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Guidance in a Nutshell

Chemical Safety Assessment

This document aims to explain in simple terms the main requirements under REACH regarding the Chemical Safety Assessment

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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1 INTRODUCTION

The REACH Regulation[1] is based on the principle that it is for the industry to ensure that the substances they manufacture, place on the market or use do not adversely affect human health and the environment. Within REACH, the chemical safety assessment plays a major role since it is the instrument to ensure that all risks are identified and under control.

This guidance document provides an overview of what a chemical safety assessment is and how it is performed and documented. It also outlines the communication needs down the supply chain and the resources required, in terms of time and expertise, to comply with the legal obligations.

The purpose of the document is to assist industry in understanding the general provisions for conducting a chemical safety assessment. The document is aimed at non-experts who want to become familiar with the legal requirements regarding substance assessment. For more in-depth advice, the reader should turn to the Guidance on Information Requirements and Chemical Safety Assessment[2]. A glossary, containing the definitions of REACH related terms, is also available in the guidance section of the ECHA website[3].

[1] Regulation (EC) No 1907/2006 of the European Parliament and 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, 93/105/EC and 2000/21/EC

[2] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1252664663

[3] http://guidance.echa.europa.eu/

2 WHAT IS THE CHEMICAL SAFETY ASSESSMENT ABOUT?

The Chemical Safety Assessment (CSA) is the process that identifies and describes the conditions under which the manufacturing and use of a substance is considered to be safe.

There are **three major steps** in the CSA process. These are:

- Hazard assessment
- Exposure assessment
- Risk characterisation

The **hazard assessment** requires the collection and evaluation of all available and relevant information on the substance. This includes information on the intrinsic properties of the substance, on the manufacturing and uses, and on the related emissions and exposures. Where existing information is insufficient to satisfy the REACH requirements, additional information has to be generated.

The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe (the so called no-effect levels).

If as a result of the hazard assessment it can be concluded that the substance does not meet the criteria for classification as dangerous or to be considered a PBT/vPvB[4], the CSA ends here. If the substance meets any of these criteria, two additional steps are required to complete the process.

The **exposure assessment** is the process of measuring or estimating the dose or concentration of the substance to which humans and the environment are or may be exposed, depending on the uses of the substance.

Within the exposure assessment, the definition of the conditions under which the substance is manufactured and used is critical in order to determine the levels of exposure. The information on the conditions under which a substance is manufactured and used is called the **exposure scenario** under REACH. For each exposure scenario, the exposure levels of humans and the environment need to be determined. The exposure scenarios will cover all identified uses and life stages of the substance.

The third step in the CSA process is the **risk characterisation**. For the risk characterisation, the levels of exposure are compared with the threshold levels for each effect. Where it is not possible to determine a threshold level for one effect, a qualitative or semi-quantitative approach is used.

[4] PBT: Persistent, Bioaccumulative and Toxic; vPvB: very Persistant, very Bioaccumulative (see section 4.1.5)

Risks are regarded as controlled under REACH when the exposure levels to the substance are below the threshold levels considered as safe, both for humans and for the environment. For effects with no threshold levels, emissions and exposures have to be minimised or avoided for risks to be considered to be controlled.

If risks are under control, the CSA ends here. **If risks are not under control**, the CSA has to be refined, either by obtaining more data on the properties of the substance, changing the conditions of manufacturing or use, or making more precise exposure estimations. The **process is iterative** and will continue until the risks are shown to be under control.

The conditions of manufacturing and use under which the risks are under control constitute what is called the **final exposure scenario.**

The CSA is documented in **the Chemical Safety Report (CSR)** and the final Exposure Scenarios (ES) are in addition communicated through the supply chain via the **extended Safety Data Sheet (eSDS)**.

If risks are not under control for a specific use of a substance, and no more iterations are either possible or economically viable, the **use will be advised against** and documented as such in the CSR and the eSDS.

Figure 1 shows an overview of the different elements of the CSA process.

