ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

Registration

The document aims to explain in simple terms the registration obligations and briefly summarises the parent guidance

Version 3.0
July 2017

LEGAL NOTICE

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European Chemicals Agency

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

DOCUMENT HISTORY

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Version 1.0 (originally unnumbered)	First edition	2009
Version 2.0 (originally unnumbered)	Update of the whole document following the update of the parent *Guidance on registration*.	2013
Version 3.0	Update of the whole document following the update of the parent *Guidance on registration*. Main changes include: - Revision of the whole document in relation to outdated, incorrect or missing information; - Update of the information on the inquiry process in section 6.1; - Update of information on data sharing procedures; - Change of the structure of section 6 (addition of a section 6.2); - Update of the text about the joint submission of data in section 6.2; - Inclusion of references to include updated technical manuals with practical instructions on how to prepare, submit and update registration dossiers.	2017

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1. Introduction

REACH[1] is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals and it is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. The responsibility for the management of the risks of substances lies therefore with the natural or legal persons[2] that manufacture, import, place on the market or use these substances in the context of their professional activities.

The registration provisions require manufacturers and importers to collect or generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures to control these risks. To ensure that they actually meet these obligations, as well as for transparency reasons, manufacturers and importers are required to prepare a registration dossier in IUCLID[3] format (by using the IUCLID software application) and submit it to ECHA via REACH-IT.

Registration applies to the manufacture, import, placing on the market and use of substances on their own, in mixtures or in articles.

There are two key concepts in REACH that go beyond the former chemical control schemes:

- It is industry that is responsible for the safe use of chemicals, with ECHA and the other regulators targeting their work to spot checks or to especially problematic areas;
- Risk assessment is central to the various REACH processes.

This Guidance in a Nutshell aims to give a simple and concise introduction to the information content of registration dossiers for chemical substances under REACH, including the information requirements, i.e. the data on physicochemical, toxicological and ecotoxicological properties, and to the chemical safety assessment. In addition, a brief outline of how to prepare and submit a registration dossier is provided. Finally, essential follow-up activities required by ECHA and the registrants upon registration submission are outlined.

[1] 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 of 30 December 2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3).

[2] For further information on 'legal personality' see section 2.1.2.1 of the *Guidance on registration* (https://echa.europa.eu/guidance-documents/guidance-on-reach).

[3] International Uniform ChemicaL Information Database

2. Who should read this Guidance in a Nutshell?

This document is designed to assist manufacturers, importers and "only representatives"[4] who are based in the European Economic Area (EEA) in clarifying their obligations under REACH relating to registration of substances either on their own, in mixtures or in articles and to help them make the right decisions to ensure that they comply with the REACH legislation. It is also relevant to companies outside the EEA exporting substances on their own, in mixtures or in articles into the EEA who need to check that those importing their products into the EEA[5] are complying with the requirements the REACH Regulation places on them.

This Guidance in a Nutshell is aimed especially at management and less experienced regulatory affairs professionals to help them make decisions on how to proceed with their registrations and to assess advice they may be given by other parties. It is also intended to introduce readers to the subject and to provide access to more detailed information necessary to prepare the registration dossiers, in particular by means of the section on references(section 8).

If still in doubt about their status, companies are advised to identify their roles and check their obligations by running the Navigator tool on the website of ECHA[6], where full *Guidance on registration* ("parent guidance") and other guidance documents can also be found.

[4] Only representatives are appointed according to Article 8 of REACH

[5] The European Economic Area is composed of Iceland, Liechtenstein, Norway and the EU Member States. Thus, the terms 'EU' or 'Community' used in this document cover the EEA States.

[6] http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/identify-your-obligations

3. Illustration of the scope of this guide

The flowchart below aims to give a simple general overview of the REACH processes, particularly with respect to activities involving ECHA. At the same time, the scope of the Guidance in a Nutshell is shown by the boxes with a red border[7].

