ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

# Registration

The document aims to explain in simple terms the registration obligations and how to prepare, submit and update a registration dossier

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**Guidance in a nutshell on registration**
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# 1 Introduction – What does this document aim to do?

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 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 format) 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 central concepts in REACH that go beyond the former chemical control schemes:

- Industry is responsible for 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 guide 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, practical guidance is provided on how to prepare and submit a registration dossier. 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.

# 2 Who should read this guidance in a nutshell?

This document is designed to assist manufacturers, importers and only representatives of substances on their own, in a mixture or in articles based in the European Economic Area[2] (EEA) in clarifying their obligations under REACH relating to registration 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 to the EEA who need to check that those importing their products into the EEA 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 references chapter.

If they are 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[3], where other guidance documents can also be found.

[2] 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

[3] 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 present guide is shown by the boxes with a red border[4].

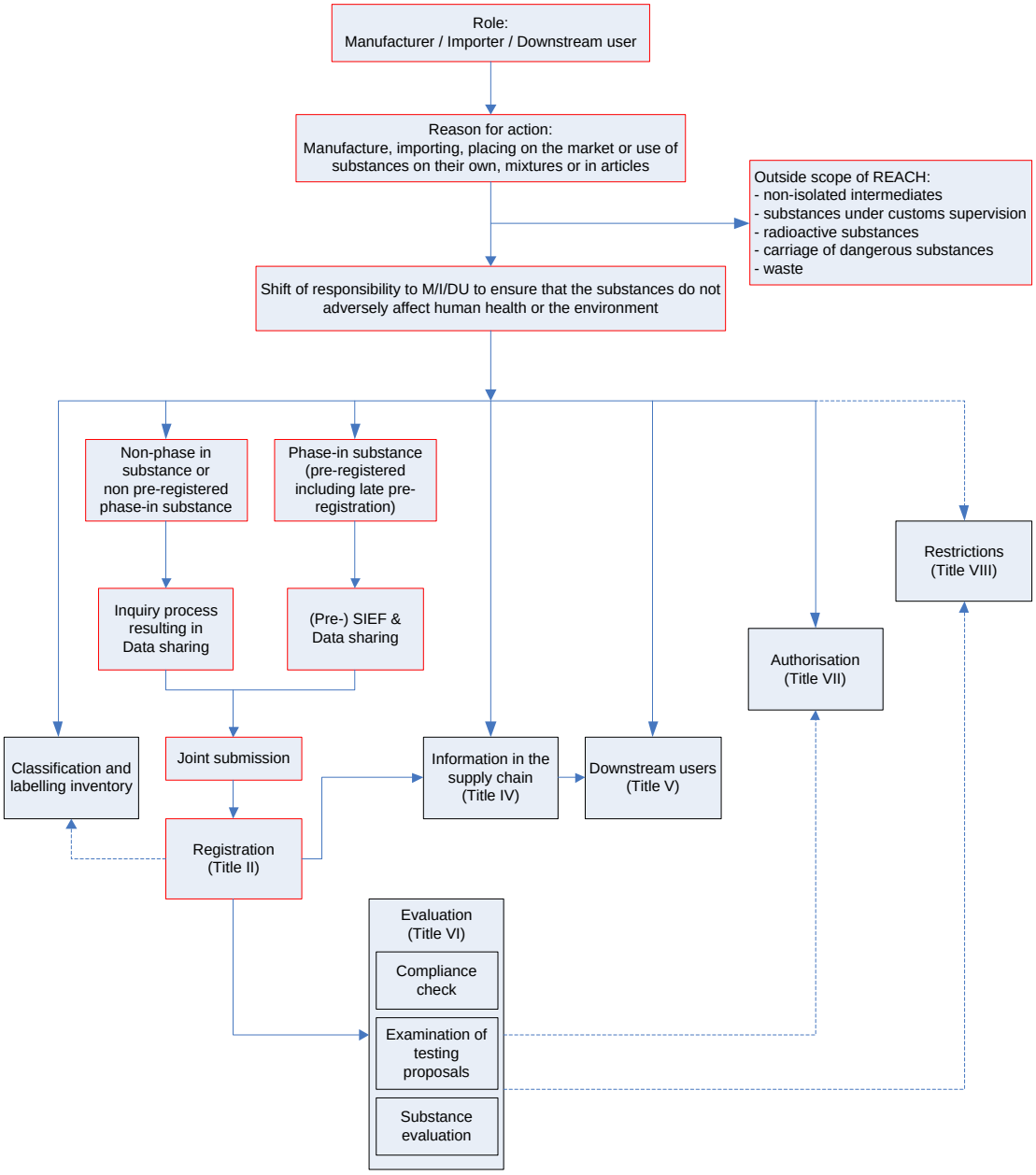


**Figure 1: General overview of REACH processes and scope of this guide**

[4] 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 is a very broad one which includes not only potentially hazardous industrial chemicals, but every type of chemical substance manufactured in or imported into the EEA. It therefore also includes substances which are already 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 REACH requirements[5], e.g. for: radioactive substances; intermediates; waste; substances used in medicinal products, food or feedingstuffs; substances in Annex IV and V; polymers; etc.

Unless explicitly exempted from its scope, REACH requires registration of substances with ECHA if they are manufactured or imported at one tonne per year or more by submission of a dossier including physicochemical, toxicological and ecotoxicological information. New substances (so-called 'non-phase-in' substances) 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[6] or R50/53[7]). The deadlines are presented in figure 2 below.

[5] For further information on substances exempted from the REACH Regulation, exempted for registration or considered as already registered see Sections 2.2.2, 2.2.3 and 2.2.4 of the Guidance on registration.

[6] 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).

[7] 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.