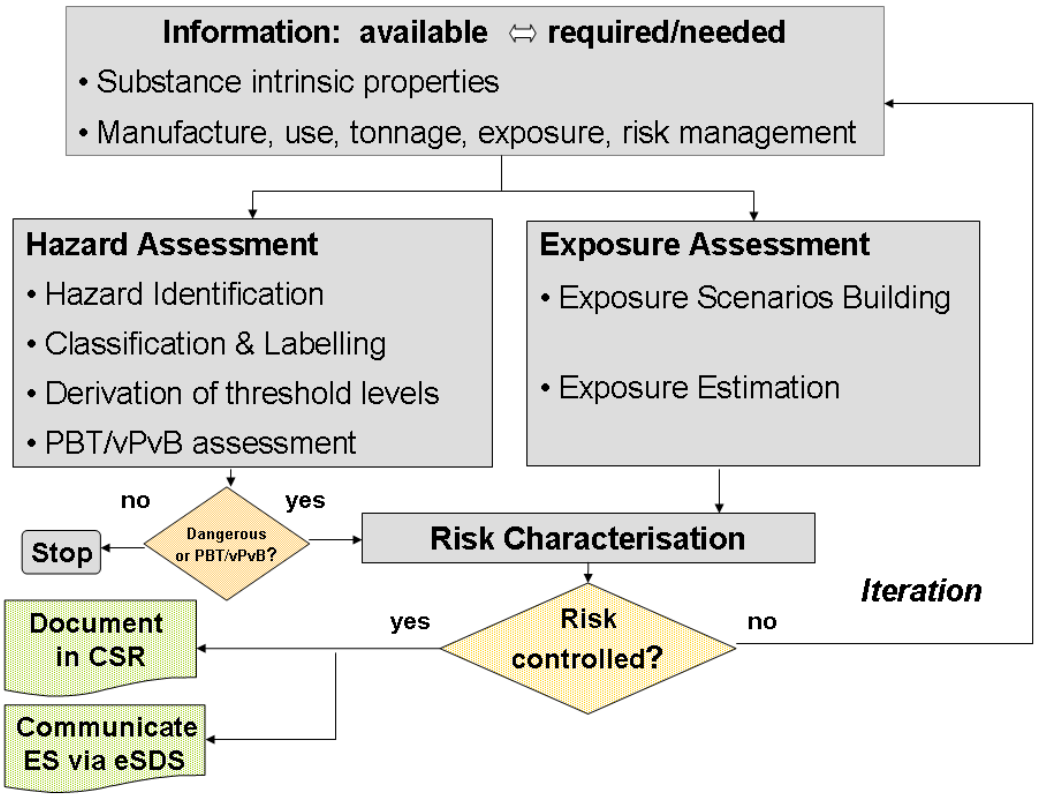

Figure 1: CSA overview

3 WHEN IS A CHEMICAL SAFETY ASSESMENT REQUIRED?

3.1 Registration process

A Chemical Safety Assessment (CSA) is required for all substances subject to registration under REACH in quantities of ten tonnes or more per year per registrant. A CSA need not be performed, however, if the substance is present in a preparation and the concentration of the substance in the preparation is below certain concentration limits (normally 1% by weight). Intermediates, manufactured and used under so called strictly controlled conditions, are also exempted.

It is normally the **manufacturer or importer** of the substance who has the duty to carry out the CSA and to document it in the Chemical Safety Report (CSR), as part of the registration process. The CSR of the manufacturer, and therefore the exposure scenarios, needs to cover the manufacturing process and all the identified uses and life cycle stages of the substance. The CSR of the importer must address only the identified uses and the resulting life cycle stages, leaving the manufacturing process out.

Producers or importers of articles that are required to register a substance under REACH are also required to make a CSA and to document it in a CSR if the substance is present in the articles in quantities of ten tonnes or more per year. The registrant's CSR will address exclusively the use of the substance related to the article and will consider the whole lifespan of the article including its disposal.

The CSR has to be submitted to the European Chemicals Agency with the technical dossier, as part of the registration process.

3.2 Downstream users requirements

Downstream users may have to make their own CSA, if the conditions of use, described in the exposure scenarios supplied with the substance or preparation, do not cover their own conditions of use or those of their customers.