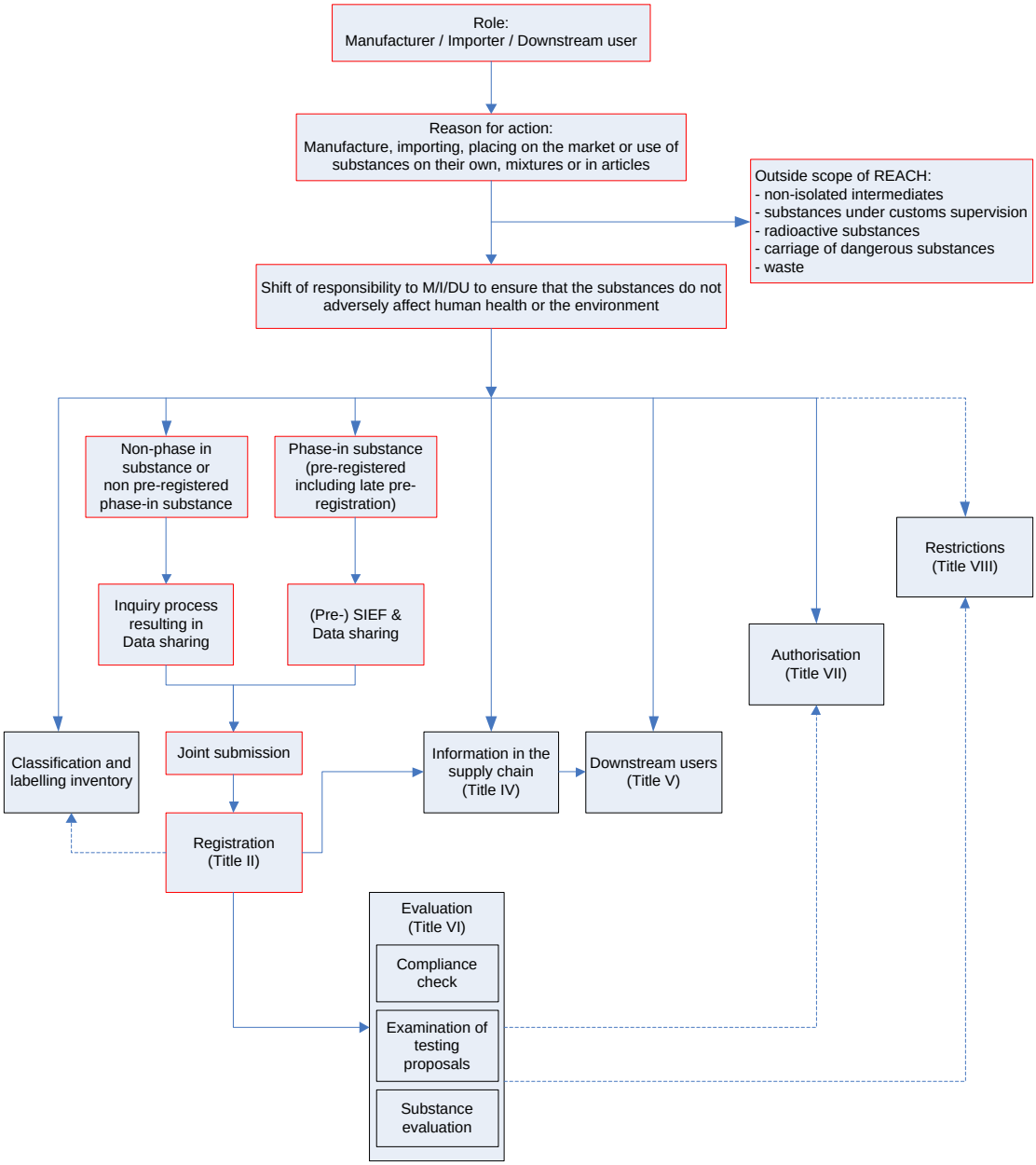

Figure 1: General overview of REACH processes and scope of this Guidance in a Nutshell

[7] Note that the flowchart may inevitably give an over-simplification of certain aspects of complex REACH processes and the inter-relationship between them. It should also be highlighted that 'downstream users' mentioned in this flowchart do not have a registration obligation.

4. Registration of substances in brief

The basic definition of a substance (Article 3(1) of REACH) is very broad. It includes not only potentially hazardous industrial chemicals, but every type of chemical substance manufactured in or imported into the EEA. It therefore includes substances which may already be closely regulated by other legislation or which typically cause no or only minimal risk to human health and the environment. For these and other reasons there are some complete or partial exemptions from the REACH requirements[8], for example, radioactive substances, intermediates, waste, substances used in medicinal products, food or feedingstuffs, substances and groups of substances listed in Annex IV and V, polymers, etc.

Unless explicitly exempted from its scope, REACH requires the registration of substances manufactured or imported at one tonne or more per year, by submission of a dossier that includes physicochemical, toxicological and ecotoxicological information. New substances (so-called 'non-phase-in' substances[9]) have to be registered before being manufactured or imported, but substances that are already on the EEA market (i.e. 'phase-in' substances that have been 'pre-registered') benefit from transitional arrangements that allow them to be registered by set deadlines depending on their tonnage and/or hazardous properties (i.e. CMRs[10] or R50/53[11]). The deadlines are presented in **Figure 2**.

[8] For further information on substances exempted from the REACH Regulation, exempted from registration or regarded as already registered see sections 2.2.2, 2.2.3 and 2.2.4 of the *Guidance on registration*.

[9] See section 2.3.1 of the *Guidance on registration* where the definitions of phase-in and non-phase-in substance are elaborated.

[10] CMRs are substances classified as Carcinogenic, Mutagenic or toxic to Reproduction, category 1 or 2, in accordance with Directive 67/548/EEC. ('Classified in accordance with Directive 67/548/EEC' refers to substances listed in Annex VI of the CLP Regulation with a harmonised classification and labelling and substances self-classified by the registrant).

[11] R50/53 are substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment in accordance with Directive 67/548/EEC. 'Classified in accordance with Directive 67/548/EEC' refers to substances listed in Annex VI of the CLP Regulation with a harmonised classification and labelling and substances self-classified by the registrant.

