delay.	Art. 50 (1)
Receipt from registrant or downstream user of former cessation of manufacture or import for a substance subject to a draft decision under Art. 46.	Art. 50 (2)
Put registered volume to zero upon receipt of notification of former cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 46.	Art. 50 (2)
Withdraw draft decision upon receipt of notification of former cessation of manufacture or import for a substance subject to a draft decision under Art. 46. Note Art. 50 (4), information may still be requested if an Annex XV dossier is being prepared. Until restart of manufacture/import or the production or import of an article, or the downstream user's use.	Art. 50 (2)
Inform Member State(s) concerned of former cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 46.	Art. 50 (2)
Receipt from registrant of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 46 in response to this (draft) decision.	Art. 50 (3)
Label registration as no longer valid upon receipt of notification of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 46.	Art. 50(3)
Inform Member State(s) concerned of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 46 in response to this (draft) decision.	Art. 50 (3)
Withdraw draft decision upon receipt of notification of cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 46, in response to this (draft) decision unless new registration is submitted. Note Art. 50 (4), information may still be requested if an Annex XV dossier is being prepared.	Art. 50 (3)
Receipt of draft decision by evaluating MS-CA together with any comments by registrant(s) or downstream user(s).	Art. 52 (1)
Receipt of proposals for amendments to draft decisions from Member States.	Art. 52 (2)[2] *Art. 51 (2)*
Take decision as proposed in draft decision on request for further information, if no proposals for amendments are received.	Art. 52(2) *Art. 51 (3)*
Modification of draft decision, if instigated by proposed amendments.	Art. 52 (2) *Art. 51 (4)*
Refer draft decision, together with any amendments proposed, to MS Committee within 15	Art. 52 (2)

[2] Article 52(2) of REACH states "The provisions of Article 51(2) to (8) shall apply *mutatis mutandi*". Therefore, in this Table, reference is made to Article 52(2) as well as the corresponding part of Article 51 in italics.

Responsibility Agency	REACH text
days of the end of the 30-day period after circulation of draft decision by evaluating Member State.	*Art. 51 (4)*
Communicate forthwith any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days.	Art. 52 (2) *Art. 51 (5)*
Receipt of comments from registrant(s) or downstream user(s) on proposal for amendment. Forward comments to MS Committee.	Art. 52 (2) *Art. 51 (5)*
Take decision accordingly if MS Committee reaches a unanimous agreement on the draft decision, within 60 days of referral.	Art. 52 (2) *Art. 51 (6)*
Inform Commission if no unanimous agreement is reached by MS Committee within 60 days of referral. Commission shall prepare a draft decision in accordance with procedure referred to in Art. 133(3).	Art. 52 (2) *Art. 51 (7)*
Receipt of information submitted by registrant.	Art. 46 (2)
Start Art. 50/52 procedure after receipt of draft decision from Member State, if applicable.	Art. 46 (3)
Receipt from Member States of notification of finished evaluation activities.	Art. 46 (4)
Monitoring of draft decisions and development of criteria and priorities in order to harmonise the approach for requests for further information.	Art. 47 (2)
Receipt of Member States' conclusions as to whether or how to use information obtained (i.e. follow up activities).	Art. 48
Inform Commission, registrant and other Member States of follow up activities.	Art. 48
Receipt of results of evaluation by Member State of use of substance as on-site isolated intermediate.	Art. 49
Inform other Member States of results of evaluation by one Member State of use of substance as on-site isolated intermediate, and make results available to them.	Art. 49
Receipt of agreement between registrants who will perform testing upon decision under Art. 46.	Art. 53 (1)
Designation of one registrant or downstream user to perform the required test(s) on behalf of other registrants, if not informed about an agreement between registrants within 90 days after decision.	Art. 53 (1)
Publication of information on evaluation.	Art. 54

Table 10 Tasks and responsibilities of the Member State competent authority (MS-CA)

Responsibility Member State competent authority	REACH text
Dossier Evaluation	
Receipt of registrants' or downstream user's comments on draft decision via Agency.	Art. 50 (1)
Receipt via Agency of information on former cessation by registrant of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 40 or 41.	Art. 50 (2)
Receipt via Agency of information on cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 40 or 41 in response to this (draft) decision.	Art. 50 (3)
Receipt via Agency of draft decision together with any comments by registrant(s) or downstream user(s).	Art. 51 (1)
Receipt of draft decision together with any comments by registrant(s) from other MS-CAs.	Art. 51 (1)

