Guidance on the Chemical Safety Report

Introduction

REACH requires the submission of a Chemical Safety Report (CSR) for all substances subject to registration in quantities of 10 tonnes or more per annum per registrant or by downstream users if their uses are not addressed by their supplier. This report forms part of the registration process or 'registration dossier' and should be a readily understandable, stand-alone document.

The chemical safety report (CSR) under REACH is divided into 2 parts:

- Section A: the summary of relevant risk management measures (RMM) for the identified use(s) of a substance, based on exposure scenario(s)and declarations that the RMM are implemented by the organisation preparing the CSR and communicated to downstream users;
- Section B: the conclusions of the chemical safety assessment (CSA) process according to Annex I of the REACH Regulations and the supporting factual information to arrive at these conclusions. The CSA contains a detailed summary of the environmental and human health hazards properties of a substance, together with an assessment of exposure and risk where such an assessment is required (Figure 1).

The CSR is an important part of the REACH process as it is the source from which information is communicated further down the supply chain, by extraction for use in extended safety data sheets (eSDS).The principles applied, the assumptions made and the conclusions drawn should be easily identifiable without the need to revert to the underlying substance data sets (i.e. the IUCLID substance data set). The preparation of the CSR needs to be carefully considered and requires a high level of expertise.

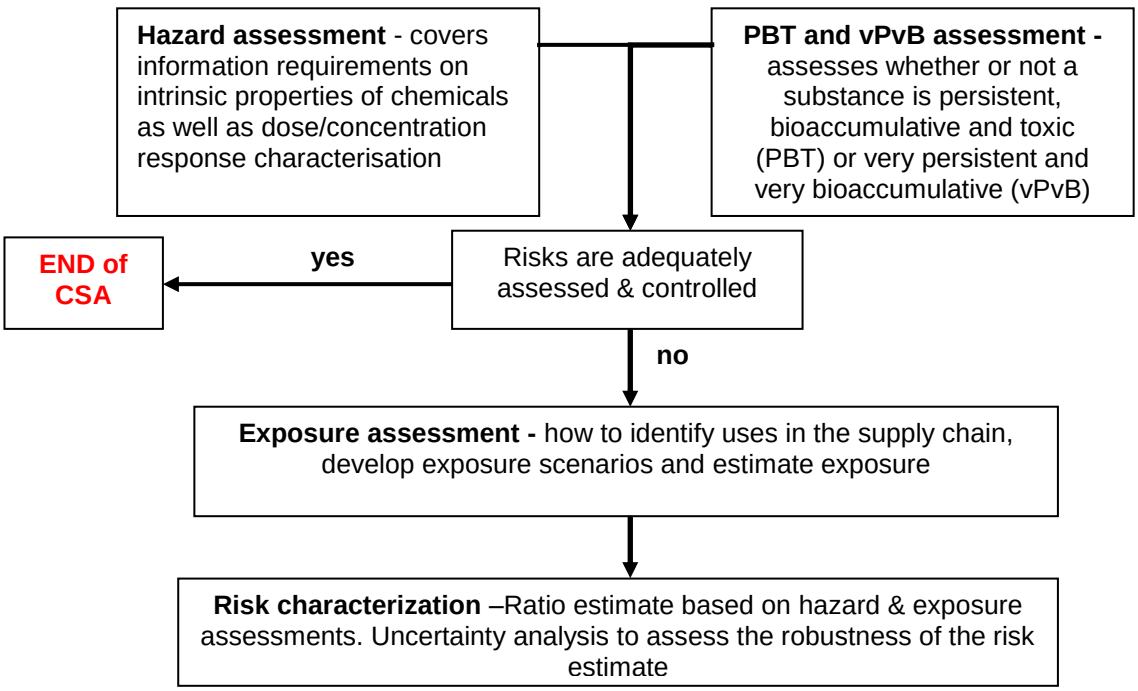
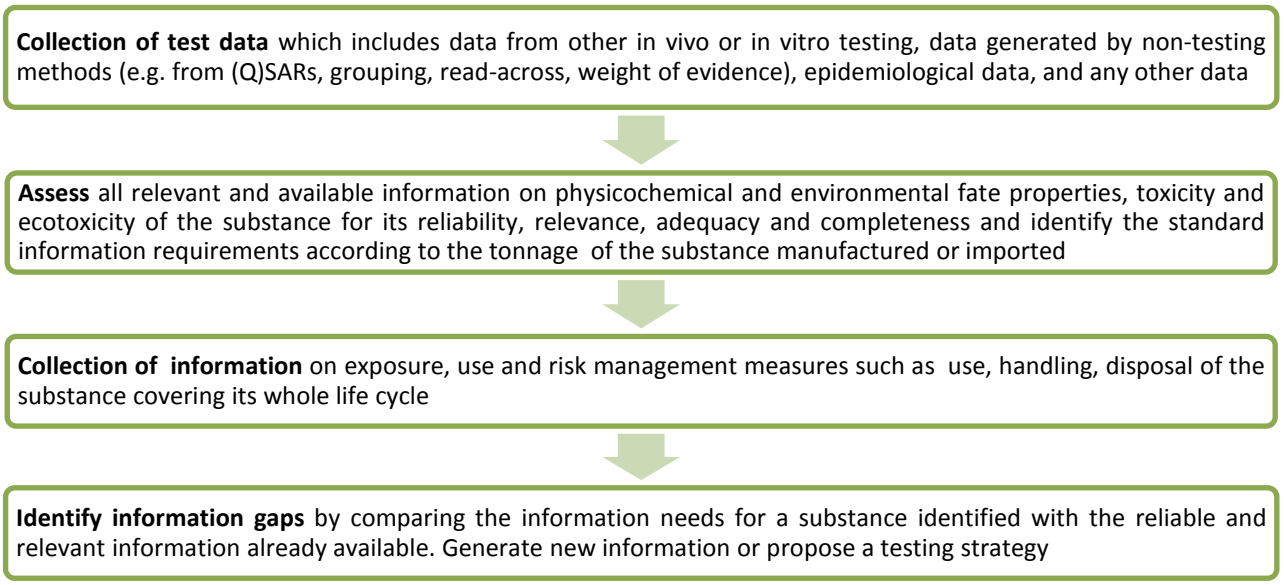


