

Cefic welcomes the move towards “One Substance-One Assessment” and supports close collaboration between EU agencies and scientific bodies

A fit-for-purpose One Substance-One Assessment approach should lead to:

- Increased efficiency and predictability;
- Enhanced consistency of assessments and their outcomes, carried out on the same dataset;
- Improved robustness of the assessments;
- Involvement of the right expertise at the right place at the right time;
- Provision of tailored assessments under specific legislations/uses if relevant;
- Optimal use of resources.

Moving towards this objective requires action at multiple levels, including:

- Upfront close coordination of assessments across different DG's, Scientific committees and Agencies at European level; this also includes stronger coordination of Member States' regulatory initiatives;
- Data exchange across Committees and Agencies;
- Application of one hazard assessment;
- Centralising exposure assessment tools and methodology on a common platform;
- Securing tailored risk management;
- Increasing transparency on the decisions and processes.

These different elements are further detailed below.

As Cefic, we are convinced that, if well implemented, both industry and authorities will benefit from the one substance one assessment approach. Clarity of process will increase predictability and help streamline resources on both sides.

Background

Currently, different agencies and scientific committees provide advice and risk assessment to the European Commission. Their areas of intervention and their competencies are determined in the relevant pieces of legislation.

As substances and chemicals have several uses, the risk assessment of the same chemical sometimes falls under different laws and therefore needs to be performed by different agencies. While it makes sense to run risk assessments under specific legislation, it may also lead to confusion, possible conflicts and duplication of efforts if other parts of the assessment (e.g. hazard assessment) take place in parallel or are not aligned (see example below).

In most cases, the delineation of areas of competencies is clear. For example, the European Chemicals Agency (ECHA) is in charge of performing environmental and occupational risk assessment for cosmetics products while the Scientific Committee on Consumer Safety (SCCS) is in charge of assessing risks of finished (consumer) products for human health, building on the data generated under REACH and CLP (though not exclusively). In some other cases, there is a potential overlap (e.g. toys, detergents or other consumer goods, nanomaterials, food contact materials, workers' protection).

There are valid reasons why different agencies / committees have been created over time, depending on the objectives of the Regulation that establishes the mandate of a given agency/committee, the type of exposure (e.g. skin contact for cosmetics) and on the type of expertise needed. But without coordination of different processes and assessment bodies, there is a risk of inefficient use of resources, duplication of assessments and even diverging opinions,¹ which is confusing to the general public and other stakeholders, including industry and its customers.

Situations that lead to divergent regulatory opinions on the hazards and intrinsic properties of chemicals need to be avoided as it creates uncertainty and inconsistency and undermines investments in safe and sustainable chemicals.

Examples of diverging opinions across Agencies:

ECHA carried out a three-year in-depth assessment of the DINP2 reproductive hazards and concluded no hazard classification was required, meaning that unlike DEHP and other low molecular weight phthalates DINP has different properties and should not be grouped with them. EFSA conducted a seven-month assessment of reproductive effects of phthalates in Food Contact Material and concluded that DINP should be grouped with DEHP, initially with no reference to the ECHA assessment.³

EU Risk Assessments and ECHA conducted extensive hazard and risk assessments on high molecular weight phthalate DINP and DIDP, as well as for consumer products (which include electrical and electronic devices), concluded no hazard classification and agreed on safe use in current consumer applications. Precautionary restrictions based on liver effects apply to DINP and DIDP exclusively on toys and childcare articles which can be placed in the mouth. RoHS consultants in a study sponsored by DG Environment have listed the non-classified high molecular weight phthalates DINP and DIDP among highly hazardous substances which are a high priority for risk assessment under RoHS. Based

¹ This was recognised by the European Commission in the Fitness Check of Chemicals legislation (excl REACH) June 2019:

² Di-"isononyl" phthalate (CAS 28553-12-0): <https://echa.europa.eu/substance-information/-/substanceinfo/100.044.602>

³ "EFSA proposed a temporary guidance value based on potency of 4 phthalates (DEHP, DBP, BBP, DINP).

However, EFSA admitted limitations of its assessment due to time constraints as well as the uncertainties identified, and concluded that the current assessment, which reflects a "conservative approach" by EFSA, "should be on a temporary basis". In 2020 EFSA received a new mandate to undertake a robust and more comprehensive risk assessment

on their recent hazard (2018) and risk (2013) assessments by ECHA, and at the request of industry, DINP and DIDP were removed from the draft priority list initially and then re-added with no justification and no reference to the extensive EU assessments which have been carried out during the past 20 years.

Another example of divergence is a case with Bisphenol A (BPA): there have been issues on the methodologies applied by ECHA vs Member States i.e. differences in the selection and assessment of studies.

Cefic proposes the following actions to optimise the process:

1. Upfront close coordination of assessments across different DG's, Scientific committees, Agencies as well as Member States at European level, to decide what is required, and who does what and when, including:

- Identification of priorities;
- Identification of substance(s) or groups of substances: Even though one substance is well defined and clear in many cases, there are situations where a specific form of a substance is approved or undergoes assessment in downstream legislation. For example, an approval as a food additive, cosmetic or as a food contact material may only apply to a specific form of a substance (e.g. nanomaterial form). The initial evaluation and substance identity need to be considered at the beginning of any assessment process;
- A clear scoping of the assessment and identification of the concern(s) one is seeking to address (e.g. risks to workers, risks to the aquatic environment, risks to consumers, oral exposure via food contact materials,); such scoping can include impact on circularity and extend to and align with waste streams;
- Analysis of risk management options and which sequence should be followed: A thorough review of existing assessments conducted for the same substance or group of substances, aimed at identifying previous regulatory conclusions that should be taken into account when examining the need for new regulatory initiatives;
- Planning of the different elements of the assessment(s): some parts will run sequentially, others in parallel;
- Assignment of responsibilities and indicative timeline: which Agency/Committee is doing what and when – taking into account legal mandates and expertise;
- Involvement of Member States in the expert working group with the European Commission and EU Agencies, as announced in the Chemicals Strategy for Sustainability;
- Alignment and coordination within the involved competent authorities of a Member State and across Member States to avoid parallel approaches in different legislative frameworks.

Note: this requires mechanisms to actively involve Member States as they can also take the initiative for assessments (e.g. under REACH following a substance evaluation a Member State can introduce different follow-up actions).

2. Ensure data exchange across Committees and Agencies to avoid duplication of data submission

Submitted data (hazard and use) are tailored to a specific legal regime and are driven by the intended use and exposure (and potential risks) of a given substance. By using standardised IT formats and databases, data can then be easily accessed and exchanged, and compatibility should be guaranteed. Critical data would then become accessible to all parties involved in the assessment and the assessment would be based on a common dataset. For some legislations and specific assessments, the common dataset will still have to be supplemented with specific information. In addition, exchange of common data should ensure the use of most recent data.

The following is important to note:

- Data exchange can only work if there is mutual acceptance of data across committees / agencies. For such exchange to work in practice, there needs to be an agreement on the format (e.g. robust study summaries in IUCLID format as currently done at ECHA).
- Committees are constituted of a fluid set of individuals with different expertise and comfort levels (“expert judgement” is prone to some subjectivity). Therefore, achieving 100% consistency on data interpretation and conclusions will be a challenge. To overcome this, some methodology alignment, such as an overarching guideline, is needed on application of weight of evidence (to include evaluation of study quality, robustness, reproducibility etc.), transparency, use of assessment factors (uncertainties assessment), interpretation of adverse effects, etc. As a general principle, one needs to ensure that best scientific principles are applied across committees/agencies. An independent review of available resources and committee expertise could be conducted.
- Some data are subject to compensation or qualify as confidential business information. This has to be safeguarded in the mechanism of exchange.
- Data may be difficult to interpret and data owners can contribute to better understanding.

3. One hazard assessment

Hazard assessment starts with hazard identification. It includes identification of the relevant intrinsic properties of a substance and derivation of safe levels in studies. It would make sense if the hazard identification was centralised up to the point of classification and labelling, which constitutes the hazard identification conclusion. CLP Hazard identification should be done by one Agency, currently ECHA, based on the available data. Hazard data coming from tests performed according to realistic situations and relevant doses should prevail.

Hazard data can come from different sources, i.e. from the literature and from different regulatory requirements, depending on the intended use (e.g. plant protection products, biocides). Agencies and Committees should take into account all scientifically valid and validated information⁴, even if available under other legislative frameworks or Agencies.

The next step, hazard characterisation, may be harmonised as well i.e. selection of the key studies and points of departure (POD) for risk assessment (i.e. NOAEL, NOAEC, BMDL for the relevant routes of exposures and environmental compartments).

However, health-based guidance values (ADI, TDI, DNEL, OEL, MOE approach) may differ by purpose or use, according to the protection goal (e.g. assessment factors may differ for the occupational situation where justified by science based considerations on the needed level of protection; key is to have alignment on the POD).

Derived safe levels could be stored in a central repository making them available for (re)use among different assessment actors. This would increase transparency and justify each purpose and each choice of assessment factors.

⁴ Example of quality scoring based on Klimisch I-II, method of assessing the reliability of toxicological studies mainly for regulatory purposes

Decision on the hazard classification and the supporting documentation should be transparently available, also when the decision is that the substance does not require classification for a certain hazard if the data do not meet the classification criteria.

4. Only one risk assessment for specific use across legislation valuing existing expertise

Risk assessment is use-specific and depends on applicable sector-specific legislation as it accounts for specific emission/exposure patterns during or after use. As a result, specific Operational Conditions /Risk Management Measures cannot be the same across sectors such as toys, food contact materials, biocides and industrial /professional uses. Thus, whereas conclusions from existing hazard and risk assessments should be considered, risk assessment and subsequent risk management should be managed by the most relevant Agency/Committee with appropriate expertise according to applicable sector legislation.

In this regard, it can be noted that REACH assessments cover the manufacture of substances, industrial use of substances, use of a substance in the manufacturing of an article, use in certain type of (consumer) formulations, the environment, whereas sector specific legislation covers, for example, cosmetics, toys, medical devices, food contact and specific topics such as water (re: Water Framework Directive), and further legislation covers waste.

While individual substance risk assessment is very specific, there can be common elements where alignment in approaches may be warranted, for example local effects versus systemic effects.

5. Exposure assessment tools and methodology could also be centralised on a common platform, for example by organising a tripartite workshop involving organisations that have actively contributed to such tools such as the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC.)⁵

The decision on under which framework a concern will be assessed should be transparent across all sectors.

6. Efficient risk management needs to be specific and tailored

Following the risk assessment, the next step is to decide on the appropriate risk management measures to control the risk(s) which have been identified and relevant agencies and scientific committees to be involved. If the assessment leads to an identified risk, several options to control the risk should be explored depending on the intended use, volume and exposure as well as the respective legislative framework(s). The legislative framework to be used should be agreed in the overarching decision makers' group (see step 1). Input from stakeholders should be possible during that process.

7. Increased transparency on the decisions and processes

The decision on which substance and concern is/will be addressed in which legislation, including which risk management measures are envisaged, should be transparently available for all stakeholders (e.g. extended Public Activities Coordination Tool-PACT including other processes under different legislative frameworks outside the scope of ECHA). To increase predictability and trust in the decision-making process, the basis for the decision take should also be transparently documented, including those leading to no actions, for example a decision not to classify a substance if the classification criteria are not met.

⁵ At an ECETOC Workshop "Advances in (Environmental) Exposure Modelling: Bridging the Gap between Research and Application.", participants agreed on the need for a platform for tiered exposure assessment and decision tree for model selection. Factsheet were also proposed to describe and facilitate selection of models. See ECETOC Report No. 35



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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production.