This requirement does not apply when the substance or preparation does not need a safety data sheet or a CSR, either because it is not classifiable as dangerous or because it is produced or imported in quantities below ten tonnes per year by the supplier. There are also other exemptions from this requirement when:

- the total amount of the substance used by the downstream user is below one tonne per year;
- the conditions of use that the downstream user has implemented for his specific use are at least as strict as the recommended ones in the safety data sheet, or
- the substance is used for research and development.

The downstream user's CSA needs to address his own use and, where applicable, the identified uses down the supply chain not covered by the supplier. The CSA process differs from the standard process in that the hazard assessment is not required, since the downstream user may make use of the available information in the safety data sheet.

A downstream user may decide also to carry out his own CSA for one or more uses advised against by the supplier. In this case, the downstream user will have to refine the initial assessment, including the hazard assessment if necessary, until the safe use of the substance can be demonstrated.

The downstream user does not have to submit his CSR to the European Chemicals Agency, but the information regarding the substance identity and the description of the use needs to be notified. This notification is only required if the quantity for the specific use is above one tonne per year.

3.3 Applications for authorisations

All substances subject to authorisation under REACH require a CSA, regardless of the tonnage involved. The CSA needs to cover the specific uses for which the authorisation is being applied for and address the risks giving rise to the authorisation requirements.

The CSA may be made by the **manufacturer, importer, article producer/importer or downstream user** covering his own use or any other uses further down the supply chain. If a CSA has already been carried out as part of the registration process, it can be used for an authorisation application.

The CSR documenting the CSA needs to be submitted for the authorisation application. A reference to the initial CSR will be sufficient, however, if it has already been handed over with the registration dossier.

If the substance use of a downstream user is covered by an authorisation granted to his supplier, the downstream user must notify his use to the European Chemicals Agency.

4 HOW TO PREPARE THE CHEMICAL SAFETY ASSESSMENT

The Chemical Safety Assessment (CSA) is meant to deliver the following outputs:

- **Assessment** of any hazards the substance may present.
- **Identification** of the conditions under which the risks arising from the manufacture and uses of the substance can be considered under control, i.e. exposure scenarios.
- **Documentation** of the relevant data, justifications and conclusions in a Chemical Safety Report (CSR).
- **Implementation** of the conditions of manufacture and use controlling risks at the registrants' premises.
- **Communication** to the customers further down the supply chain of the conditions of use ensuring control of risks.

Although the CSA may vary case by case depending on the available information, the hazardous properties of the substance and the exposure conditions, the general process will follow the steps presented in Figure 1. These steps are explained in detail in the following sections.

4.1 Hazard assessment

The CSA starts with the hazard assessment. The assessment normally comprises the following steps:

1. Information gathering and evaluation
2. Hazard identification
3. Classification and labelling
4. Derivation of threshold levels
5. PBT and vPvB assessment

4.1.1 Information gathering and evaluation

Under REACH, the registrants are obliged to collect **all relevant and available information on the intrinsic properties of a substance.** This includes all **physicochemical, toxicological and ecotoxicological** information that may assist in identifying the presence or absence of hazardous properties of the substance.

The registrant needs to evaluate this information for its quality, including its **reliability, relevance and adequacy** for hazard assessment. The information should also be evaluated for its **completeness**, i.e. its capacity to meet the minimum information requirements defined in REACH. These requirements, known as the **standard information requirements**, depend on the tonnage manufactured or imported and

increase with increasing tonnage. The standard information requirements for each tonnage level are covered in Annex VII to X of the REACH Regulation.

The standard information requirements **may be adapted** according to the specific rules for adaptation set up under REACH for each requirement. Further adaptations to the standard information requirements are also possible based on general rules and exposure considerations, as defined in Annex XI of REACH. Each adaptation from the standard requirements must be fully justified and documented by the registrant.

Where the information collected does not cover the information requirements, additional tests need to be performed to fill the gap. For certain properties, the registrant must prepare a **testing proposal** and implement or recommend to downstream users provisional risk management measures to cover the risks, while waiting for the results.

The collection and evaluation of the information on the intrinsic properties of a substance is a general requirement for registration under REACH, not only for substances for which a CSA is required. The information has to be documented in the technical dossier and in the CSR, where applicable. This information forms the basis for all further CSA activities.