Figure 1.

Hazard Assessment

The hazard assessment can be defined as the gathering of all information on intrinsic properties of a substance and hazard characterization. Hazard characterization involves the evaluation and integration of the available information, classification and labelling as well as derivation of the hazard threshold levels for human health and the environment. Information on classification and labelling criteria for substances and mixtures are provided in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation).

Information requirements
The standard data requirements are summarised in REACH Article 10 and 12. Annexes VI-XI of the regulation also outline detailed information requirements for each tonnage band. As a minimum, REACH requires that all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant be included in the registration dossier. The information requirements are summed up below:



All data should be well documented to ensure that the registration dossier is properly completed and to avoid repetition at a later stage as each manufacturer or importer is required to assemble and keep available all information used to carry out duties under REACH for 10 years after the last manufacture or import of the substance as required under Article 36.

Hazard Characterization
This describes the potential for adverse effects, i.e. 'the potency' of the substance as an input for the risk characterisation and can be determined by deriving threshold and non-threshold effects levels. To assess human health information is needed with respect to the substances' fate in the body (toxicokinetics, i.e. absorption, distribution, metabolism, and excretion) and on the following human health endpoints; acute toxicity, irritation and corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, and reproductive toxicity as well as any other available information on the toxicity of the substance.

This hazard information should then be evaluated to derive a DNEL (Derived No-Effect Level). The DNEL represents a level of exposure above which humans should not be exposed. In cases where no DNEL(s) can be derived, REACH requires a qualitative assessment to be performed. However, for the non-threshold endpoints (e.g. non-threshold carcinogenicity), if data allow, the development of a (semi)quantitative reference value (DMEL=derived minimal effect level) may be useful. The methods for the calculation and the science that went into the process are too complex to discuss in this report, but it is discussed in Part B of ECHA's technical guidance for chemical safety assessment https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