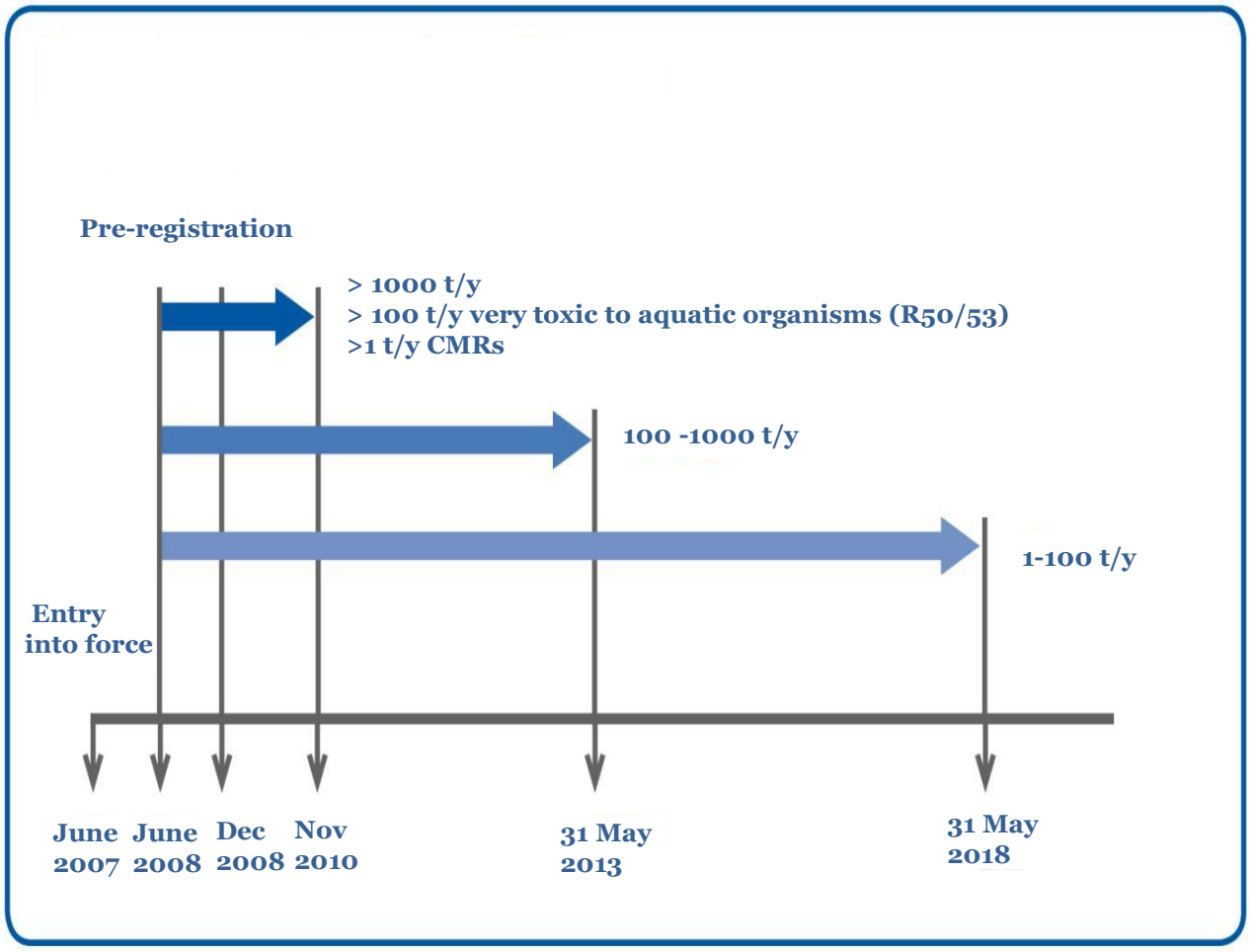

Figure 2: Registration deadlines under REACH

The main pre-registration period ended on 1 December 2008, although potential registrants (who for the first time had manufactured or imported a phase-in substance in a quantity of one tonne or more per year after 1 December 2008), could still have benefited from the transitional regime (late pre-registration) and the phase-in deadlines for registration according to Articles 23 and 26(6) of REACH.

The deadline for late pre-registrations for substances that need to be registered by 31 May 2018, was 31 May 2017. For substances that have not been (late) pre-registered, potential registrants need to submit an **inquiry** to ECHA before registering.

If a manufacturer or importer does not register by the appropriate deadline, the substance may not be manufactured in the EU or placed on the EU market until it has been registered. Registered substances can in principle circulate freely on the internal market.

For all substances that are manufactured or imported in volumes of 10 tonnes or more per year, a chemical safety assessment (CSA) has to be carried out, and recorded in the registration dossier as a stand-alone document, this is called the chemical safety report (CSR).

Upon submission, all registration dossiers must pass a 'completeness check' by ECHA to ensure that all elements required by the legislation (including the required information and the

registration fee) have been provided[12]. The completeness check includes a manual verification of certain elements of the registration dossier that cannot be checked automatically. The aim of this manual verification is to establish a level playing field between registrants who follow the standard information requirements set out in REACH, and those who waive or deviate from these requirements, by ensuring that the latter provide justifications foreseen by the legislation. If this check is passed successfully, ECHA issues a registration number[13]. For more technical information on the completeness check, see section 7.1 of this guidance. Please consult also the ECHA document "Information on manual verification at completeness check" at: https://echa.europa.eu/manuals.

5. Registration process

The aim of this section is to explain the information that is required (or may be omitted) to complete a registration dossier under REACH. To obtain the required information, the registrants have to assess and document the different properties of the substance (see section 5.1). Information to be normally provided in each dossier is listed in Annex VI of REACH. So-called 'standard information requirements' depend on the tonnage band and are detailed in column 1 of Annexes VII to X. Specific rules for the adaptation of standard information requirements are given in column 2 of these Annexes and Annex XI establishes general rules for adaptation of those requirements (see section 5.2). Section 5.4 of this document will outline the concept of the chemical safety assessment.

Please note that registrants also have obligations related to the sharing of data on both phase-in and non phase-in substances. The data sharing obligations are outlined in section 6.1.

5.1 Properties of substances

Manufacturers and importers will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the manufacture and use of the substances and to ensure that these risks are controlled. The information gathered and the assessment performed have to be documented in the registration dossier and submitted to ECHA for the registration of the substance.

The registrant must obtain information on the properties of the substance. The registration information requirements depend on the tonnage band of the substance, as discussed in the next section. It is important to keep in mind the purpose of determining the data:

- To define and characterize the identity of the substance (see *Guidance on identification and naming of substances under REACH and CLP*[14]);
- To identify the hazardous properties for hazard communication;
- To identify and quantify the hazardous properties for risk assessment;
- To obtain parameters necessary for exposure assessment and risk characterisation.

The information on the properties of the substance is then used by industry to make sure the substance can be used safely and is presented in the registration dossier.

The hazardous properties of chemicals can be categorized as follows:

[12] In practice the dossier has to pass a virus and XML format check as well as a so-called 'business rules validation' to be accepted for processing by ECHA. For further information, please consult ECHA manual 'How to prepare registration and PPORD dossiers' accessible at: http://echa.europa.eu/manuals.

[13] For more information on the 'completeness check' see Section 7.1 of this document.