Additional information on the manufacturing and uses of the substance and on the related emissions and exposures may be needed at this stage. The registrant may require this information for example to,

- justify the waiving of certain standard information requirements based on demonstrated absence of exposure, or

- determine whether an exposure route or environmental sphere requires specific testing.

4.1.2 Hazard identification

In order to identify the hazards of a substance, the registrant needs to assess and integrate all the available information and determine the capacity of the substance to cause adverse effects to human health and the environment.

The identification of the physicochemical hazards will entail the evaluation of the capacity of the substance to produce a dangerous event (explosion, fire, etc.). This evaluation is required at least for the following physicochemical properties: flammability, explosivity and oxidising properties.

The registrant is also required to identify the toxicological and ecotoxicological hazards and determine for each adverse health and environmental effect the dose descriptor of the substance. The dose descriptor is the term used to identify the relationship between a specific effect of a substance and the dose at which it takes place. The dose descriptors will be used later for deriving the no-effect threshold levels for human health and the environment. When a quantitative dose-response relationship cannot be defined, a semi-quantitative or qualitative analysis will have to be done.

4.1.3 Classification and labelling

Directive 67/548/EEC[5] and Directive 1999/45/EC[6] lay out the criteria to classify substances and preparations as **dangerous** based on their intrinsic properties. Substances and preparations can be classified in different categories of danger (very toxic, toxic, harmful, corrosive, etc.) depending on the hazards identified for human health and the environment. Directive 67/548/EEC[5] and Directive 1999/45/EC[6] define also the labelling requirements to ensure the safe handling and storage of dangerous substances and preparations[7].

The determination of the appropriate classification and labelling of a substance on its own, in a preparation or in an article is a requirement under REACH and has to be documented both in the registration technical dossier and in the CSR.

The classification of a substance as dangerous is a critical input in the CSA process since, together with the results of the PBT and vPvB assessment, it will determine the need to carry out an exposure assessment and risk characterisation.

4.1.4 Derivation of threshold levels

Based on the hazard identification, the registrant will define, where possible, the threshold levels for exposure below which risks for human health and for the environment are considered to be controlled.

Derived No- Effect Level (DNEL)

The **Derived No-Effect Level or DNEL** is the level of exposure to the substance above which humans should not be exposed.

The DNEL measures the potential of the substance to cause adverse health effects. This potential will vary depending on the exposure pattern to the substance. The **exposure pattern** is usually defined by a combination of the following elements:

- the **population** likely to be exposed to the chemical, i.e. workers, consumers or humans exposed through the environment. In some cases, specific vulnerable subpopulations can be considered such as pregnant women or children,
- the **frequency and duration** of the exposure, e.g. single exposure or continuous exposure for eight hours,
- the **route** of exposure: dermal, inhalation or oral.

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[5] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

[6] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

[7] Directives 67/548/EEC and 1999/45/EC will be gradually replaced by the new CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures) as from 1 December 2010 and 1June 2015.

For each health effect and each relevant exposure pattern, a DNEL needs to be established. The DNELs are calculated by dividing the value of the health effect dose descriptor by an **assessment factor**. Dose descriptors are determined in the toxicological studies on the hazards of the substance and are usually expressed as NOAEL, NOAEC, LD50, LC50[8], etc. Since dose descriptors are obtained from experimental data, an assessment factor is required to allow for extrapolation to real human exposure situations.

From all health effects, the lowest DNEL for each exposure pattern will be documented in the CSR and in the safety data sheet, where required. These DNELs will later be used for risk characterisation in the CSA.

It may not always be possible to derive DNELs for each health effect. This may be the case, for example, for carcinogenicity, where no safe threshold level can be obtained. In these cases a semi-quantitative value, known as the **DMEL or Derived Minimal Effect level** may be developed if data allow. The DMEL values represent exposure levels where the likelihood that the identified adverse effect occurs in a population is sufficiently low to be of no concern. DMELs can be used later on in the risk characterisation process in the same way as DNELs.

Predicted No Effect Concentration (PNEC)

The **Predicted No Effect Concentration or PNEC** is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short term exposure. The PNEC needs to be determined for each environmental sphere (aquatic, terrestrial, atmospheric, sewage treatment, food chain).