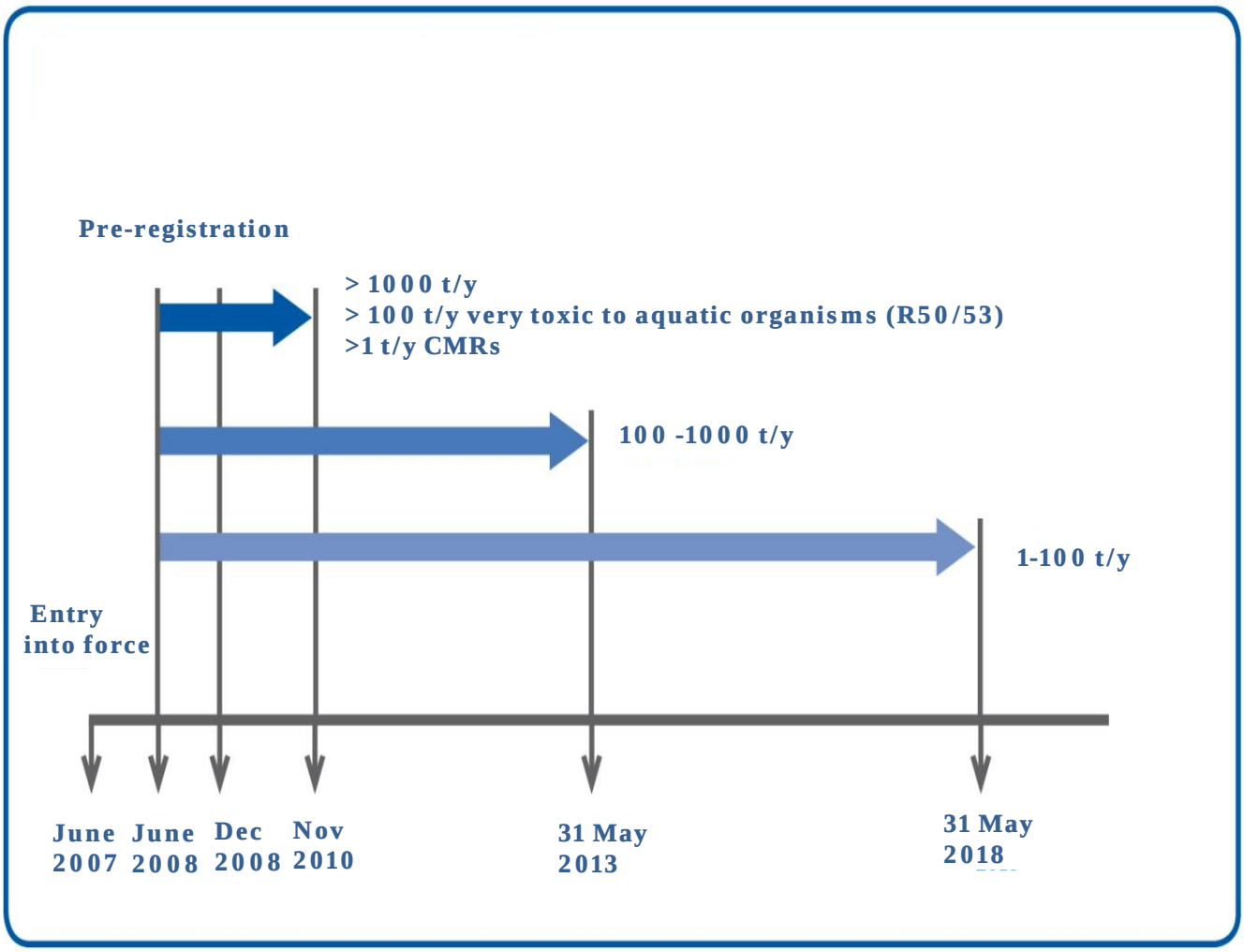


**Figure 2: Registration deadlines under REACH**

Although the main pre-registration period ended on 1 December 2008, potential registrants who **for the first time** manufacture or import a phase-in substance in a quantity of one tonne per year or more after 1 December 2008 can still benefit from the transitional regime (late pre-registration) and the phase-in deadlines for registration. In order to achieve this, the potential registrant would have to submit to ECHA a pre-registration dossier within six months of first manufacturing or importing the substance and no later than 12 months before the relevant registration deadline, i.e. the deadline given for his tonnage band.
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, 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[8]. If this check is successful, ECHA issues a registration number[9].

# 5 Registration process

The aim of this chapter is to explain what information is required (or may be omitted) to complete a registration dossier under REACH. In order 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 through X and 'specific rules' for their adaptation are given in column 2 of these Annexes (see Section 5.2). Section 5.4 will outline the CSA.

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 the risks that the substances may present are controlled. The information gathered and the assessment performed has 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 of the substance, as discussed in the next section. It is important to keep in mind the purpose of determining these data:

- To define and characterize the identity of the substance (see guidance on substance identification)
- 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 for risk assessment.

These studies are intended to model the (potential) effects of the chemical substance on the systems of real interest, i.e. human health and the environment. The information 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:

[8] Note that in practice the dossier has to pass a virus and XML format check as well as a so-called 'business rules validation' in order to be accepted for processing by ECHA. For further information on this, please see 'REACH-IT Industry User Manual Part 6 – Dossier submission' and 'Data Submission Manual 4 – How to Pass Business Rule Verification ("Enforce Rules") , to be found at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration.

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

- 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. Specific toxic effects include 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 have to be conducted.

## 5.2 Information Requirements

Manufacturers and importers have to collect **all available 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 set up by 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[10] 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 (IR&CSA) explains in detail the process for information gathering and data generation.

Please note that special information requirements apply to certain types of intermediates (see below).

**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 in quantities of 1 to 10 tonnes.

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

It should be noted that the registrant must establish the chemical identity of the substance 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.

As a minimum, a dossier should include Annex VI information and in addition the information based on 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')[11].

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 **registrant is obliged to share or generate data with other registrants** of the same substance, instead of generating data by himself, **if this would involve animal experiments** (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 laboratory practice or other international standards recognised as being equivalent by ECHA or

[11] For further information on adaptation of information requirements see Chapter R5 of the Guidance on IR&CSA see Chapters R2 to R5.

the Commission and with the provisions of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

Information on intrinsic properties of substances may be generated by using sources of information other than *in vivo* testing. The registrant may use a variety of alternative methods such as *in vitro* tests, (Q)SARs ((Quantitative) Structure Activity Relationships), grouping or read-across, provided that the use of alternative methods is justified. All these different sources of information can also be used in a weight of evidence approach.

Note that the registration dossier must also include an indication as to which of the information submitted relating to the manufacture and use(s), the classification and labelling, study summaries or robust study summaries for Annexes VII to XI or the Chemical Safety Report (if required) has been reviewed by an assessor chosen by the registrant and having appropriate experience.