The Environmental equivalent of the DNEL is the Predicted No-Effect Concentration of a given environmental compartment ($PNEC_{comp}$). The PNEC describes the concentration of a chemical in any compartment below which unacceptable effects on the aquatic ecosystem and its organisms will most likely not occur during long term or short term exposure. Toxicity data for living organisms living in specific environmental compartments are used to derive the PNEC for the respective compartment. This can be obtained through laboratory testing or by non-testing methods. However, if no experimental data are available for organisms of a given compartment, a PNEC value can be estimated based on extrapolation methods. This is further discussed in in Part B of ECHA's technical guidance for chemical safety assessment
https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

PBT/vPvB assessment

This assessment determines whether or not a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). In addition to the CSR document, a PBT/vPvB assessment will need to be carried out for: a substance present in a mixture, if the concentration is less than 0.1% weight by weight (Article 14(2)); on-site isolated (Article 17) or transported intermediates (Article 18); and Product and Process Oriented Research and Development (Article 9).

The properties of a substance can be compared to the PBT/vPvB characteristics as defined by the criteria laid down in Annex XIII of the REACH Regulations (summarised in the appendix below) to determine the persistency, bioaccumulative ability and toxicity of the substance. A substance that fulfils all three of the criteria for persistence, bioaccumulation and toxicity described is a PBT substance.

If a substance is confirmed to be a PBT/vPvB substance, a second step is needed to determine the emission characterization which is used to estimate the amounts of the substance released to the different environmental compartments during all activities carried out by the registrant for all identified uses. In depth guidance on the PBT and vPvB assessment, including emission characterisation is covered in Part C ECHA's technical guidance for chemical safety assessment
https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Exposure Assessment

The exposure assessment develops exposure scenarios (ES) based on the uses of a substance and estimates the exposure of the substance to human health and the environment. The ES should cover the entire life cycle of the substance and should be communicated down the supply chain with the

extended safety data sheet (eSDS). The ES needs to include details of exposure to workers, the general public and the environment that are specific to expected use patterns of the substance or mixture (see below for mixtures). Generic scenarios can be used (e.g. Lubricants, paints, chemical processing aids) and although they should be suitably comprehensive to cover generic locations, may be site specific if appropriate.

Occupational and consumer exposure are the end-point of a human health exposure assessment and can be estimated using data on types and routes of exposure (inhalation, dermal or oral), characteristics of substances, products, processes, tasks/work activities and the mapping and compilation of information on consumer uses of the substance, including operational conditions and risk management measures. Predicted Environmental Concentration (PEC) is the end-point of an environmental exposure assessment and can be calculated using data for the degradation or distribution of the substance in the environment (between water, sediments, soil and air) using physico-chemical and biodegradation data. Detailed methodologies including the exposure estimations can be found in Part D of ECHA's technical guidance for chemical safety assessment https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Risk Characterisation Ratio (RCR**)**

The hazard and exposure assessments must be performed in an iterative manner as initial testing will help indicate if there is a risk of exposure from a substance. The ratio between PEC and PNEC, or between workplace exposure and the DNEL, is ultimately used as an indicator of risk or RCR, allowing it to be quantitatively labelled. RCRs are used to consider if environmental concerns can be adequately controlled for each environmental compartment and to assess the potential effects of substances on human health.

If the RCR (PEC:PNEC ratio) > 1, then it can be assumed that there is an environmental risk and likewise, if humans are exposed to concentrations greater than the DNEL, there may be a health risk, suggesting that recommendations for risk reduction are necessary. Risk reduction may include risk management and/or engineering controls.

If the RCR is < 1, it can be assumed that the use of a substance is considered to be of no immediate concern and the risk assessment can be concluded. However, monitoring and review of the substance is recommended to ensure no future concerns.

Risk assessment software

To help users of chemicals, software can be obtained for free; although following similar algorithms, three main models are used;

- CHESAR – tool that can be added to IUCLID and will extract use details and details of the substance properties to make an estimate of exposure and risk characterisation. Although easy to use, it must be used with caution as many substance types do not work well.
- ECETOC TRA – this is a large spread-sheet with default exposure parameters that can be extracted for different uses and different properties of the substance. This is more transparent than CHESAR and is useful for downstream users as data input is easy.
- EUSES – the oldest model, but still valid. This is primarily for the environment, but will include consumer exposure and does incorporate the worker EASE model.