Responsibility Member State competent authority	REACH text
Proposal of amendments to draft decisions under Art. 40 or 41 to Agency within 30 days of circulation.	Art. 51 (2)
Using the required information for highlighting a substance for addition to the Community rolling action plan.	Art. 42 (2)
Using the required information for preparation of an Annex XV dossier to propose and justify the identification of PBTs, vPvBs or a substance of equivalent concern and the restriction of the manufacture, placing on the market or use of a substance within the Community.	Art. 42 (2)
Substance Evaluation	
Contribution to the development of criteria for prioritising substances with a view to further evaluation, in co-operation with the Agency.	Art. 44 (1)
Receipt of draft Community rolling action plan.	Art. 44 (2)
Prepare an opinion on draft Community rolling action plan, input via MS Committee.	Art. 44 (2)
If applicable, appoint another body to act on MS behalf in substance evaluation.	Art. 45 (1)
Selection of substances from Community rolling action plan with the aim of becoming competent authority for the purpose of Art. 46-48.	Art. 45 (2)
Adopt substance for evaluation if decided by MS Committee or Commission (under procedure Art. 45 (3)).	Art. 45 (3)
Evaluation of allocated substances.	Art. 45 (4)
Evaluation of proposed substances by MS after addition to Community rolling action plan.	Art. 45 (5)
Notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation.	Art. 45 (5)
Preparation of draft decision with request for further information, if considered necessary, within 12 months after publication of Community rolling action plan (procedure Art. 50 and 52).	Art. 46 (1)
Send draft decision under Art. 46 to Agency.	Art. 50(1)
Receipt of registrants' or downstream user's comments on draft decision via Agency.	Art. 50 (1)
Amendment of draft decision taken under Art. 46, if necessary based on registrants' or downstream user's comments.	Art. 50 (1)
Receipt via Agency of information on former cessation by registrant of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 46.	Art. 50 (2)
Receipt via Agency of information on cessation of manufacture or import for a substance or the production or import of an article, or the downstream user's use subject to a (draft) decision under Art. 46 in response to this (draft) decision.	Art. 50 (3)
Prepare request for information despite notification of cessation of exposure in specific cases.	Art. 50 (4)
Circulation of draft decision together with any comments by registrant(s) or downstream user(s) to Agency and other MS-CAs.	Art. 52 (1)
Receipt of draft decision together with any comments by registrant(s) or downstream	Art. 52 (1)

Responsibility Member State competent authority	REACH text
user(s) from other MS-CAs.	
Proposal of amendments to draft decisions under Art. 46 (of other Member States) to Agency within 30 days of circulation.	Art. 52 (2)[3] *Art. 51 (2)*
Prepare an opinion on amended draft decision, input via MS Committee. Take comments on proposed amendments from registrants or downstream users concerned into account (Art. 52 (2)/Art. 51 (5).	Art. 52 (2) *Art. 51 (4)*
Receipt and examination of any information submitted by registrant to Agency.	Art. 46 (3)
Preparation of draft decision, within 12 months after submission of information.	Art. 46 (3)
Complete evaluation activities within 12 months of the start of the evaluation of the substance or within 12 mo of the information being submitted under Art. 46(2).	Art. 46 (4)
Notify Agency of completed evaluation activity.	Art. 46 (4)
Use all relevant information, including information from structurally related substances, in the evaluation.	Art. 47(1)
Consider how to use information obtained for purpose of preparation of Annex XV dossier.	Art. 48
Inform Agency of conclusions as to whether or how to use information obtained (i.e. follow up activities).	Art. 48
Receipt of follow up activities from other Member States via Agency.	Art. 48
Consider whether risks equivalent to use of substances of very high concern (Art. 57) arise from use as on-site isolated intermediate are adequately controlled.	Art. 49
Prepare request for further information (directly related to the risk identified) to registrant (with written justification)	Art.49
Examine any information submitted and, if necessary, recommend any appropriate RRM.	Art. 49
Inform Agency of results of evaluation of use as on-site isolated intermediate.	Art. 49
Receipt from Agency of results of evaluation by other MS-CAs of use of substances as on-site isolated intermediate.	Art. 49

Table 11 Tasks and responsibilities of the Member State Committee (MS Committee)

Responsibility MS Committee	REACH text
Form an opinion on the draft Community rolling action plan presented by the Agency.	Art. 44 (2)
Decide on who should be the competent authority in cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, if requested by the Agency. If no unanimous agreement is reached, matter should be referred to the Commission by the Agency.	Art. 45 (3)
Form an opinion on whether or not to add substance (as proposed by Member States) to the Community rolling action plan.	Art. 45 (5)
Form an opinion on draft decision under Art. 40, 41 or 46, together with any amendments proposed, within 60 days of the referral by the Agency. (If no unanimous agreement is reached, the matter should be referred to the Commission by the Agency.)	Art. 51 (4), Art. 52 (2)

[3] Article 52(2) of REACH states "The provisions of Article 51(2) to (8) shall apply *mutatis mutandi*". Therefore, in this Table, reference is made to Article 52(2) as well as the corresponding part of Article 51 in italics.

Table 12 Tasks and responsibilities of the Commission

Responsibility Commission	REACH text
Take a decision to vary the percentage of dossiers selected for compliance check and amend or include further criteria.	Art. 41 (7)
Take decision, in accordance with the procedure referred to in Art. 133(3), on which competent authority shall be the competent authority evaluating a substance if the MS Committee did not reach unanimous agreement (in those cases where two or more Member States have expressed an interest in evaluating the same substance and they previously could not agree on who should be the competent authority).	Art. 45 (3)
Receipt of information on follow up activities after substance evaluation for the purposes of Art. 59(3), 69(4) and Art. 115(1) from Member States via Agency.	Art. 48
Preparation of a draft decision, in accordance with procedure referred to in Art. 133(3), if the MS Committee failed to reach unanimous agreement on a draft decision under Art. 40, 41 or 46.	Art. 51 (7), Art. 52 (2)
Adopt implementing measures according with the procedure referred to in Art. 133(3).	Art. 47

Table 13 Tasks and responsibilities of the registrant(s) or downstream user(s)