**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[12]:

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

Non-isolated intermediates are completely 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 isolated intermediates considerably less information is needed for registration of the two forms above, 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 if in need of more detailed information. The guidance is designed to support potential registrants of intermediates in assessing whether the conditions of manufacture and use fulfil the requirements to be considered as strictly controlled conditions

## 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:

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

□ 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)

Registrants are entitled to claim confidentiality in the registration dossier for certain information not to be disclosed on ECHA's website, e.g. degree of purity, identity of impurities and/or additives, total tonnage band, study summaries, etc. This request needs to include a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

## 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 forecasts 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:

<u>Hazard assessment:</u>

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 Chapter R.8 of the IR&CSA Guidance).

In a similar way, environmental hazard assessment comprises a decision on the classification and labelling of the substance and to determine a predicted no effect concentrations (PNEC[13]) 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.9 of the IR&CSA Guidance).

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 from explosivity, flammability and oxidising potential (guidance on how to assess physicochemical properties is available in Chapter R.7 of the IR&CSA Guidance).

If the result of the previous steps indicates 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 exposures.

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.

The **risk characterisation** is the final step in the chemical safety assessment where it should be determined whether risks arising from 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 of assessing 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 (SDS).

[13] See also the explanation given for PNECs in the previous section.

The following figure provides a final graphical overview of the elements of the CSA:

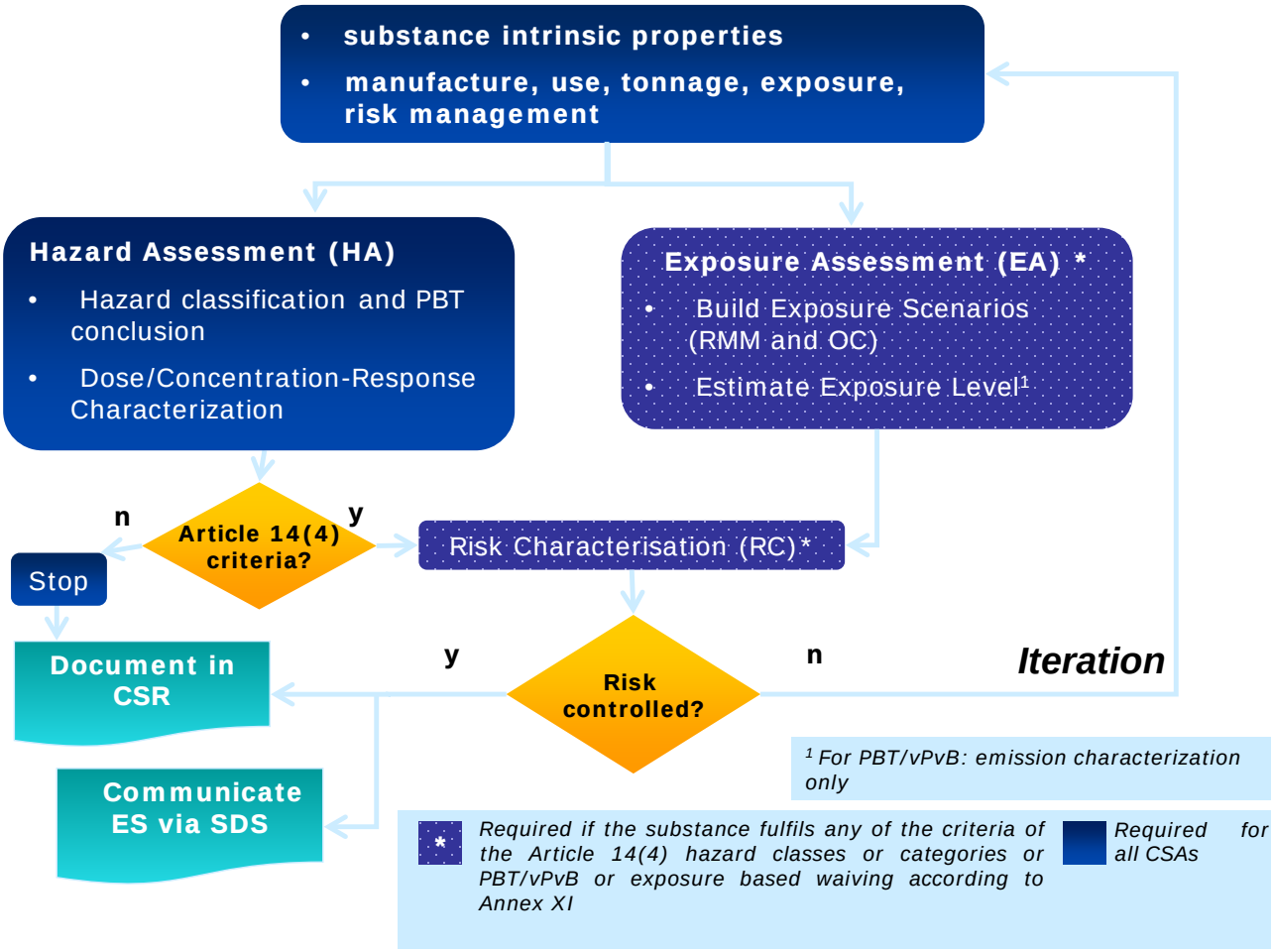


**Figure 3: Elements of the Chemical Safety Assessment**

# 6 Dossier preparation and submission

The aim of this chapter is to give an overview on how (and by whom) a registration dossier is prepared and eventually submitted to ECHA. The sharing of data and joint submission to ECHA of common parts of registration information by registrants of the same substance is a core principle of the REACH process. Hence, registrants of the same substance are usually required to work closely together and share costs for the information collection and generation (see Section 6.1). Additionally, registrants have to be familiar with the IT tools provided by ECHA for actual registration (see Section 6.2).

## 6.1 Data sharing, 'SIEFs' and joint registration

The purpose of data sharing is to increase the efficiency of the registration system as well as to reduce 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*).*

In order 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**. In general, pre-registration is relevant for phase-in substances and inquiry for non phase-in and phase-in substances that have not been pre-registered.

**Therefore, 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.**

**Phase-in substances**
In order to allow the data-sharing scheme to operate for registration of phase-in substances, companies had to make a pre-registration (as already mentioned in Section 4, even if the main pre-registration period has already ended, potential registrants can still benefit from late pre-registration under certain conditions).

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[14] are also participants of the SIEF.

In order to initiate SIEF formation, pre-registrants who indicated the same substance identifiers were grouped into REACH-IT into a 'pre-SIEF'. Based on this grouping, companies are then required to have dialogue with their fellow 'pre-SIEF' members in order to identify and form one SIEF for each substance. The aims of SIEF are to:

- facilitate the mandatory 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.

**Non-phase-in substances**

Inquiry is the process by which every potential registrant must inquire from ECHA whether a registration has already been submitted for the same substance. This is to ensure that data are shared by the relevant parties. The duty to inquire applies to non phase-in substances and to phase-in substances that have not been pre-registered.