[14] http://echa.europa.eu/guidance-documents/guidance-on-reach

- Physicochemical hazards, such as explosivity, oxidising properties and flammability, are caused by the intrinsic physical or chemical properties of the substance;
- Toxicological hazards arise from chemicals causing harmful effects to humans. Toxic effects may be acute or chronic, local or systemic and reversible or irreversible, resulting from oral, dermal or inhalation exposure and are influenced by the toxicokinetic profile of the substance. Specific toxic effects include corrosivity and irritancy to skin, eyes and the respiratory tract, skin and respiratory sensitisation, target organ toxicity, carcinogenicity, mutagenicity and effects on reproduction;
- Environmental hazards relate to ecosystems for the different compartments of air, soil or water, including groundwater and sediment, and hence are influenced by the environmental fate of the chemical and its degradation products.

There are different ways to fulfil the information needs for registration, as discussed in the next sections. As a last resort, new studies may need to be conducted.

5.2 Information requirements

Manufacturers and importers have to collect **all freely available[15] existing information** on the properties of the substance for registration purposes, regardless of the tonnage manufactured or imported. This information has in turn to be compared with the standard information requirements specified in the REACH Regulation.

Annexes VI to XI of REACH specify the information that must be submitted for registration purposes as part of the 'technical dossier'. This section addresses the information requirements for each[16] registration (Annex VI) and the 'standard information requirements' depending on the tonnage band (Annexes VII–X).

These standard requirements may, however, be adapted (waived or increased) when appropriately justified according to the criteria set out in Annexes VII to XI. Therefore, **for each substance the precise information requirements may differ depending on the available information on intrinsic properties as well as on tonnage, use and exposure.**

The *Guidance on information requirements and chemical safety assessment*[17] explains in detail the process for information gathering and data generation. Please note that special information requirements apply to certain types of intermediates (see section 5.2.2).

5.2.1 Substances

The general technical, commercial and administrative information needed for all registrations is specified in Annex VI of the REACH Regulation. This includes the following key information:

1) General information on the registrant;
2) Identification of the substance;
3) Information on the manufacture and use(s) of the substance;
4) Classification and labelling of the substance;
5) Guidance on safe use;
6) Exposure information for substances registered in quantities of 1 to 10 tonnes.

[15] i.e. companies must include all information that is available to them at no additional cost.

[16] Except for certain types of intermediates, see later in this section.

[17] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

The registrant must establish the chemical identity of the substance described in the registration dossier. This includes the name of the substance, its chemical identifiers (EC number, IUPAC name and CAS number, etc.), the molecular and structural formula and its composition (degree of purity, constituents, analytical data, etc.). If it is not technically possible, or if it does not appear scientifically necessary to give information on one or more of the substance identification parameters, the reasons must be clearly stated. Information on the principles of substance identification can be found in the *Guidance on identification and naming of substances under REACH and CLP* (http://echa.europa.eu/guidance-documents/guidance-on-reach).

As a minimum, a dossier should include Annex VI information and in addition the information based on requirements of Annexes VII to X as presented in Table 1.

Table 1: Standard information requirements of Annexes VII - X

Substance criteria	Standard Information Requirements
Non-phase-in substances at ≥ 1 tonne per year	Annex VII
Phase-in substances at ≥ 1 tonne per year meeting one or both of the criteria specified in Annex III	Annex VII
Phase-in substances at ≥ 1 tonne per year which do not meet either of the criteria specified in Annex III	Annex VII, section 7 (physicochemical properties of the substance)
Substances at ≥ 10 tonnes per year	Annexes VII and VIII
Substances at ≥ 100 tonnes per year	Annex VII and VIII data and testing proposals for information specified in Annex IX
Substances at ≥ 1,000 tonnes per year	Annex VII and VIII data and testing proposal for information specified in Annexes IX and X

If any of the standard studies required for Annexes VII to X are impossible to conduct for technical reasons they can be omitted, with a justification in the technical dossier to explain this. Testing may in certain cases also be omitted based on exposure assessment, if it can be demonstrated that there is no exposure to humans or the environment (so-called 'substance-tailored exposure-driven testing')[18].

Where available data are not adequate to meet the requirements of REACH, additional testing may need to be generated. It should be noted that any study required to fulfil the information requirements defined in Annex IX and X should not be conducted by the registrant at the stage of registration. Instead, the registrant will have to develop a **testing proposal** and include it in his registration dossier.

It has to be stressed that where possible the **existing registrants and potential registrants must share or generate data with other registrants of the same substance**, instead of generating data themselves **if this would involve animal testing** (see section 6.1 on data sharing).

Where tests on substances are required to generate information on intrinsic properties of substances, they must be conducted in accordance with the test methods laid down in Commission Regulation (EC) No 440/2008 and its amendments or in accordance with other international test methods recognised by the Commission or ECHA. Ecotoxicological and toxicological tests and analyses must be carried out in compliance with the principles of good

[18] For further information on adaptation of information requirements see Chapters R2 to R5 of the *Guidance on information requirements and chemical safety assessment*.

laboratory practice (GLP) or other international standards recognised as being equivalent[19] by ECHA or the Commission and with the provisions of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Before proposing to carry out a test involving vertebrate animals, the registrant needs to consider all the relevant and available data sources as well as available testing methods other than *in vivo* tests to avoid unnecessary animal testing. For example, the registrant may use a variety of alternative methods such as *in vitro* or *in chemico* tests, (Q)SARs ((Quantitative) Structure Activity Relationships), grouping or read-across, provided that the use of such methods is justified. All sources of information can also be used in a weight of evidence approach. If the outcome of this analysis justifies a proposal for animal testing, registrants need to make their justifications for animal testing clear in the registration dossier, including a documented analysis of alternative methods they have considered.

Note that the registration dossier must also include an indication as to whether the information on the manufacture and use, the classification and labelling, the (robust) study summaries and/or if relevant the chemical safety report, has been reviewed by an assessor[20].

5.2.2 Substances used as intermediates

An intermediate is also a 'substance' in the sense of REACH, with the special nature that it is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. Therefore, intermediates should not be present in the final manufactured substance (except possibly as an impurity).

