Cefic's views on the interplay between REACH & OSH legislation

Introduction

One of the priorities[1] of the Von der Leyen Commission is to protect citizens' health from hazardous chemicals. These priorities are developed in the Green Deal[2], the Chemical Strategy for Sustainability[3] and expected in the forthcoming Europe's Beating Cancer Plan[4].

Over the years, the importance of clarifying the REACH and OSH legislation interface with regards to the way to assess the level of exposure at the workplace has been underlined in different fora, such as the ex-post evaluation of OSH legislation, the 2nd REACH Review[5] from March 2018, the Council Conclusions[6] from December 2019. The coexistence of these two legal frameworks has generated uncertainties on compliance for manufacturers and downstream users of chemicals, and the discussions on how best to deal with their interplay is still on-going.

Cefic sees OSH and REACH legislations as complementary to each other in the context of workers protection that must be risk-based and supported by a strong engagement of Social Partners in enhanced Social Dialogs. Cefic also recognises the need for clarification on the interface between these two legislative frameworks to avoid overlapping conclusions to help micro and SMEs assessing their risks and taking the appropriate level of protection for their Workers.

According to the TFEU art 152, **OSH legislation requires the involvement of the social partners,** and thus of workers' representatives, which contributes to its acceptability and finally its effectiveness. The proper implementation of OSH-legislation is the responsibility of **each employer at company level.** At the same time, we do recognise different levels of implementation and control in the Member States. However, enforcement campaigns should ensure proper implementation and authorities should not address the shortcomings in the enforcement of one legislation by imposing another piece of legislation.

The present document reflects Cefic's views on the interplay between REACH and OSH legislation in the context of exposure and risk assessment on key issues as follows:

1. Cohabitation of two risk assessment (RA) processes (how REACH can improve the OSH RA process)/Obligations for downstream users imposed via OSH-legislation and REACH (including ES);
2. Safe use values: DN(M)ELs versus OELs;
3. Social dialog, Controlling risks via OSH-legislation as a relevant option in the framework of RMOA;

[1] https://ec.europa.eu/info/sites/info/files/political-guidelines-next-commission_en_0.pdf
[2] https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF
[3] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN
[6] https://data.consilium.europa.eu/doc/document/ST-14630-2019-INIT/en/pdf

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

4. OSH-legislation acceptance in the context of authorisation exemption based on REACH Article 58(2).

Hence, this document constitutes the basis for further discussions which, we hope, will follow soon to provide concrete proposals to best address these issues.

1. Cohabitation of two risk assessment (RA) processes (how REACH can improve the OSH RA process)/Obligations for downstream users imposed via OSH-legislation and REACH (including ES)

REACH and OSH-legislation aim, among others, to ensure that Workers exposure to chemicals risks are under control. However, **risks assessments in REACH and OSH are of two different natures**. Exposure scenarios (ES) generated by registrants in the context of REACH, even with the support of sector specific information, are by nature "generic"[7], whereas the OSH RA are intended to include workplace and task specific information in a comprehensive way. ES can provide useful information for OSH RA, however not always easily understandable for the OSH practitioners.

The identified uses of a REACH registered substance, for which exposure scenarios have been developed, are displayed in section 1 of the SDS and in the ESs attached to the SDS. When the identified Use is covered in Section 1 of the SDS and in table of contents in the Annex of the ES, a more pragmatic approach on the implementation of the content of ES at user level should be allowed.

ES should be considered **as an information source and/or screening tool in the context of the workplace specific RA** considering a phase-in approach **starting with a generic RA**, as required by REACH legislation, **followed by in-depth and task specific (OSH) RA**. While the objective of the implementation of the ES is to contribute to the safe use of a chemical, under OSH legislation it needs to be demonstrated that the risk is adequately controlled for the respective activities. **In the latter case, it should be accepted as compliant with the ES without the need to prepare a downstream user CSR and notify ECHA in case of deviation from the exact content (OC/RMM) of the ES**.

The acceptance of the coverage of the identified use and of the ES as an information source/screening tool is expected to result in a **better incorporation of the REACH information into the OSH RA**. This will contribute to a more effective implementation by companies of their workplace OSH RA, and thus to the improvement of the safety and health of workers. This would also allow more clarity on the obligations arising from both legislations and the actions that need to be taken at the workplace level. Furthermore, it will require a change in ECHA's guidance.

2. Safe use values: DN(M)ELs versus OELs

In accordance with REACH Article 31(1), a Safety Data Sheet (SDS) needs to be provided to the recipient of a substance. When compiling a SDS, the Occupational Exposure Limits (OELs) and/or Derived No (Minimal) Effect Levels (DN(M)ELs)[8] shall be provided, where available. The coexistence of these values can create confusion for receivers of SDS.

[7] A use by definition covers a diversity of workplaces along the value chain.

[8] In the context of this document DMELs are not addressed.

Safe use under Chemical Agents Directive (CAD)/Carcinogens and Mutagens Directive (CMD) can be confirmed when exposures to the substance(s) is below the OEL and, in the case of a Carcinogen or Mutagen, technical measures are used to reduce exposure as low as technically feasible. The **hierarchy of control should be applied** and used in combination e.g. engineering controls, administrative controls and PPE in combination. Confirmation can be quantitatively assessed using appropriate validated sampling and analytical methods or qualitatively using professional judgement by a competent person.