The CSR

The total length of the CSR may run into many pages, depending on how many exposure scenarios need considering. The guidelines do however suggest that only the main hazards are considered and that only the scenarios with the highest level of exposure need covering in detail. In other words, if the scenarios with high exposure are not a cause of concern, the other scenarios should be acceptable.

Section A

1. Summary of risk management measures
2. Declaration that risk management measures are being implemented
3. Declaration that risk management measures are communicated

This is very important in view of communication as it demonstrates that risk management measures (RMM) have been determined and have been implemented by the organisation preparing the CSR. It also confirms that you have informed your customer about the RMM (by way of SDS, for example).

Section B

1. Identity
2. Manufacture, use patterns
3. Classification / labelling
4. Environmental fate assessment
5. Health hazard assessment
6. Physical hazard assessment
7. Environmental hazard assessment
8. Persistent / Bioaccumulative / Toxic (PBT) assessment
9. Exposure assessment
10. Risk characterisation

Sections 1 – 8 can be extracted directly from IUCLID 6 data summary sections, but ideally, there needs to be some added input by the risk assessor to relate the endpoints to exposure conditions and to ensure that the whole CSR is a valid stand-alone document that is scientifically robust.

Mixtures

Under the communication requirements of REACH, it is acceptable to prepare safety assessments and ES for mixtures as part of an extended SDS. However, the legal text only states that the hazard and exposure details of ingredients classified as hazardous and above threshold concentrations of concern need to be communicated; it is therefore possible to communicate the findings of each substance and not consider the mixture as a whole.

It is recommended that the hazard and exposure specific to the mixture is considered and it is worth noting that many of the essential tests for hazard assessment cannot be performed on mixtures, including solubility, partition coefficient, biodegradation, bioaccumulation etc. Likewise, it is not possible to assign PBT or vPvB to mixtures, only their components.

Irrespective of how a substance is placed on the market, the CSR supporting the registration process must be for the substance being registered and if importing a mixture, a CSR on each component of the mixture is needed, even though an extended-SDS for the mixture is provided to customers.

Need more help?

If you need to produce a chemical safety report or extended Safety Data Sheet, then attending one of REACHReady's training events might be a good way for you to find out more. Our varied events programme offers workshops and training days, and we can also arrange bespoke in-house consultancy with someone from our team of experts. In-house events are held in confidence to allow company policy and strategies to be discussed in the presence of an adviser.

Alternatively, if you don't feel you have the expertise to do these things in house, then you can use our Matchmaker service to get in touch with REACHReady approved service providers who can help.

For more information contact us at enquiries@reachready.co.uk or +44 (0) 207 901 1444, or visit our website http://www.reachready.co.uk/

Annex

PBT criteria according to Annex XIII of REACH Regulation (EC) No 1907/2006

Property	Description	PBT criteria
Persistence	Resistant to biological/chemical breakdown in the environment	Half-life (T1/2) > 40 days in fresh or estuarine water or T ½ > 60 days in marine water, or T1/2 > 120 days in fresh or estuarine sediment or T ½ > 180 days in marine sediment, or T1/2 > 120 days in soil, or Not readily or inherently biodegradable, or Predicted biodegradability in a time frame of weeks-months
Bioaccumulation	Bio-concentration in food chain, wildlife and humans	BCF > 2000 L/kg, or Log K_{ow}> 4.5
Toxicity	Toxicity of flora, fauna and ecosystems, toxicity of humans and/or interference with the body's natural hormonal system	Chronic NOEC < 0.01 mg/L, or Substance is CMR : carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or Other evidence of chronic toxicity such as endocrine disrupting (ED) effects

vPvB criteria according to Annex XIII of REACH Regulation (EC) No 1907/2006

Property	Description	PBT criteria
Very persistent	Resistant to biological/chemical breakdown in the environment	Half-life (T1/2) > 60 days in marine, fresh or estuarine water, or T1/2 > 180 days in marine, fresh or estuarine sediment, or T1/2 > 180 days in soil
Very Bioaccumulative	Bio-concentration in food chain, wildlife and humans	BCF > 5000 L/kg