Different types of intermediates are defined under REACH[21]:

1) Non-isolated intermediates;
2) Isolated intermediates:
    a) On-site (non transported) isolated intermediates;
    b) Transported isolated intermediates.

Non-isolated intermediates are exempted from the scope of REACH. Note however that quantities of the same substance may be used in other operations or under other conditions, which implies that those quantities cannot be regarded as non-isolated intermediates. Only the quantities of the substance used under the conditions qualifying it as a non-isolated intermediate are exempted from REACH. For the remaining quantities, the relevant requirements under REACH must be fulfilled.

Regarding the two types of isolated intermediates mentioned above, considerably less information is needed for their registration, provided that they are manufactured and used under the 'strictly controlled conditions', otherwise the standard data requirements apply.

The reader is advised to consult the *Guidance on intermediates*[22]*,* which supports potential registrants of intermediates in assessing whether the conditions for manufacture and use fulfil the requirements to be considered as strictly controlled conditions.

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[19] Note that no other international standards have so far been recognised as being equivalent.

[20] A person chosen by the registrant with appropriate experience in:
- Information on the manufacture and use,
- Classification and labelling of the substance,
- (Robust) Study summaries on the information requirements defined in Annexes VI to X,
- Chemical safety report preparation.

[21] See Article 3 (15) of REACH for the precise definition of the different types of intermediates.

[22] https://echa.europa.eu/guidance-documents/guidance-on-reach

5.3 Registration dossier

The registration dossier is the set of information submitted electronically by a registrant for a particular substance. It consists of two main components:

- a **technical dossier**, always required for all substances subject to the registration obligations. The technical dossier contains a set of information about:
    1. the identity of the manufacturer/importer;
    2. the identity of the substance;
    3. information on the manufacture and use of the substance;
    4. the classification and labelling of the substance;
    5. guidance on its safe use;
    6. study summaries of the information on the intrinsic properties of the substance;
    7. robust study summaries of the information on the intrinsic properties of the substance, if required;
    8. an indication as to whether the information on manufacture and use, the classification and labelling, the (robust) study summaries and/or if relevant the chemical safety report, has been reviewed by an assessor;
    9. proposals for further testing, if relevant;
    10. for substances registered in quantities between 1 and 10 tonnes, information on exposure;
    11. a request as to which information should be considered confidential, including a justification.
- a **chemical safety report (CSR)**, required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year. A CSR is the documentation of the registrant's chemical safety assessment (CSA) (see section 5.4 of this guidance).

Registrants have the possibility to flag as confidential certain sections in the registration dossier according to Article 119 of REACH (i.e. company name, degree of purity, identity of impurities and/or additives, total tonnage band, endpoint study records, etc.). This request needs to include a justification as to why publication of such information on the ECHA website could be harmful for his or any other concerned party's commercial interests. Confidentiality claims are subject to fee payment. For technical instruction on how to make a confidentiality claim, please consult ECHA manual 'Dissemination and confidentiality requests under REACH Regulation' accessible at http://echa.europa.eu/manuals.

5.4 Chemical safety assessment

The chemical safety assessment ('CSA') is the instrument to assess the hazards and risks to human health and the environment and to determine how to control them by applying suitable risk management measures. In practice, the CSA is an iterative process if the initial assessment demonstrates that risks to human health and/or to the environment are not controlled. The assessment can be refined by obtaining more information on the properties of the substance, improving the exposure assessment or the risk management measures. There may have to be several cycles of successive refinement of the assessment before risks can be demonstrated to be under control.

The CSA is required for all substances subject to registration in quantities of 10 tonnes or more per year per registrant (except for intermediates under strictly controlled conditions). It comprises the following steps:

Hazard assessment:

1) Human health hazard assessment;
2) Physicochemical hazard assessment;
3) Environmental hazard assessment;
4) Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

The objective of the human health hazard assessment is to determine the classification and labelling of the substance and to define the level of exposure above which humans should not be exposed. This level of exposure is known as the **derived no-effect level(s) (DNEL)**. The DNEL is regarded as an exposure level below which an adverse effect will not occur (for a particular route and duration of exposure). DNELs are normally derived from toxicity test results using appropriate assessment factors. Further information about DNEL derivation can be found in *Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health* (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment). The reader is also advised to consult the Practical Guide: 'How to prepare toxicological summaries in IUCLID and to derive DNELs' available at http://echa.europa.eu/practical-guides.

The objective of the physicochemical hazard assessment is to determine the classification and labelling of a substance and to assess, as a minimum, the potential effects to human health for explosivity, flammability and oxidising potential. Guidance on how to assess physicochemical properties is available in sub-chapter R.7.1 "Physicochemical properties" within "Chapter R.7a: Endpoint specific guidance" of the *Guidance on information requirements and chemical safety assessment*.

Environmental hazard assessment comprises a decision on the classification and labelling of the substance and a determination of a **predicted no-effect concentrations (PNEC)** below which adverse environmental effects are not expected to occur for each compartment of the environment. Further information about PNEC derivation can be found in Chapter R.10: Characterisation of dose [concentration]-response for environment within the *Guidance on information requirements and chemical safety assessment*.

The objective of the PBT/vPvB assessment is to determine if the substance fulfils the criteria given in REACH Annex XIII and if so, to characterise the potential emissions of the substance. Guidance on how to perform a PBT/vPvB assessment is available in *Chapter R.11: PBT/vPvB assessment* of the *Guidance on information requirements and chemical safety assessment*.

If the results of the previous steps indicate that the substance meets the criteria for any of the hazard classes or categories set out in article 14(4) or is assessed to be a PBT or vPvB, the CSA must include the following additional steps:

- Exposure assessment:
  - Generation of exposure scenario(s);
  - Exposure estimation;
- Risk characterisation.