Safe use in the context of REACH can be confirmed when the modelled exposure is below the DNEL. The operational conditions (OC) and risk management measures (RMMs) communicated as regards to the substance and the process categories (PROC) are implemented as defined in the exposure scenario supplied in an annex to the SDS from registrant or actor in the supply chain (where an extended SDS is required). The DNEL has been used to identify the correct operational conditions and risk management measures in a risk assessment approach.

Given the above, it becomes evident that **DNELs & OELs for the assessment of inhalation** exposure serve different purposes and are derived in different ways, by using different methodologies (assessment factors, dose-response curves, level of acceptability for non-threshold substances, …). For these reasons, the DNELs and OELs can coexist. Furthermore, it should be acknowledged that:

- Indicative (I) OELs are health-based reference values, feasibility of the measurement techniques (sampling and analytical) is also considered when deriving the values;
- The Binding (B) OELV setting process includes not only health considerations but also takes into account socio economic aspects.
- DNELs are, in principle, used to compare modelled exposure to determine the correct OCs /RMMs and to demonstrate safe use within the REACH framework;
- Workplace risk assessment is task(s) based and has to be workplace specific.

Therefore, and taking into account the respective regulatory frameworks, the following cases should be considered:

- If an OEL is available,
  - it must be considered in the workplace risk assessment process;
  - it can also be used as an inhalation DNEL (for short/ long term exposure for workers) in the chemical safety assessment.
- If compliant with an OEL, it should be considered that the risk for workers from the inhalation exposure is sufficiently controlled. Dermal route exposure is usually performed through qualitative assessment and DNEL dermal for workers is not really helpful in the OSH context.
- If no OEL is available,
  - a semi-quantitative assessment according to OSH provisions can be performed; in that case, a DNEL should be accepted as part of the OSH toolbox in the workplace risk assessment process. (DNEL can serve to determine hazard band in control banding methods.)
- A guidance should be developed to describe the implementation of the different reference values (e.g. practical recommendations on how to deal with the hierarchy of the values short/long term, systemic and the notations).

3. Social Dialog, Controlling risks via OSH-legislation as a relevant option in the framework of RMOA

The purpose of a regulatory management option analysis (RMOA) is to help authorities clarify whether (additional) regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern. When such concern relates to workers safety, **the RMOA should always consider OSH legislation and its instruments to address it.** Hence, in such cases, the REACH Competent Authorities **should not limit the assessment to REACH experts but should also involve, on an equal footing, Experts on Occupational Health and Safety area**.

Furthermore, when the concern to be addressed relates to workers safety, the assessment to be made should take into account:

- That the risk assessment (RA) set under OSH legislation is specific for workplaces, including all tasks, while the REACH RA is generic for the substance. It should be acknowledged that different approaches of performing the workplace RA and different control strategies are valid.
- The efficiency of OSH legislation should be assessed not only on the basis of EU directives, but also on **national legislations**, their guidance and operational practices; terms and methods are known by workers and employers since decades.
- OSH legislation has a wider scope as it addresses combined exposure to different chemical agents at the workplace.

4. OSH-legislation acceptance in the context of authorisation exemption based on REACH Article 58(2)

Considering the decision of the Court of Justice of the EU in Case C-651/15 P VECCO v Commission (the VECCO decision), it is recognised that OSH legislation meets the requirements of Article 58(2) REACH if the following **two cumulative conditions** are met:

> **Condition 1**: There is existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance; and
>
> **Condition 2**: On the basis of that legislation, the risk is properly controlled.

In this decision, the Court specified that the exemption mechanism of Article 58(2) REACH implies a substance-specific regulation of its uses or categories of uses.

Thus, should Directive 98/24 or Directive 2004/37[9] provide for a substance-specific regulation (e.g. by establishing a binding occupational exposure limit value), it is expected that this would constitute a specific legal provision that sets minimum requirements for protection during use. Measures implemented to comply with the limit value grant proper control of the risk. Fulfilment of the two conditions mentioned above allows an exemption from the authorisation requirement.

At the time of the judgment, Directive 2004/37 did not contain a substance-specific regulation on an occupational exposure limit value for chromium trioxide. This aspect is addressed in paragraph 40 of the first instance judgement (Case T-360/13): "*The Commission […] was […] fully entitled to take the view that, in the absence of limit values, the directive at issue did not constitute 'existing specific Community*

[9] Directive 98/24 on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' within the meaning of Article 58(2) of Regulation No 1907/2006".In the Staff Working Document for the second REACH Review[10], the Commission interpreted the VECCO decision as confirming that the OSH legislation does not constitute a 'specific Union legislation' within the meaning of Article 58(2) REACH.

Had there been different conditions, e.g. limit value for chromium trioxide, the Court might have reached a different conclusion. Hence, cases may exist where OSH legislation contains provisions fulfilling the conditions set in Article 58(2) REACH. Clarification would be welcomed.

[10] SWD(2018) 58 final, Part 1/7, 5.3.2018.