The PNEC for each environment is estimated by dividing the dose descriptor by the relevant **assessment factor**. Since dose descriptors are obtained from laboratory tests involving a limited number of species, the assessment factor is required to account for the uncertainties involved in the extrapolation to the real ecosystems. Where several dose descriptors are available for an environment, all the possible PNECs will be derived.

The lowest PNEC for each environmental sphere is reported in the CSR and in the safety data sheet, where required. The PNECs will later be used for risk characterisation in the CSA.

Qualitative approach

It may not always be possible to derive a DNEL, DMEL or PNEC for each health effect or environmental sphere. This may be the case for effects with a non-threshold mode of action or where testing is not technically possible. If a risk characterisation is required later on in the CSA, it will have to be based on a **qualitative analysis**, considering the likelihood that adverse effects are avoided. The qualitative approach should be justified and documented in the CSR.

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[8] NOAL: No Observed Adverse Effect Level
NOAEC: No Observed Adverse Effect Concentration
LD50: Lethal Dose 50%
LC50: Lethal Concentration 50%

4.1.5 PBT and vPvB assessment

PBT substances are substances that are **persistent, bioaccumulative and toxic** while vPvB substances are characterised by a **high persistency and a high tendency to bioaccumulate**, but not necessarily by proven toxicity.

Experience with these substances has shown that they can give rise to specific concerns due to their potential to accumulate in parts of the environment and to the unpredictability of the effects of such accumulation in the long term. The PBT/vPvB assessment is required for all substances for which a CSA must be conducted so that these specific concerns are taken into account.

The objective of the PBT/vPvB assessment is to determine if the substance fulfils the **criteria set up under REACH** for persistence, bioaccumulation and toxicity. The assessment will be based on all the relevant information available, including the exposure information generated in the context of the CSA.

If the data on the properties of the substance do not allow a direct comparison with the PBT/vPvB criteria and further information is needed, the registrant may decide to conduct additional testing to generate the data or directly treat the substance as if it were PBT/vPvB. Where additional testing is required, the registrant will have to submit a testing proposal to ECHA and implement provisional risk management measures in order to minimise emissions and exposure until the results allow for a final conclusion.

If the substance is confirmed to be a PBT/vPvB substance, the registrant will have to perform an exposure assessment and risk characterisation as part of the CSA.

If it is concluded that the substance does not fulfill the PBT/vPvB criteria, the PBT/vPvB assessment stops here. An exposure and risk assessment could still nevertheless be required if the substance is classified as dangerous in accordance with Directives 67/548/EEC and 1999/45/EC.

4.2 Exposure assessment

Where the hazard assessment shows that the substance meets the classification criteria as dangerous according to Directive 67/548/EEC or the PBT or vPvB criteria, an **exposure assessment** will be required to define the levels of exposure.

If the substance does not fulfil any of the above criteria, the exposure assessment will not be needed. In this case the registrant can directly end the CSA after completion and documentation of the hazard assessment in the CSR.

An exposure assessment entails the following two steps:

1. Development of exposure scenarios and

2. Exposure estimation.

The assessment needs to cover the manufacturing and all identified uses of the substance and the life cycle stages resulting from these identified uses. This will include the waste stage and, where relevant, the service-life of articles containing the substance.

4.2.1 Development of exposure scenarios

An exposure scenario is a set of information describing the conditions of manufacturing and use of a substance that may give rise to exposure to humans and/or to the environment. These conditions include:

- **Operational conditions**, such as duration and frequency of use, amount of substance employed, concentration of substance in a product and process temperature.

- **Risk management measures** such as local ventilation, air filtering systems, waste water treatment and personal protection equipment.

The registrant will start by gathering all available information on the operational conditions and existing risk management measures in the manufacturing, identified uses and life cycle stages of the substance. This information will allow the registrant to build one or more **initial exposure scenarios** that will serve as a starting point for estimating exposure.

Once the initial exposure estimation is made, an initial **risk characterisation** can be performed by comparing the expected levels of exposure to the predicted no effect levels from the hazard assessment. If as a result of the initial risk characterisation, risks can be demonstrated to be under control, the initial exposure scenario(s) will become the final exposure scenario(s). If risks are not controlled, further **refinement of the CSA** will be required, until the safe use of the substance can be proved or its use or uses advised against. The refinement involves one or more **iterations of the CSA**.