Responsibility registrant(s) or downstream user(s)	REACH text
Receipt of notification by Agency of draft decision under Art. 40, 41 or 45.	Art. 50 (1)
Provide comments on draft decision to Agency within 30 days of notification.	Art. 50 (1)
Inform Agency if manufacture or import of a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 40, 41 or 46 has formerly ceased.	Art. 50 (2)
Inform Agency if manufacture or import of a substance or the production or import of an article, or the downstream user's use subject to a draft decision under Art. 40, 41 or 46 is ceased in response to this (draft) decision.	Art. 50 (3)
Receipt from Agency of any proposal for amendment of draft decision.	Art. 51 (5), Art. 52 (2)
Provide comments on proposals for amendment of draft decision to Agency within 30 days of receipt.	Art. 51 (5), Art. 52 (2)
Submit information as required to Agency by deadline set.	Art. 40 (4), Art. 46 (2)
Receipt of follow up activities after substance evaluation from Member States via Agency.	Art. 48
Receipt of request by Member State for further information related to risks identified for use of substances as on-site isolated intermediate.	Art. 49
Receipt of recommendations by Member State to reduce risks identified for substances used as on-site isolated intermediate.	Art. 49
Agree on who is to carry out testing on behalf of other registrants in case of multiple registrants.	Art. 53 (1)
Inform Agency of registrant who carries out testing, within 90 days.	Art. 53 (1)
Share costs of testing equally, if one registrant or downstream user performs test on behalf of others.	Art. 53 (2)
Provide copy of full study report to other (paying) registrants.	Art. 53 (3)
If applicable, make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market.	Art. 53 (4)
Update of registration without undue delay with relevant new information and submitting it to the Agency.	Art. 22

APPENDIX 2 COMMUNICATION BETWEEN THE ACTORS

Informal communication during testing proposal examination

Informal communication may take place during the period between the submission of the testing proposal and the draft decision by the Agency. Beyond this period, only formal discussions should take place (as described in and according to Articles 50 and 51).

Initially, informal communication in the frame of testing proposals examination can be foreseen at the following levels:

- **Informal** communication intended to clarify the testing proposal submitted and to facilitate its examination by the Agency which might lead to an update of the testing proposal in the registration dossier:
    - Clarification of the justification of the testing proposal provided by the manufacturer/importer or downstream user.
    - Clarification of any data in the registration dossier which can justify the testing proposal or which can be used to waive the testing proposal.
- Informal communication on the draft decision about:
    - the best way to perform the test (e.g. possible modifications).
    - the best testing strategy (e.g. in cases where additional tests should be performed).

All the information and exchanges between the Agency and the registrant which clarify the testing proposal and its examination should be recorded in the relevant folder in REACH-IT at the Agency.

After the examination of the testing proposal is completed, the Agency shall submit the draft decision through a formal process to the registrant. Any further communication on this draft decision will take place through the **formal** process as described in Articles 50 and 51 and in Section 2.1.

Communication under compliance check

Communication is essential in order to make transparent what has been done and what are the results after evaluation of the registration dossiers.

There is a need for communication between

- The Agency and the registrant(s):
    - **Informal** communication over the period of the compliance check is recommended in order to clarify uncertainties. Thereby preparation of a draft decision might be avoided by clarification beforehand. Setting adequate time limits for submission of further information might be done after informal consultation between the Agency and the registrant.

- **Formal** communication between the Agency and the registrant(s) is foreseen when the draft decision is sent to the registrant(s) requesting further information to bring the registration dossier into compliance as well as to specify time limits for the submission (ref. Articles 41(3) and (4)).

- The Agency and third parties:
  - Third parties may submit information to the Agency relating to substances that are published on the Agency's website for pre-registration. **Informal** communication in order to clarify uncertainties regarding adequacy of information submitted by third parties is recommended.

- The different actors performing the dossier evaluation (Agency) and the substance evaluation (Member States).
  - **Informal** communication is highly recommended if the Agency gives priority for checking compliance of dossiers of substances which are listed on the Community rolling action plan in order to avoid double work and eventually to focus the compliance check on the parts of the dossiers for which there is a suspicion of risks to human health or the environment.
  - **Formal** communication between the Agency and the MS-CAs is foreseen when a list of dossiers being checked for compliance is made available to the MS-CAs. Additionally the MS-CAs are involved in the adoption process of a draft decision and should be informed about information obtained and any conclusions made after the dossier is updated by the registrant (ref. Articles 41(2), 50 and 51).

- The different actors involved in the draft decision process (Articles 50 and 51 procedure).
  - **Formal** communication in accordance with Articles 50 and 51 is foreseen.

Communication under substance evaluation

The legislative text includes no specific requirement for Member States to engage in consultation with stakeholders during the substance evaluation process, yet involvement of registrants/downstream user and others who are also consulted in the process is important. Informal consultation may be an important and efficient way for the MS to obtain additional information and/or to remove the concern, e.g. by voluntary adaptation of RMM by registrant(s) in response to the concern expressed by the authority.

APPENDIX 3 EXAMPLES FOR THE EXAMINATION OF TESTING PROPOSALS

The examples provided in this Appendix are intended to illustrate the different tasks when assessing testing proposal.

Background: substance, when registered, is imported into the EU in quantities of >100 tpa and <1000 tpa.