If a registration already has already been submitted, they can use data from substances registered under REACH 12 or more years previously as of 'right' for their new registration. Studies from substances registered less than 12 years before are protected, but the two parties are put into contact with a view to reaching an agreement to share data, and animal studies cannot be repeated. It should be noted that both the potential registrant and the existing registrant are obliged to come to an agreement on the sharing of data involving tests on vertebrate animals. For studies not involving tests on vertebrate animals the same obligation applies for any studies specifically requested by the potential registrant.

[14] Except for substances regarded as registered because they were notified a notification according to Directive 67/548/EEC has been submitted (NONS).

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.

The inquiry dossier can be prepared on line using the REACH-IT web application or in IUCLID 5 and subsequently submitted via REACH-IT to the Agency.

**Joint submission**

Although each registrant is obliged to submit his own registration dossier for each of his substances, in cases where a substance is manufactured or imported or intended to be manufactured or imported by more than one company, they are required to submit certain information together. The joint submission of data applies both for the registration of phase-in substances and 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 and can, if they agree to do so, also jointly submit the guidance on safe use and the chemical safety report (CSR)** (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. 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.

## 6.2 IT tools for registration

Registrations under REACH shall be prepared and submitted using IT tools specified by ECHA, namely REACH-IT and IUCLID 5. Essentially, the technical dossier containing all the required information has to be compiled by the registrant in the format of IUCLID 5 and then submitted electronically via REACH-IT to ECHA.

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[15] for the CSA. The tool has been developed to help registrants perform a CSA and generate a CSR. It 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/.

If the same substance is manufactured or imported by more than one company, these companies are required to submit certain information together (so-called joint submission of data), and certain information separately[16].

In practical terms, companies should take the following steps in order to prepare and submit their registrations to ECHA:

1) Sign-up in REACH-IT to create an account for your company.