There are basically three options to refine the CSA process:

- **improve the hazard assessment** by obtaining more data;

- **improve the exposure assessment** by ensuring that the exposure estimation is realistic and reflects the conditions of use defined in the initial exposure scenario, or

- **improve the conditions of manufacturing or use**, e.g. by introducing more stringent risk management measures or changing the operational conditions in the exposure scenario.

It is up to the registrant to decide the most effective strategy for refinement in each case.

The exposure scenario(s) that result from the CSA refinement, is called the **final exposure scenario.** The final exposure scenario can be defined as the set of information describing the conditions under which the risks associated with the manufacturing and the identified uses of a substance can be controlled. It defines the operational conditions and risk management measures required to ensure the safe use of the substance for each exposed population during all life stages of the substance,

including the waste stage and the article service life, where applicable. The final exposure scenario(s) needs to be documented in the standard format shown in Table1[9].

The exposure scenario plays a core role within the CSA process. It constitutes the basis for the exposure estimation but it is also the major risk communication tool in the supply chain, together with the safety data sheet. For both functions it is essential that the information in the exposure scenario be presented in a standardized and comprehensive way. In this context, the **use descriptor system**[9], can help to structure the communication on uses and conditions of use between customers and suppliers.

The use descriptor system is based on four elements: sector of use, chemical product category, process category and article category. For each descriptor, a pick-list is provided so that the right category can be chosen. The combination of the four descriptors allows, in most cases, the proper description of the identified uses. It can also be used as a short title for the exposure scenario.

Some of the categories in the use descriptor system can be used directly as input data in some of the existing exposure estimation models. The development of exposure scenarios can be started from characterising the uses of a substance with the use descriptor system. However, in most cases, more information regarding the conditions of use is needed for carrying out an exposure estimate and deriving the final exposure scenario.

4.2.2 Exposure estimation

Exposure estimation needs to be performed for each of the exposure scenarios under development until the final exposure scenario is defined.

When estimating exposure**, all human populations liable to exposure and all environmental spheres for which exposure to the substance is known, need to be addressed.**

Ideally, the process for estimating exposure should be based on **actual measurements of exposure.** In practice, the availability of reliable exposure data is scarce and mostly limited to the workplace, which implies that, in most cases, exposure estimation has to be based on exposure estimation models.

There is a wide range of **exposure estimation models** that can be used for the specific purpose of developing exposure scenarios. Of these, the most convenient ones are those that can be directly linked to standard parameters in the exposure scenarios, such as the use descriptors, the concentration of a substance in a product, the applied amount, the duration of exposure or the presence of local exhaust ventilation. Available models that are suitable for performing initial exposure estimation include the following:

[9]The exposure scenario format and the use descriptor system are currently under revision. The draft proposals can be consulted on http://guidance.echa.europa.eu/guidance4_en.htm

Table 1: Standard format of an exposure scenario[9]

1	Short title of the exposure scenario
2	Processes and activities covered by the exposure scenario
Operational Conditions of Use	
3.	Duration and frequency of use *Specify for workers, consumers, environment (where relevant)*
4.1	Physical form of substance or preparation; surface to volume ratio of articles *Gas, liquid, powder, granules, massive solids;* *Surface area per amount of article containing the substance (if applicable);*
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity *Specify for workers, consumers, environment (where relevant)*
5	Other relevant operational conditions of use *For example* • *Temperature, pH, mechanical energy input;* • *capacity of receiving environment (e.g. water flow in sewage/river; room volume x ventilation rate)* • *wear and tear with regard to articles (if applicable); conditions related to service-life-time of articles (if applicable)*
Risk Management Measures	
6.1	Risk management measures related to human health (workers or consumers) *Type and effectiveness of single options or combination of options on exposure to be quantified [options to be phrased as instructive guidance]; specify for oral, inhalation and dermal route;*
6.2	Risk management measures related to the environment *type and effectiveness of single options or combination of options to be quantified [options to be phrased as instructive guidance]; specify for waste water, waste gas, protection of soil;*
7	Waste management measures at the different life cycle stages of the substances (including preparations or articles at the end of service life);
Information on estimated exposure and DU guidance	
8	Exposure estimation and reference to its source *Estimation of exposure resulting from the conditions described above (entries 3-7 and the substance properties; make reference to the exposure assessment tool applied; specify for routes of exposure; specify for workers, consumers; environment)*
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES *Guidance on how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of variables (and a suitable algorithm) which together indicate control of risk, but which have some flexibility in the respective values for each variable. Note: This will mostly be specific conditions for a certain type of product; this section may also include a link to a suitable (e.g. easy-to-use) calculation tool.* *Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here as well.*