Exposure assessment consists of determining, quantitatively or qualitatively, the dose/ concentrations of the substance to which humans or the environment are or may be exposed. It includes as a first step, the generation of exposure scenarios (ES) for all the identified uses and stages in the life cycle and secondly their use as a basis to estimate the exposure.

An exposure scenario is a set of conditions that describe how a substance (whether on its own, as a component of a formulated mixture or in an article) is manufactured or used during its lifecycle in the EU and how the manufacturer or importer or downstream user controls or

recommends controlling exposure of humans and the environment. It must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are controlled.
For an overview on how the scope of exposure assessment can be determined, please consult the *Guidance on information requirements and chemical safety assessment,* Part D.

Risk characterisation is the final step in the chemical safety assessment where it should be determined whether risks arising from the manufacture/import and uses of the substance are controlled. It is carried out for each exposure scenario. This involves comparing the DNELs and PNECs with the estimated exposure concentrations to humans and the environment respectively.

Risk assessment for hazardous physicochemical properties consists also of the assessment of the likelihood and severity of an adverse effect. If the estimated exposure levels are below the DNELs and PNECs, risks are considered to be under control. If not, iteration of the CSA should be carried out until risks can be demonstrated to be under control.

The CSA is documented in the chemical safety report (CSR), which is submitted, together with the technical dossier to ECHA as part of the registration process. The registrant transmits the relevant information documented in the CSR to the actors further down the supply chain by means of the extended safety data sheet (extended SDS).

Figure 3 provides a graphical overview of the elements of the CSA:

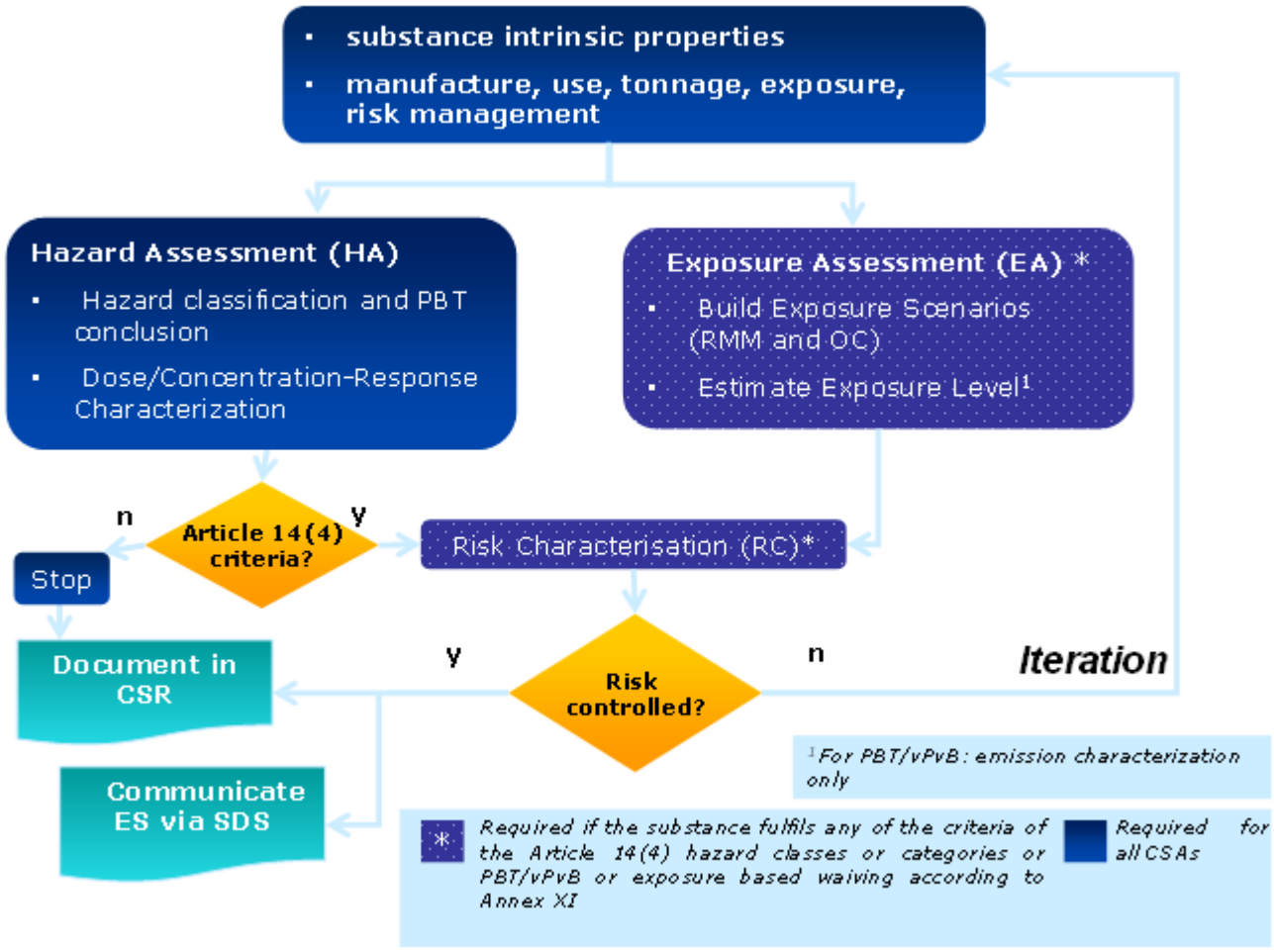

Figure 3: Elements of the chemical safety assessment

6. Dossier preparation and submission

The aim of this section is to give an overview on how (and by whom) a registration dossier is prepared and eventually submitted to ECHA. This section also briefly describes two core principles of REACH: data sharing and joint submission of registration to ECHA. Finally, section 6.3 outlines briefly the IT tools provided by ECHA for registration.

6.1 Inquiry, 'SIEFs' and data sharing

The purpose of data sharing is to increase the efficiency of the registration system as well as to minimise costs and to reduce testing on vertebrate animals. Duplicate animal testing has to be avoided and tests on vertebrate animals must only be undertaken as a last resort (Article 25).

To facilitate data sharing, the REACH Regulation requires that, prior to registration, all substances must either be pre-registered or an inquiry must be submitted according to Article 26. In general, pre-registration is relevant for phase-in substances and inquiry for non phase-in substances, as well as for phase-in substances that have not been pre-registered.

Non-phase-in substances or substances that have not been pre-registered

The submission of an inquiry is the process by which every potential registrant must inquire from ECHA whether a valid registration has already been submitted for the same substance. This is to ensure that data are shared by the relevant parties.

For non phase-in substances and for phase-in substances that have not been pre-registered an inquiry must always be submitted before proceeding with the registration of the substance.

Upon receipt of the inquiry dossier, ECHA will perform a substance identity check to identify existing registrants and successful inquirers of the same substance. ECHA will provide the potential registrant with access to the contact details of the existing registrants and successful inquirers of the same substance. Based on the information submitted in the inquiry, ECHA will provide the potential registrant with a list of relevant study summaries or robust study summaries already submitted and available to ECHA.

Potential registrants can freely use any studies submitted in the framework of a registration at least 12 years previously. Regarding studies from substances registered less than 12 years previously[23], the two parties (potential registrant and existing registrants) are put into contact with a view to reaching an agreement to share data.

A potential registrant must request from the existing registrants data in the case of information involving tests on vertebrate animals. It may request from the existing registrants of the same substance information not involving tests on vertebrate animals.

The potential registrant and the existing registrant must make every effort to reach an agreement on the sharing of data and ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. The obligation to make every effort applies to any information requested, whether this concerns data involving testing on vertebrates, other data not involving testing on vertebrate animals, or conditions of access to joint submission.

The inquiry dossier is prepared in IUCLID and subsequently submitted via REACH-IT to ECHA. Practical instructions for the preparation of an inquiry are available in the ECHA manual 'How to prepare an inquiry dossier' accessible at: http://echa.europa.eu/manuals.

Phase-in substances

To allow the data-sharing scheme to operate for registration of phase-in substances, companies

[23] In addition, for data that has already been submitted within a notification dossier under Directive 67/548/EEC, these data will be available for the purpose of registration, starting 12 years after their submission date.

have to make a pre-registration (see section 4 of this guidance). The general principles of data-sharing described above for non-phase-in substances also apply for phase-in substances.

All potential registrants and data holders for the same pre-registered phase-in substance are participants in a 'Substance Information Exchange Forum' (SIEF). Registrants who registered the same phase-in substance earlier, or whose substance is considered as registered[24] are also participants of the SIEF. The aims of SIEF are to:

- facilitate data-sharing for the purposes of registration, thereby avoiding the duplication of studies, and
- agree on the classification and labelling of the substance concerned where there is a difference in the classification and labelling of the substance between the potential registrants.

Participants are free to organise themselves as they see fit to carry out their duties and obligations under REACH. The organisation used for the SIEF co-operation may also be used to jointly submit the relevant Annex VII-XI information.

For practical information regarding the organisation of the SIEF and related data gathering and data-sharing processes, visit the following ECHA website: http://echa.europa.eu/support/registration/working-together. Please consult also the *Guidance on data sharing* (http://echa.europa.eu/guidance-documents/guidance-on-reach) which provides extensive information on the rights and duties of SIEF participants.

6.2 Joint submission

Each registrant is obliged to submit a registration dossier for each of his substances. In cases where the same substance is manufactured or imported or intended to be manufactured or imported by more than one company, all the registrants are obliged to be part of the same joint submission for that substance. The joint submission obligation applies for both the registration of phase-in substances and for that of non-phase-in substances.

Registrants are required to jointly submit information on the intrinsic properties of the substance (studies and testing proposals, if any) and its classification and labelling. Registrants may decide to jointly submit the guidance on safe use of the substance, the chemical safety report (CSR) and an indication of what information submitted for the CSR has been reviewed by an assessor (Article 11).

The information that needs to be submitted jointly is submitted by one lead registrant on behalf of the other registrants (the so-called 'member registrants'). Other information needs to be submitted by all registrants individually. This is only possible after the lead dossier has been accepted for processing.

There is the possibility to opt-out of certain parts of a joint submission only if the cost would be disproportionate, where there would be a breach of confidentiality or if there is a disagreement with the lead registrant on selection of information submitted in the lead registration. However, the **joint submission is required even if the registrant decides to opt-out**. The registrant still remains part of the same joint submission and will be able to submit his dossier only after the lead dossier has been accepted for processing. Hence, even though a registrant can opt-out from certain information requirements he cannot opt-out of the joint submission as such. More information on the opting out possibilities and mechanisms is given in the *Guidance on data sharing*.

The Implementing Regulation (EU) 2016/09 on joint submission and data-sharing establishes rules to ensure an efficient implementation of the data-sharing and joint submission obligations.

[24] Except for substances regarded as registered because they were notified according to Directive 67/548/EEC.

6.3 IT tools for registration

Registrations under REACH must be prepared and submitted using IT tools specified by ECHA, namely IUCLID and REACH-IT. The technical dossier containing all the required information has to be compiled by the registrant in the IUCLID format and then submitted electronically via REACH-IT to ECHA. If you need to register as a member of a joint submission (not as the lead), you have the possibility to prepare your registration dossier online directly in REACH-IT. This option could particularly benefit you if you are new to IUCLID.

In addition, if a chemical safety assessment is required, the registrant also needs to compile a chemical safety report and submit it together with the technical dossier to ECHA. ECHA has developed an IT tool called Chesar (**Che**mical **sa**fety assessment and **r**eporting tool) to help registrants perform CSAs and generate CSRs. Chesar provides a structured workflow for carrying out a standard safety assessment for the different uses of a substance. The tool also helps to structure the information needed for the exposure assessment and risk characterisation, which will facilitate the generation of a transparent CSR. The tool can be downloaded free of charge from http://chesar.echa.europa.eu/.

Companies should take the following steps to prepare and submit their registrations to ECHA:

1) Sign-up in REACH-IT to create an account for the company;

   Read carefully the manual on 'How to prepare REACH and PPORD dossiers'. The manual is available at https://echa.europa.eu/manuals, and is also integrated in the IUCLID help system;

2) Prepare the registration by creating a technical dossier in IUCLID. Registrants are strongly encouraged to verify the technical completeness of their dossiers before submission by using the "Validation Assistant plugin";

   Submit the registration dossier to ECHA via REACH-IT.

7. Registration follow-up by ECHA and registrant

Once a registration dossier has been submitted, ECHA undertakes a 'completeness check' and – if the registration is complete – assigns a registration number.

Please note that the 'completeness check' is fundamentally different from the 'compliance check' of registrations. 'Compliance check' and the 'examination of testing proposals'[25] by ECHA are the two pillars of the 'dossier evaluation' procedures under REACH. The dossier evaluation is done after a successful completeness check and may require the registrant to update his registration dossier in accordance with a decision by ECHA (See section 7.2). Apart from that, the registrant is also responsible, on his own initiative, for updating his registration dossier with relevant new information when needed.

7.1 Completeness check

The completeness check process comprises two distinct sub-processes:

1) **Technical completeness check**

   This process is aimed at checking the technical completeness of the dossier. The main purpose of this check is to make sure that all information as required according to REACH has been provided. However, there is no scientific assessment of the quality or adequacy of the data or of any justifications for omitting studies. If the check fails, the

[25] For details on compliance check and examination of testing proposals visit the ECHA Evaluation webpages accessible via the following links:
http://echa.europa.eu/web/guest/regulations/reach/evaluation and
http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/public-procedures

registrant is informed of any missing information necessary to complete the dossier, and then has to resubmit the completed dossier to ECHA within a given deadline. Registrants are strongly encouraged to verify the technical completeness of their dossiers before submission with the help of the "Validation Assistant plugin". This tool offers registrants the possibility to check the completeness of the dossier **before** submitting it to ECHA. It is recommended to run the plugin first on the substance dataset and then on the final dossier. Using the plugin in both steps is vital to avoid any unnecessary failures and potential rejection.

The completeness check performed by ECHA includes a manual verification of certain elements that cannot be checked automatically by the "Validation Assistant plugin". When preparing your dossier, keep in mind that the registration dossier should not only be prepared to pass the completeness check. It should contain all the information on the substance as specified by REACH, including a clear identification of the substance that is being registered, and should aim to demonstrate that the substance is used in a safe manner. Please consult the ECHA document "Information on manual verification at completeness check" available at https://echa.europa.eu/manuals.

2) **Financial completeness check**

Once a dossier is accepted for processing, ECHA issues an invoice (if relevant), according to the REACH Regulation. Invoices are communicated only through REACH-IT and include a deadline for payment. If the full payment of the fee is received within the payment deadline, the dossier will be considered financially complete.

Once a dossier is considered both technically and financially complete (i.e. the required information has been provided and the appropriate fee has been received), ECHA issues a registration number.

7.2 Duty to keep registration information up-to-date

The information in the registration dossier submitted to ECHA must be kept up-to-date. It is the responsibility of the registrant to update his registration dossier when needed. There are basically two types of situations where a registrant needs to update the information concerning his registration:

1) *Update on the registrant's own initiative*

Registrants are required to report to ECHA **without undue delay** any new relevant available information (e.g. new tonnage band, new uses) concerning their registration (Article 22 (1)).

2) *Update as a consequence of a decision made by ECHA or the Commission*
The registrant has to update his registration as a consequence of an ECHA or a Commission decision under the evaluation procedure but also, when relevant, following any decision made in accordance with the authorisation and the restriction processes. These updates must be submitted **within the deadline** specified by ECHA/the Commission in the decision (Article 22(2)).

Note that an update will, in certain cases, be subject to the payment of a fee in accordance with the Fee Regulation (Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended).

Section 7 of the *Guidance on registration* explains in further detail the different situations which trigger an update of the registration dossier. Once such an update is submitted to ECHA, ECHA has to undertake a completeness check within three weeks of the submission date, or within three months of the relevant deadline (see section 4) as regards registrations of pre-registered phase-in substances submitted in the course of the two-month period immediately preceding that deadline (Article 20(2)).

The registrants should consider their registration dossiers as "living documents" and regularly update them whenever new information is available or a need to improve the quality of data is identified. Special attention should be paid to the following areas of the registration dossier: substance identity, use, exposure information and justifications for adaptations to information requirements and for using alternative methods. Better quality of information on substances helps ECHA and MSCAs to select and prioritise substances for regulatory attention. This may also benefit registrants since, with better and more transparent information, their substances may be deprioritised from regulatory actions.

8. References and further information

Websites:

- ECHA website: http://echa.europa.eu/
- Registration section of ECHA website: https://echa.europa.eu/support/registration
- REACH 2018 support pages: https://echa.europa.eu/reach-2018
- ECHA guidance website: http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation
- ECHA Q&As about REACH: https://echa.europa.eu/support/qas-support/qas
- ECHA legislation website: http://echa.europa.eu/web/guest/regulations/reach

Guidance documents:

- *Guidance on registration*
- *Guidance on data sharing*
- *Guidance for intermediates*
- *Guidance for identification and naming of substances under REACH and CLP*
- *Guidance on information requirements and chemical safety assessment*

IT tools and technical manuals for registration:

1. IUCLID website: http://iuclid.echa.europa.eu/
2. REACH-IT webpage: https://echa.europa.eu/support/dossier-submission-tools/reach-it

Technical manuals: https://echa.europa.eu/manuals

3. Chesar website: http://chesar.echa.europa.eu/

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