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DISCUSSION PAPER

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Chemicals Strategy for Sustainability

One Substance, One (hazard) Assessment

Issue

- Currently, scientific advice and risk assessment are provided to the Commission by different agencies and scientific committees. Their areas of intervention and their competencies are determined in the relevant pieces of legislation.
- In most cases, the delineation of areas of competencies is clear e.g. for cosmetics ECHA is doing the environmental risk assessment while the Scientific Committee on Consumer Safety (SCCS) is in charge of assessing risks for human health, building on the data generated under REACH and CLP (though not only). In some other cases, there is a potential overlap (e.g. toys, detergents or other consumer goods, nanomaterials, food contact materials, worker's protection).
- There are good 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 and on the type of expertise needed. Without coordination of different processes and assessment bodies, there is a risk of inefficient use of resources, duplication of assessments and even issuance of diverging opinions,[1] which is confusing to the general public and other stakeholders, including industry and its customers.
- We need to avoid a situation where divergent regulatory opinions on the hazards and intrinsic properties of chemicals create uncertainty as well as inconsistencies, and undermine investments in safe and sustainable chemicals.
- Coordinating different processes and assessment bodies requires, as a pre-requisite, that the regulatory pathway of a given (group of) substance is clear and known. The Regulatory Management Options Analysis tool serves this purpose. Thus, RMOA and OSOA together have the potential to significantly increase regulatory predictability for the European chemical industry, which is deeply needed (see our discussion paper on Level-Playing Field).

Approach proposed

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

- increased **efficiency** and **predictability**: today the chemicals management activities are seldom aligned when it comes to data management and risk assessment, sometimes leading to duplication of efforts
- Enhanced **consistency** of assessments and their outcomes, carried out on the same datasets
- Improved **robustness** of the assessments
- Involvement of the right **expertise** at the right place at the right time
- Provision of **tailored assessments for specific legislations/uses** if relevant.

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

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

Moving towards this objective likely requires action at multiple levels:

1. **Upfront close coordination of assessments across different DG's, Scientific committees and Agencies**, to decide what is required, and who does what and when, including:

- Identification of priorities,
- A clear scoping of the assessment and identification of the concern(s) one is seeking to address (e.g. risks to worker, 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 sequence (Regulatory Management Options Analysis)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 and
- Assignment of responsibilities: which Agency/Committee is doing what – taking into account legal mandates and expertise.

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

2. **Ensure data exchange across Committees and Agencies**. Submitted data (hazard and use) are tailored to a specific legal regime and are driven by the intended use (and potential risks) of a given substance. By using standardised IT formats and databases, data can then be easily accessed and exchanged. 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 assessment, the common dataset will still have to be supplemented with specific information. In addition, exchange of common data should secures use of the latest available 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 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. Nevertheless, to facilitate this, some methodology alignment is needed on transparency, application of weight of evidence, transparency, use of assessment factors (uncertainties assessment), interpretation of adverse effects, etc. As a general principle, we need 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.

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.
The next step, hazard characterisation**,** could 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, according to the protection goal (e.g. EFSA may conclude on a different ADI than ECHA for the public oral DNEL; 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. **Risk assessment is sector-specific** (related to use) as it accounts for specific emission/exposure patterns during or after use and specific Operational Conditions /Risk Management Measures that cannot be the same across sectors such Toys, Food contact materials, Biocides and Industrial / Professional uses. Thus, whereas conclusions from existing hazard and risk assessments should be taken into account, risk assessment and subsequent risk management should be managed by the most relevant Agency/Committee according to applicable sector legislation. In this regard it can be noted that REACH assessments cover the manufacture of substances, industrial use of substances, manufacture of articles and their uses, some consumer formulations, some consumer articles, 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.
Exposure assessment tools could also be centralised on a common platform, for example by involving a tripartite vehicle such as ECETOC[2].

5. **Efficient risk management needs to be specific and tailored**. The closing step of a risk assessment is to decide on the appropriate risk management. If the assessment leads to an identified risk, several options to control the risk should be explored. These options have to be selected on the basis of the particular legislation, expertise and use scenario, considering an RMOA should be run at the beginning of the process. Therefore, this last step goes beyond OSOA and cannot be harmonised.

Examples

- ECHA carried out a 3 year in-depth assessment of DINP reproductive hazards and concludes no hazard classification required i.e. DINP is quite unlike DEHP and other low molecular weight phthalates and effectively should not be grouped with them. EFSA did a 7-month assessment of

[2] 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

reproductive effects and concluded that DINP should be grouped with DINP, initially with no reference to the ECHA assessment.

- EU Risk Assessments and ECHA conduct extensive hazard and risk assessments including consumer products (which include electrical and electronic devices) and conclude no hazard classification and no further risks demonstrated beyond toys which can be placed in the mouth (precautionary restrictions based on liver effects). RoHS consultants in a study sponsored by DG Environment are in the process of concluding that DINP and DIDP belong in the group of highly hazardous substances which are a high priority risk assessment under RoHS –with no reference to the extensive EU assessments which have been carried out.
- Another example of divergence has been experienced 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.