[15] "Chesar" stands for Chemical safety assessment and reporting tool
[16] See above under Section 6.1.

2) Prepare your registration by creating a technical dossier in IUCLID 5. Use the IUCLID plug-ins to ensure your dossier is fit for purpose: Technical Completeness Check, Fee calculator as well as Dissemination plug-in.
3) Consult ECHA's REACH-IT Supporting Documents[17]. It is important to read carefully the 'Data Submission Manuals', especially Parts 4 and 5, before preparing your dossier. Also the 'REACH-IT Industry User Manual - Part 6 (Dossier Submission)' will help you by providing step-by-step instructions leading you in the process.
4) Submit your 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[18]. The 'completeness check' is fundamentally different from the 'compliance check' of registrations. 'Compliance check' and the 'examination of testing proposals' by ECHA are the two pillars of the 'dossier evaluation'[19] procedures under REACH. The dossier evaluation is done subsequent to 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 has also to take care on his own initiative of updating his registration dossier when needed.

## 7.1 Completeness check

The completeness check process comprises two distinct sub-processes:

- **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 in REACH has been provided. However, there is no scientific assessment of the quality or adequacy of the data or of any justifications to omit studies. The 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 by applying the IUCLID Technical Completeness Check (TCC) plug-in.

- **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 complete (i.e. the required information has been provided and the appropriate fee has been received) ECHA issues a registration number.

[17] See under http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/

[18] Note that in practice the dossier has to pass a virus and XML format check as well as a so-called 'business rules validation' in order to be accepted for the completeness check. For further information on this, please see 'REACH-IT Industry User Manual Part 6 – Dossier submission' and Data Submission Manual Part 4 – How to Pass Business Rule Verification' , to be found at http://echa.europa.eu/support/dossier-submission-tools/reach-it

[19] The 'substance evaluation' under REACH is not further addressed in this document. For detailed information on this procedure you are advised to consult the ECHA Guidance on dossier and substance evaluation at http://echa.europa.eu/guidance-documents/guidance-on-reach

## 7.2 Duty to keep registration information up-to-date

The information submitted in the registration dossier to ECHA will have to 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:

- *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) concerning their registration (Article 22 (1)).

- *update as a consequence of a decision made by ECHA or the Commission*[20]

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 have to be performed **within the deadline** specified by ECHA/ the Commission in the decision (Article 22(2)).

For substances regarded as registered because they were notified according to Directive 67/548/EEC (so-called 'NONS'[21]), registrants need to submit updates of their dossier when any of the situations mentioned above occurs, including updates following decisions taken according to Directive 67/548/EEC and now regarded as Agency decisions (Article 135). However, the update does not have to meet the full information requirements under REACH corresponding to the respective tonnage band, unless the quantity manufactured/ imported of the notified substance by the registrant reaches the next tonnage threshold [22].

Note that an update will in certain cases be subject to the payment of a fee in accordance with Commission Regulation (EC) No 340/2008 (Fee Regulation) (see section 9.2 of the Guidance on registration).

The Guidance on registration explains in further detail the different situations which trigger an update of his registration dossier. Once such an update is submitted to ECHA, it has to undergo a completeness check within three weeks of the submission date.

# 8 References and further information

- ECHA website: http://echa.europa.eu/
- ECHA Frequently Asked Questions about REACH: http://echa.europa.eu/web/guest/support/faqs/frequently-asked-questions
- ECHA legislation website: http://echa.europa.eu/web/guest/regulations/reach
- ECHA guidance website: http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation
- Guidance on registration
- Guidance on data sharing
- Guidance for intermediates

[20] For further information please see Section 7.3 of the Guidance on registration

[21] Notification of New Substances.

[22] For further details on NONS and their practical handling under REACH you may consult the Questions and Answers for the Registrants of Previously Notified Substances at http://echa.europa.eu/support/faqs

- Guidance on dossier and substance evaluation
- Guidance for identification and naming of substances in REACH
- Guidance on information requirements and chemical safety assessment

IT tools for registration

1. IUCLID 5 website : http://iuclid.echa.europa.eu/
2. REACH-IT and technical manuals : http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it
3. Chesar website: http://chesar.echa.europa.eu/
4. Questions and Answers for the Registrants of Previously Notified Substances: http://echa.europa.eu/support/faqs

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