Testing proposal submitted? 90-day repeat dose toxicity study via the oral route (OECD 408)

The testing proposal submitted is for a test under Annex IX or X or is a higher level study? Yes, the endpoint appears in Annex IX.

Available information in the technical dossier:

● **Relevant data available from Annex VII**

- Substance is a solid powder of which 75% has a particle size <2µm.

● **Relevant data available from Annex VIII**

- Acute oral study available, LD50> 2000 mg/kg. No effects reported.

- Acute inhalation study available, LC50> 3 mg/l 4h exposure (whole body; maximum attainable concentration). Mass median aerodynamic diameter 3µm. Reported effects limited to colouration of the lungs in all treated animals.

- 28-day repeat dose oral toxicity study available but not conducted to current OECD guidelines (OECD 407), with very limited organ weight and histopathological data available. Effects observed in the study were limited reductions in female haemoglobin at 1000 mg/kg/day ($p<0.05$). NOAEL 250 mg/kg/day.

Based on the information currently available, the substance is not classified for mutagenicity. Data available are a negative Ames, negative mammalian cell gene mutation study and a negative in vitro cytogenetics study, all conducted to current OECD guidelines.

● **Relevant information in the CSR**

There are no data on carcinogenicity. Use of substance indicates that there is sufficient potential for occupational exposure via the inhalation route, for a risk to have been identified.

Possibility of using waiving or alternative methods (columns 2 of Annexes IX and X and XI)? No waiving is possible. No alternative methods available to evaluate the risk.

Is the testing proposal adequate? No

● **Modification of the testing proposal needed?** Yes, the Agency recommends that a 90-day repeat dose toxicity study by the inhalation route (OECD 413) should be conducted instead of one via the oral route. Although both tests are 90-day repeat dose toxicity studies, they differ in the route of exposure and refer to two test guidelines. This means the proposed testing has to be rejected and another test requested instead.

● **Reason for modification**: An inadequate 28-day oral study is the only repeat dose toxicity data currently available, and sufficient potential for human exposure exists. Therefore, further repeat dose toxicity testing is required. Since a high percentage of the substance (75%) has a particle size < 2μm and potential for exposure via the inhalation route has been identified, a modification of the testing proposal from the oral to inhalation route is necessary.

● **Further additional testing required**. Not at present. Further studies for this endpoint will be considered once the results of the 90-day study are known, as indicated in Annex IX (8.6.2, column 2).

Conclusion

Another study with a different rout of exposure is adequate. The two tests refer to two separate guidelines, therefore the 90-day repeat dose toxicity study by the inhalation route is considered as additional testing and not as a modification of the toxicity study via the oral route.

Decision c (rejection and additional testing required)

The Agency recommends that a 90-day repeat dose toxicity study by the inhalation route (OECD 413) should be conducted instead of one via the oral route.

APPENDIX 4 REPORTING FORMAT FOR TESTING PROPOSALS

Example of a reporting format that could be updated when the Agency has gathered more experience.

Dossier Evaluation

Reporting Format for Testing Proposal

PART A

DECISION ON TESTING PROPOSAL

Identity of the registrant:

Identity of the substance: name, CAS, other?

Registration number:

Testing proposal examined:

Conclusion:

Decision a)

( ) The testing proposal is accepted.

The study summary of the test(s) should be provided to the Agency before the *[indicate the deadline of submission]*

Decision b)

( ) The testing proposal is accepted but the test(s) shall be carried out under the following modified conditions:

[list modified conditions]

The study summary of the test(s) should be provided to the Agency before the *[indicate the deadline of submission]*

Decision c)

( ) The testing proposal is accepted.

The following additional test(s) should be performed:

[list additional test(s)]

The study summary of the test(s) should be provided to the Agency before the *[indicate the deadline of submission]*

( ) The testing proposal is accepted.

The study summary of the test(s) should be provided to the Agency before the *[indicate the deadline of submission]*

Depending on the results of the test(s) performed, the following additional test(s) may have to be performed:

[list additional test(s)]

The selection of the additional test(s) and the deadline for the submission of their results will be provided by the Agency in due time.

( ) The testing proposal is accepted but the test(s) shall be carried out under the following modified conditions:

[list modified conditions]

The following additional test(s) should be performed:

[list additional test(s)]

The study summary of the tests should be provided to the Agency before

the *[indicate the deadline of submission]"*

( ) The testing proposal is rejected.

The following additional test(s) should be performed:

[list additional test(s)]

The study summary of the test(s) should be provided to the Agency before the *[indicate the deadline of submission]*

Decision d)

( ) The testing proposal is rejected.

Decision e) *(to be used in addition to decision a, b or c)*

( ) The same testing proposal was provided by the following registrants:

[list the name and address of the registrants]

It is recommended that an agreement should be reached on who will perform the test on behalf of the others and you should inform the Agency on the conclusion of this agreement before [indicate the deadline which corresponds to 90 days after the draft decision].

If no information on such agreement within this deadline has been received, the Agency will designate one of the registrants to perform the test(s) on behalf of all of them.

PART B

JUSTIFICATION OF THE DECISION

[free text on justification]

APPENDIX 5 CHECKLIST FOR COMPLIANCE CHECK OF THE TECHNICAL DOSSIER

Table 14 Checklist for any endpoint in the technical dossier

Technical Dossier[4]			
Name of the endpoint	**Yes**	**No**	**Jointly submitted part**
Is the letter of access to the respective full study report (Article 10) available?			
1. Substance			
1.1. Phase-in substance?			
1.2. Non-phase-in substance?			
2. Study Summary			
2.1. If phase-in substance: Has the correct key study been selected?			
3. Robust Study Summary			
3.1. Quality statement?			
3.1.1. Good Laboratory Practice?			
3.1.2. Other accepted quality standards (e.g. ISO 17025)?			
3.1.3. Is the quality statement adequate/acceptable?			
3.1.4. Is the information reviewed by an assessor chosen by manufacturer/importer?			
3.2. Method			
3.2.1. Standard test method (e.g. equivalent to OECD TG)?			
3.2.2. Is the selected method adequate?			
3.3. Adaptations			
3.3.1 Modified standard method?			
3.3.2. Adaptations according to the testing strategy (Guidance on information requirements)?			
3.3.3. Adaptations of standard requirements according to column 2 of Annexes VII to X?			
3.3.4. Adaptations of standard requirements according to Annex XI?			
3.3.5. Is the justification for adaptations adequate?			
3.4. Results			
3.4.1. Is the presentation of the results adequate?			
3.4.2. Is the result plausible?			
3.5. Conclusions			
3.5.1. Are the conclusions of the study reliable?			
4. Classification & Labelling			
4.1. Does the result of the test require/justify classification & labelling?			
4.2. Is the given classification & labelling correct?			
5. Decision			
5.1. Is the information submitted for this endpoint considered to be in compliance?			

[4] Note that this list is not exhaustive and may be regarded as an example.

APPENDIX 6 CHECKLIST FOR THE CHEMICAL SAFETY REPORT (CSR)

Table 15 Checklist for the CSR

CHEMICAL SAFETY REPORT			
	Yes	**No**	**Jointly submitted part**
0. Availability Check			
0.1. Are all required issues available in the CSR (e.g. classification & labelling)?			
0.2. Is the substance classified as dangerous according to Directive 67/548/EEC?			
1. Cross check if the information provided in the CSR corresponds to that in the technical dossier			
1.1. Identification of the substance?			
1.2. Information on manufacture and use(s)?			
1.3. Endpoint specific classification & labelling?			
1.4. Information on environmental fate properties?			
2. Endpoint specific hazard assessment (human health, physicochemical properties, environment)			
2.1. Is the derivation of the DNEL/PNEC values plausible/acceptable (e.g. assessment factors)?			
2.2. Is the calculation of the DNEL/PNEC values correct?			
3. PBT and vPvB assessment			
3.1. Is the assessment in accordance with Annex I, section 4?			
3.2. Is the available information used in an adequate manner for the assessment?			
4. Exposure Assessment (incl. Exposure Scenarios)			
4.1. Have all stages of the life-cycle of the substance, from its manufacture to its identified uses, been considered in the exposure scenarios?			
4.2. Are the RMMs and Operational Conditions defined in a way that allows exposure estimation?			
4.3. Are the efficiency figures credibly, as well as the other characteristics of the type of RRM proposed?			
4.4. Are the exposure estimations based on the exposure scenarios?			
5. Risk Characterisation			
5.1. Has the risk characterisation been carried out for each exposure scenario?			
5.2. Has the risk characterisation been done in accordance with Annex I?			
5.3. Does the risk characterisation demonstrate that the risks are adequately controlled if the exposure scenarios (including the RMMs and Operational Conditions) are implemented?			
6. Decision			
6.1. Is the Chemical Safety Report considered to be compliant?			

APPENDIX 7 DRAFT DECISION FORMAT FOR COMPLIANCE CHECK

Example of a draft decision format for compliance check

N.B. The format may have to be further developed when the Agency has gathered more experience.

Dossier Evaluation

Draft Decision Format for Compliance Check

PART A

DRAFT DECISION ON COMPLIANCE CHECK

Identity of the registrant:

Identity of the substance: name, CAS, other?

Registration number:

Conclusion:

During compliance check the following section(s) of the registration dossier was (were) identified to be not in compliance with the legal requirements (ref. Article 41(1)) of the REACH Regulation.

Part(s) of the registration dossier which is (are) not in compliance[5]:

( ) Technical dossier:
[indicate the section(s) which is (are) not in compliance]

( ) Chemical Safety Report (CSR):
[indicate the section(s) which is (are) not in compliance]

The following information is needed, to bring the registration dossier into compliance:
[list the information needed]

This information should be provided to the Agency before the:
[indicate the deadline of submission]

In case of joint registration:
For jointly submitted non compliant data, all relevant registrants will be informed about the request for information to bring the dossier into compliance. It is recommended that an agreement should be reached between the registrants of the consortium on who will provide the information on behalf of the others and to inform the Agency on the conclusion of this agreement before*:*
[indicate the deadline which corresponds to 90 days after the draft decision]

If no information on such agreement within the deadline set has been received, the Agency will designate one of the registrants to perform the test(s) on behalf of all of them.

[1] Disclaimer: Sections of the registration dossier not mentioned in section 2 of this format can not automatically be regarded as being in compliance with the legal requirements of the REACH Regulation. Re-evaluation of the dossier for compliance may be triggered for different reasons during the life time of a registration.

PART B

JUSTIFICATION OF THE DECISION

Case of joint submission

The explanation for separate submission of information is not acceptable: ( )

[add further information if necessary]

Case of category and/or read across approaches

The justification for the inclusion of the substance in the category or for the read-across approach is not acceptable: ( )

[add further information if necessary]

Compliance check of the technical dossier

The information in the technical dossier does not comply with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X: ( )

[add further information if necessary]

The adaptations of the standard information requirements and the related justifications submitted in the technical dossier do not comply with the rules governing such adaptations set out in Annexes VII to X and the general rules set out in Annex XI: ( )

[add further information if necessary]

Compliance check of the CSR (reason for non-compliance)

Derivation of DNEL and PNEC ( )

[add further information if necessary]

PBT/vPvB assessment ( )

[add further information if necessary]

Exposure assessment ( )

[add further information if necessary]

Adequacy of Risk Management Measures ( )

[add further information if necessary]

Risk Characterisation ( )

[add further information if necessary]

Further details

APPENDIX 8 FORMAT FOR SUBSTANCE EVALUATION REPORT

SUBSTANCE EVALUATION REPORT

Substance Name:

EC Number:

CAS Number:

Rapporteur Member State:

Version:

CONCLUSION OF THE SUBSTANCE EVALUATION

Substance Name:

EC Number:

CAS number:

Registration dossiers numbers:

Conclusion of the substance evaluation:

INFORMATION ON HAZARD AND RISKS

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

[click here to insert text]

1.1 Name and other identifiers of the substance

Chemical Name:

EC Name:

CAS Number:

IUPAC Name:

1.2 Composition of the substance

For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.

Chemical Name:

EC Number:

CAS Number:

IUPAC Name:

Molecular Formula:

Structural Formula:

Molecular Weight:

Typical concentration (% w/w):

Concentration range (% w/w):

1.3 Physico-chemical properties

Table 1: Summary of physico- chemical properties

REACH ref Annex, §	Property	IUCLID section	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 kPa	3.1		
VII, 7.2	Melting/freezing point	3.2		
VII, 7.3	Boiling point	3.3		
VII, 7.4	Relative density	3.4 density		
VII, 7.5	Vapour pressure	3.6		
VII, 7.6	Surface tension	3.10		
VII, 7.7	Water solubility	3.8		
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient		
VII, 7.9	Flash point	3.11		
VII, 7.10	Flammability	3.13		
VII, 7.11	Explosive properties	3.14		
VII, 7.12	Self-ignition temperature			
VII, 7.13	Oxidising properties	3.15		
VII, 7.14	Granulometry	3.5		
XI, 7.15	Stability in organic solvents and identity of relevant degradation products	3.17		
XI, 7.16	Dissociation constant	3.21		
XI, 7.17,	Viscosity	3.22		
	Auto flammability	3.12		
	Reactivity towards container material	3.18		
	Thermal stability	3.19		
	[enter other property or delete row]			

2 MANUFACTURE AND USES

2.1 Manufacture

2.2 Identified uses

2.3 Uses advised against

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

This should include the classification (including specific concentration limits) listed in Annex I of Directive 67/548/EEC (including the Index Number)

3.2 Self classification(s)

This should include the classification, the labelling and the specific concentrations limits. The reason and justification for no classification should be reported here.

It should be stated whether the classification is made according to Directive 67/548/EEC criteria or according to GHS criteria.

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Stability

Corresponds to IUCLID 4.1

4.1.2 Biodegradation

4.1.2.1 Biodegradation estimation

4.1.2.2 Screening tests

4.1.2.3 Simulation tests

4.1.3 Summary and discussion of persistence

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Corresponds to IUCLID 4.4.1

4.2.2 Volatilisation

Corresponds to IUCLID 4.4.2

4.2.3 Distribution modelling

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

4.3.1.1 Bioaccumulation estimation

4.3.1.2 Measured bioaccumulation data

4.3.2 Terrestrial bioaccumulation

4.3.3 Summary and discussion of bioaccumulation

4.4 Secondary poisoning

Assessment of the potential for secondary poisoning

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2 Acute toxicity

5.2.1 Acute toxicity: oral

5.2.2 Acute toxicity: inhalation

5.2.3 Acute toxicity: dermal

5.2.4 Acute toxicity: other routes

5.2.5 Summary and discussion of acute toxicity

C&L including weight-of-evidence considerations.

5.3 Irritation

5.3.1 Skin

5.3.2 Eye

5.3.3 Respiratory tract

5.3.4 Summary and discussion of irritation

C&L including weight-of-evidence considerations.

5.4 Corrosivity

5.5 Sensitisation

5.5.1 Skin

5.5.2 Respiratory system

5.5.3 Summary and discussion of sensitisation

C&L including weight-of-evidence considerations.

5.6 Repeated dose toxicity

5.6.1 Repeated dose toxicity: oral

5.6.2 Repeated dose toxicity: inhalation

5.6.3 Repeated dose toxicity: dermal

5.6.4 Other relevant information

5.6.5 Summary and discussion of repeated dose toxicity:

C&L, dose-response estimation including weight-of-evidence considerations.

5.7 Mutagenicity

5.7.1 In vitro data

5.7.2 In vivo data

5.7.3 Human data

5.7.4 Other relevant information

5.7.5 Summary and discussion of mutagenicity

C&L, dose-response estimation including weight-of-evidence considerations.

5.8 Carcinogenicity

5.8.1 Carcinogenicity: oral

5.8.2 Carcinogenicity: inhalation

5.8.3 Carcinogenicity: dermal

5.8.4 Carcinogenicity: human data

5.8.5 Other relevant information

5.8.6 Summary and discussion of carcinogenicity

C&L, dose-response estimation including weight-of-evidence considerations.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.2 Developmental toxicity

5.9.3 Human data

5.9.4 Other relevant information

5.9.5 Summary and discussion of reproductive toxicity

C&L, dose-response estimation including weight-of-evidence considerations.

5.10 Other effects

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

5.11.1 Overview of typical dose descriptors for all endpoints

5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation)

5.11.3 Application of assessment factors

5.11.4 Selection/ identification of the critical DNEL(s)/ the leading health effect

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1 Explosivity

Including C&L

6.2 Flammability

Including C&L

6.3 Oxidising potential

Including C&L

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

Short-term toxicity to fish

Long-term toxicity to fish

7.1.1.2 Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Long-term toxicity to aquatic invertebrates

7.1.1.3 Algae and aquatic plants

7.1.1.4 Sediment organisms

7.1.1.5 Other aquatic organisms

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

7.1.2.2 PNEC sediment

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macro organisms

7.2.1.2 Toxicity to terrestrial plants

7.2.1.3 Toxicity to soil micro-organisms

7.2.1.4 Toxicity to other terrestrial organisms

Toxicity to birds

Toxicity to other above ground organisms

7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

7.3 Atmospheric compartment

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic micro-organisms

7.4.2 PNEC for sewage treatment plant

7.5 Calculation of Predicted No Effect Concentration for secondary poisoning (PNEC_oral)

7.6 Conclusion on the environmental classification and labelling

8 PBT AND VPVB ASSESSMENT

8.1 Comparison with criteria from annex XIII

8.2 Assessment of substances of an equivalent level of concern

8.3 Emission characterisation

8.4 Conclusion of PBT and vPvB assessment

9 EXPOSURE ASSESSMENT

9.1 General discussion on releases and exposure

9.1.1 Summary of the existing legal requirements

9.1.2 Summary of the effectiveness of the implemented risk management measures

9.2 Manufacturing

9.2.1 Occupational exposure

9.2.2 Environmental release

9.3 "Use 1"

For each use include such a sub-chapter. Subsequently, if there is another "Use 2" this will lead to sub-chapter 9.4 "Use 1" including 9.4.1 Human exposure, 9.4.1.1 Occupational exposure, 7.4.1.2 Consumer exposure and 9.4.2 Environmental release. The other sub-chapters will then be renumbered.

9.3.1 Human exposure

9.3.1.1 Occupational exposure

9.3.1.2 Consumer exposure

9.3.2 Environmental release

9.4 Other sources (for example natural sources)

9.4.1 Human exposure

9.4.1.1 Occupational exposure

9.4.1.2 Consumer exposure

9.4.2 Environmental release

9.5 Environmental exposure assessment

9.5.1 Summary of emissions

9.5.2 Predicted environmental concentrations

9.5.3 Regional concentrations

Atmosphere

Aquatic compartment

Sediment

Soil compartment

9.5.3.1 Local concentrations

Atmosphere

Aquatic compartment

Sediment

Soil compartment

9.5.4 Exposure concentrations of man via the environment

9.5.5 Measured levels

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

9.5.6 Selected environmental concentrations of risk characterisation

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

9.5.7 Combined human exposure assessment

10 RISK CHARACTERISATION

10.1 Human health

10.1.1 Workers

10.1.2 Consumers

10.1.3 Indirect exposure of humans via the environment

10.1.4 Combined exposures

10.2 Environment

10.2.1 Aquatic compartment (including sediment and sewage treatment plant and secondary poisoning)

10.2.2 Terrestrial compartment (including secondary poisoning)

10.2.3 Atmospheric compartment

10.2.4 Microbiological activity in sewage treatment systems

OTHER INFORMATION

It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g registration dossiers, other published sources) used for the dossier could also be indicated here.

APPENDIX 9 FORMAT FOR A REQUEST FOR FURTHER INFORMATION WITHIN SUBSTANCE EVALUATION

Proposal for a Request for further information under Article 46 and 49 of REACH.

Evaluating Member State: <fill in Member State that performed the evaluation>

Date: <fill in date of decision>

Substance

Chemical name : <fill in chemical name evaluated substance>

EC number : <fill in EC number of evaluated substance>

CAS number : <fill in CAS number of evaluated substance>

Registrant(s) :

<fill in name of 1st registrant> <fill in registration no.> <fill in registration date>

<fill in name of next registrant(s)> <fill in registration no.> <fill in registration date>

Justification for selected registrants:

<provide justification for addressing above registrants>

Information requested:

<describe the information requested, including quality criteria>

Justification for requested information:

<fill in justification for requested information>

Deadline for submission: <fill in time period after date of final decision>

APPENDIX 10 EXAMPLES OF FURTHER INFORMATION THAT CAN BE REQUESTED UNDER A SUBSTANCE EVALUATION

In this Appendix, some examples are presented related to information on intrinsic properties of substances and to information on exposure that could be considered in a request for further information. The list is in random order, is not exhaustive and the types of information needed to address the concern will vary on a case-by-case basis.

Intrinsic properties

- Annex VII-X or comparable studies

  Studies being part of the standard information requirements as specified in Annex VII-X may be requested e.g. if only non-guideline tests are available but the weight-of-evidence is not convincing to the MS-CA to clarify a concern.

- Information on degradation products or metabolites

  For example, for substances that are not themselves persistent, but have degradation products or metabolites that have PBT or vPvB properties. Information on degradation of a substance, especially under environmental conditions, may also be relevant in relation to a harmonised classification for effects on the environment.

- Information on impurities

  The identity and composition of the impurities in a substance may differ between various registrations for the same substance and thus lead to differences in classification and labelling of such a substance. In these cases, a substance evaluation could be performed to clarify the concern related to the differences in impurities for various registrations of the same substance. The Guidance on substance identification should be taken into account.

- Epidemiological data

  When there are indications that a causal relationship may be established between exposure and the occurrence of health effects in certain human populations, it could be considered to ask for an epidemiological survey. This could help in the interpretation of available data e.g. for respiratory sensitisation. Also, if several studies are already available, a meta-analysis of the data could be considered. Because of the costs associated with this type of study, a proper justification should be provided.

- Information on the potency to induce specific effects

  For example, in the case of a group of substances a ranking of the substances based on their potency to exert a given effect may be helpful in the evaluation of the group. Further information could be requested to determine the possible members and/or ranking of the group or to aid in the extrapolation of data of one (or more) compounds to the (rest of the) group of substances.

- Information on the DNELs and/or PNECs

Where different registrants have derived different DNEL or PNEC values, and the argumentation provided for the choice of key studies or assessment factors is not clear, the MS-CA may consider asking for further clarification on these issues.

- Information relating to PBT or vPvB properties of a substance

  The criteria to be used for identification of a substance as a PBT or a vPvB substance are outlined in Annex XIII of REACH. The main types of studies that could be considered are discussed in detail in the Guidance on Annex XV for C&L, the Guidance on identification of SVHC and the Guidance on Annex XV for restrictions.

- Information related to serious effects to humans or the environment (equivalent concern)

  A key part of the definition of equivalent concern relates to their being scientific evidence of probable serious effects to humans or the environment. This can be taken to mean that any effects, should exposure occur, will be at least equivalent to those that could occur from substances included under points (a) to (e) of Article 57, and this will need to be clearly demonstrated. Examples could be substances having endocrine disrupting properties or substances that near-missed the criteria laid down in Annex XIII. Guidance on this issue has been developed in the Guidance on identification of SVHC.

Exposure

A request for further information on exposure could include the following elements.

- **Production or import tonnage**

  Information on the produced or imported tonnage is to be presented in the registration dossiers for the calendar year of the registration. In case the concern is (partly) based on aggregated tonnage from the registrations submitted by several registrants, the MS-CA may wish to request the most recent information on tonnage produced or imported into the relevant markets in the Member States from the individual registrants.

- **Details of the uses of the substance**

- **Estimates or measurements of exposure to humans resulting from use of the substance.**

  This should address the assessment of exposure (e.g. occupational exposure, consumer exposure, number of people exposed) under the current situation and conditions (including implemented RMMs as described in the exposure scenarios).

  Where the concern relates to a specific activity or a specific exposure situation, then a focussed monitoring programme could be developed. The issues involved in the review of monitoring data, as set out in the CSA guidance, should be taken into account in the planning of such programmes.

- **Monitoring data from field studies**

  Measured data in abiotic and biotic compartments may provide an indication of risks to environment or man and can be considered of superior value to modelled data. For example, measured data in biota provide a clear indicator that the substance is taken up by an organism. The Arctic Monitoring and Assessment Programme (AMAP, 2001) has published recommendations with regard to assessing the quality of monitoring data for use in determining spatial and temporal trends and other types of data interpretations.

Monitoring data for biota in remote regions may provide indications that the substance is both transported long-distances (and so is relatively persistent) and is taken up by organisms (although this is not sufficient to say the substance has a high bioaccumulation potential). However, considering the costs, a request for monitoring data in remote regions would only be made in exceptional cases.

- **Time trend data on environmental levels**

  Time trend data can provide very useful information in terms of whether the levels of the substance are building up over time in the environment, although again the interpretation of such data may not always be straightforward (for example increasing concentrations in the environment may reflect increasing use rather than a high persistence/accumulation potential). Given the anticipated costs for such a monitoring program, a thorough justification of the need for such a program is compulsory.

- **Regional concentrations of the substance**

  It is possible that regional PECs may be based on measured concentrations, which by definition would represent the overall exposures from all relevant sources. These could in principle apply to all registration dossiers, so if they are considered valid then they could be used to replace any calculated values.

- **Simulation studies**

  This type of study could be requested in cases where testing under real life conditions is difficult to perform.

- **Distribution**

  This could include studies on the distribution of a substance in different environmental compartments.

- **Information on Risk Management Measures (RMM)**

  This could include information on the effectiveness, practicality and monitorability of RMM. Issues like past effectiveness of RMMs and implementation tools and past experience pertaining to the assessment of RMMs could be addressed. Guidance on assessing the effectiveness of implemented RMMs has been developed in the Guidance on Annex XV for restrictions.