- ECETOC TRA[10] model for workers and consumer exposure estimation
- EUSES model[11] for environmental exposure estimation

Each of these models offers an initial estimation of exposure based on conservative or worst case exposure conditions. This estimation is usually defined as Tier 1 estimation. When the risk characterisation shows that risks are not under control for these exposure conditions, additional estimation based on more detailed and specific data may be needed. This higher Tier estimation can be done using more sophisticated and detailed models or measured exposure data. However, the assessor may also come to the conclusion that a specific use cannot be demonstrated to be safe and decide not to include this use in his registration.

When estimating **human exposure** to a substance, all the possible exposure patterns arising from an exposure scenario have to be considered. This implies that for each population, each frequency and duration of exposure and each possible exposure route, an **exposure leve**l will have to be determined.

Similarly, for each environmental sphere, an exposure level needs to be determined, both at local and regional scale. The **environmental exposure leve**l is known as the **Predicted Exposure Concentration (PEC).**

4.3 Risk characterisation

The exposure values will be compared with their respective threshold levels (DNEL/DMEL or PNEC) in the risk characterisation. Where no threshold level is available, a qualitative risk characterisation will be required.

The risk characterisation needs to be carried out for each exposure scenario in order to determine if the operational conditions and risk management measures ensure control of risks of the substance.

Risk characterisation for physicochemical properties

Substances will be assessed as a minimum for their explosivity, flammability and oxidising potential. The assessment will include an analysis of the processes in which the substance is used and a description of the measures taken to prevent an accidental release or negative health effects in case of an event.

Based on the assessment, the registrant will determine whether the use of the substance can be considered to be of no immediate concern or further risk reduction measures are required.

[10] Available free at www.ecetoc-tra.org

[11] Available free at www.ecb.jrc.it/euses

Risk characterisation for human health

The quantitative risk characterisation for human health is carried out by comparing the estimated exposure level for a given exposure pattern with the lowest DNEL/DMEL value, i.e. the critical DNEL/DMEL, for that exposure pattern. The comparison needs to be done for each exposure pattern resulting from a given exposure scenario.

When no DNEL/DMEL is available for a health effect, a qualitative risk characterisation for that effect will be required. The purpose of the qualitative risk characterisation is to assess the likelihood that adverse effects are avoided when implementing the exposure scenario. Operational conditions and risk management measures need to be directed at reducing/avoiding contact with the substance.

In practice, the lack of a DNEL or a DMEL for a given health effect, e.g. sensitisation or mutagenicity, does not allow to determine if that health effect is less or more critical than the other ones for which a DNEL/DMEL can be derived. Therefore, in this situation, two different kinds of risk characterisation will have to be conducted to ensure control of risks. On the one hand a quantitative or semi-quantitative risk characterisation will take place by comparison of the exposure levels with the critical DNEL or DMEL and, on the other hand, a qualitative risk characterisation will be required for the health effects for which no DNEL/DMEL is available. Both assessments will have to demonstrate control of risks.

Risk characterisation for the environment

The quantitative risk characterisation for the environment is carried out by comparing the Predicted Exposure Concentration (PEC) with the PNEC. This is done separately for each environmental sphere, both at a local and regional scale.

When no PEC or PNEC can be derived, a qualititative risk characterisation should be conducted. This may be the case for PBT and vPvB substances for which no PNEC can be derived for any environmental sphere. The objective of the qualitative risk characterisation will be to assess the level of control over the risks generated by the substance. Operational conditions and risk management measures will be directed to minimise emissions and exposure to the environment.

Combined exposures

The risk characterisation also needs to consider risks from combined exposures via different routes or via different sources. This may be the case where the same person is potentially exposed to the same substance via different routes of entry into the body or from different products containing the same substances.

Risk under control

The risk characterisation will determine if the risk to humans and the environment is under control or not for a given exposure scenario.

Risk will be considered to be adequately **controlled** if:

- the likelihood and severity of an event occurring due to the physicochemical properties of the substance is negligible;

- the estimated exposure levels do not exceed the appropriate DNEL/DMEL or PNEC, and

- for substances for which a DNEL/DMEL or PNEC cannot be determined, the emissions and exposures are minimised by the implementation of the exposure scenario to the level that they do not pose risk.

The exposure scenario that ensures that risks are under control is called the **final exposure scenario.** Its implementation by the manufacturer, importer and/or downstream user implies the safe use of the substance.

If risks cannot be demonstrated to be under control, further **iteration of the CSA** (as explained in section 4.2.1) will be required, until the final exposure scenario can be defined or the use of the substance has to be advised against.

The final exposure scenario has to be attached to the extended Safety Data Sheet (eSDS) and be communicated down the supply chain.

5 TIME AND EXPERTISE NEEDED

When planning the actions and resources needed to register a company's substance portfolio within the deadlines set by REACH, the registrant needs to be aware of the major drivers with regard to time and money. These drivers include for example:

- Collection and assessment of all the available information to establish whether it is sufficiently reliable and relevant to satisfy the REACH information requirements. Particular expertise is needed here.

- Interaction and cooperation among different companies registering the same substances in order to share data and to submit a joint registration dossier.

- Determination of the substances for which a CSA with or without exposure assessment is required.

- Mapping of the uses and the conditions of use in the market of each individual substance to be registered. This will involve the use of in-house knowledge and interaction with customer organizations or individual representative customers. In those sectors where generic exposure scenarios have been worked out and validated, these can be used by an individual registrant to the extent that they are applicable to his specific market.

- Feeding the information from the uses into the standard exposure estimation models. This work needs experience and expertise in order to "translate" the uses information into the input values needed to run such an exposure estimation tool in a correct way.

- Further investigation regarding the conditions of use and/or the identification of additional risk management measures may be needed, where conservative exposure assessment is unable to demonstrate control of risk. Particular expertise and potentially measurement of exposure is needed for such in-depth assessment.

6 INFORMATION VIA THE SUPPLY CHAIN

Manufacturers and importers of a substance under REACH need to address the manufacturing and all identified uses of the substance, as appropriate, in their CSR for the registration of the substance. To be able to do so, the manufacturer or importer has to collect the relevant information on the different uses of the substance, including information on appropriate risk management measures and the specific conditions of use. Part of this information will be available in-house, especially in regard to the manufacturing and own use of the substance. Additional information on the conditions of use down the supply chain will most likely have to be collected externally, through the customers or customers associations.

The manufacturer or importer needs to communicate the relevant information documented in the CSR to the downstream users, to ensure a safe use of the substance. This transmission is done by means of the safety data sheet and the exposure scenarios attached, also known as the **extended Safety Data Sheet (eSDS)**.

The eSDS includes information on the substance properties, the operational conditions of use and the appropriate risk management measures to ensure control of risks. The information covers all the identified uses of the substance, relevant to the downstream users, and addresses all life stages, including the waste stage. It may also include advice that refers to uses beyond downstream users under REACH, like instructions to the general public or information on appropriate waste disposal methods.

Each downstream user of a substance or preparation who is supplied with an eSDS must ensure that his use conditions are covered by the exposure scenarios. If this is not the case, **the downstream user has the right to make his use known to the supplier in writing** with the aim of having it identified and included in the registrant's CSA.

Although the downstream user can make his use known in writing for a registered substance at any time, it is advisable to do so before registration takes place. In this case it should be done at least one year before the registration deadline for the substance to ensure that it is included in the registration, if not advised against.

Downstream users are also required to communicate up the supply chain any **new information on the hazardous properties** of the substances as well as any other information that might call into question the **appropriateness of the risk management measures** identified in the eSDS.

If a downstream user decides to carry out his own CSA for any use not covered by the registrant's assessment, it is the downstream user who takes over the responsibility for the definition of the safe conditions of use, including the communication down the supply chain.

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu