POSITION PAPER

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How to get the interface between the REACH & OSH in motion?

In the EU context, one of the priorities of the Von der Leyen Commission is to protect citizens' health from hazardous chemicals as mentioned in the Green Deal. This priority is developed within the actions coming from the most recent initiatives such as Chemical Strategy for Sustainability (eg REACH Revision), and the EU strategic framework on health and safety at work for 2021-2027.

Cefic sees Occupational Safety and Health (OSH) and REACH as complementary legislations in the context of worker protection. The OSH legislation is designed to ensure the protection of industrial and professional workers including measures to control exposure to hazardous chemicals at the workplace. OSH regulation should be the preferred choice to achieve an adequate protection level for both professional and industrial workers. Therefore, in case a potential risk to workers has been identified, OSH hierarchy of control needs to be fully considered and explored to assess the most appropriate regulatory risk management option. In turn, if a substance is deemed a general risk to people and the environment, REACH allows for a holistic review of all use cases based on the available exposure scenarios. Should this analysis demonstrate the need for additional protective measures for professional and industrial uses, REACH allows for complementary options to an OELV, e.g. mandatory training programs. 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.

This paper proposes possible ways forward on some of the issues identified in the *Cefic's views on the interplay between REACH & OSH legislation:*

- Controlling risks via OSH-legislation as a relevant option in the framework of RMOA;
- Cohabitation of two risk assessment (RA) processes.

Controlling risks via OSH-legislation as a relevant option in the framework of RMOA: process for a systematic decision on regulatory measures

Regulatory Management Option Analysis (RMOA) is a voluntary tool that has proven to be of added value in identifying the most appropriate regulatory action to address a concern. A more harmonised approach and giving it a more formal place in legislation could further increase its value.

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Cefic proposes a process with a harmonised set of criteria for identifying the most appropriate regulatory action when the use of a substance poses a health and safety risk for workers in industrial setting and professional uses[1]:

1. Systematic collection of information available to start the process from EU and national levels: on substance properties (hazardousness), on socio-economic aspects, availability of alternatives (substitution) and regulatory measures already in place. EUCLEF might be considered as a source of information to understand how a substance is regulated in the EU and what legal obligations are in place.
2. Type of use for substance: Industrial and professional setting at the workplace, including any uses not covered by REACH authorisation[2] or restriction processes (uses (potentially) covered by authorisation, restriction and OSH respectively)
3. Identify the route of exposure: inhalation; dermal, ingestion (indirectly) for certain substances (e.g. lead, mercury)
4. How is the identified risk managed and documented currently? Is this properly addressed? If not, how to further address it?
   - Hierarchy of control for OSH (eg: minimisation principle, organizational measures: training, STOP[3]): is not a pick list, hence appropriate risk management measures should be used in combination to provide good exposure control.
   - Are there already Occupational Exposure Limits (OELs) established (EU-binding/indicative OELs, national..)?
5. How does the use of the substance impact the health of workers at the workplace?[4]
6. Based on the information collected, the following criteria should apply,

➢ a) the OSH route should be selected:

- when OSH prevention measures according to the hierarchy of control and the (REACH) risk management measures (RMMs) mentioned in the safety data sheet (SDS) are in place to protect workers for all routes of exposure.
  or
- When the main exposure route is by inhalation and it is feasible to derive a Binding Occupational Exposure Limit (BOEL).
  In case an EU-wide BOEL is not yet set, the substance should be prioritised for EU-wide OEL setting. If an OEL is available, the potential need for reviewing the existing occupational exposure limits should be assessed.

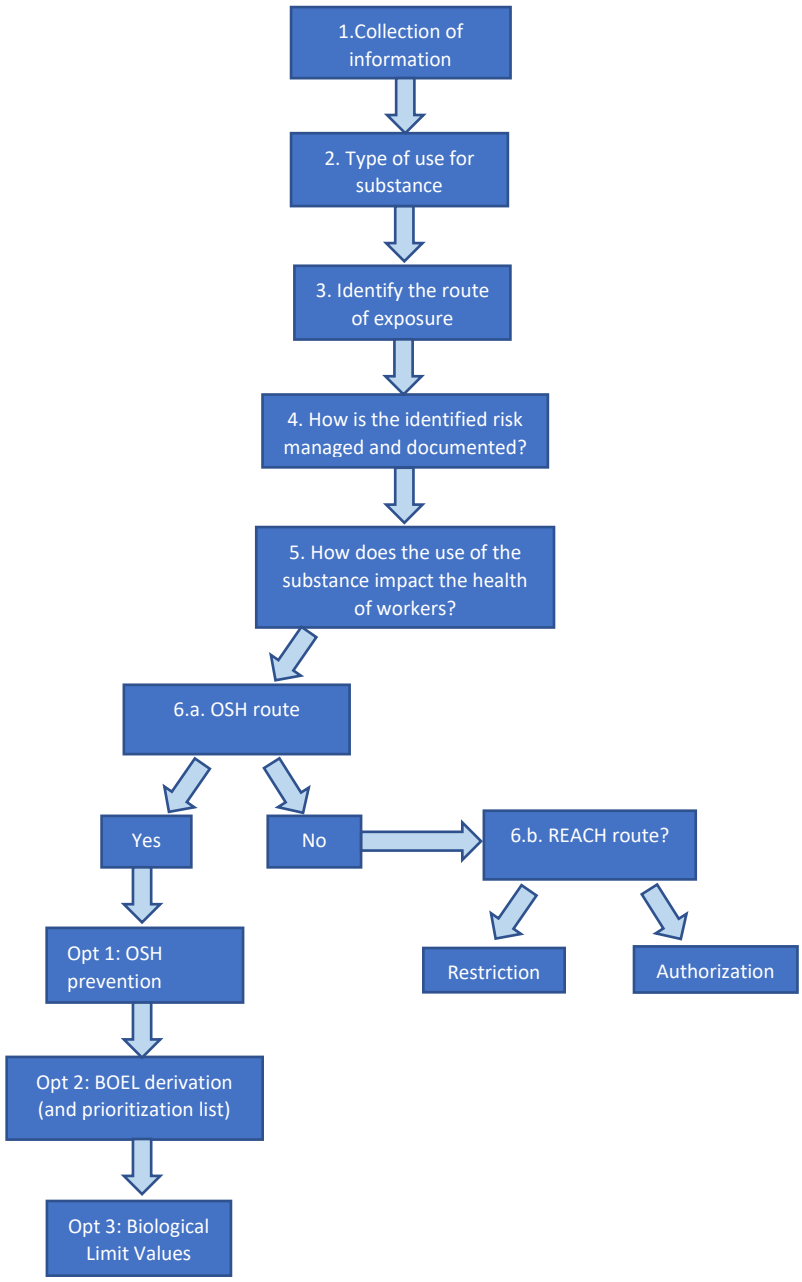
  or
- In case of multiple routes of exposure and when an OEL is considered as not sufficiently protective, the option to develop Biological Limit Values (BLV) should be investigated.

➢ b) REACH Authorisation and Restriction processes could be considered:

[1] The flowchart only addresses the interface between OSH & REACH in the context of occupational health and safety risk management. It does not address the environmental risk management that could be considered through other regulatory regimes.
[2] E.g. intermediate uses
[3] STOP = Substitution, Technical measures, Organizational and Personal protective equipment
[4] Eg number of workers potentially exposed, Severity/ frequency of the effects

- when the outcome of the risk assessment process indicates the need for mandatory additional RMMs beyond OELs and BLVs, e.g. training programs. However, the added value of keeping both REACH & OSH processes in parallel should be demonstrated.

Figure 1: Process and harmonised criteria for a systematic decision on regulatory measures



Cohabitation of two risk assessment processes: how can REACH improve the OSH risk assessment process and *vice versa*?

Both REACH and OSH legislation[5] aim to ensure that risks from worker exposure to chemicals are adequately controlled. However, risk assessments in REACH and OSH are of different natures.

In the context of REACH, the primary objective of the implementation of Exposure Scenario (ES) is to contribute to the safe use of a chemical, whereas the OSH legislation's key aim is to demonstrate that all risks including the chemical risk are adequately controlled for task specific workplace activities. SDS and ES are a key tool for OSH practitioners.

Exposure scenarios (ES) generated by registrants in the context of REACH, even with the support of sector specific information, are by nature "generic"[6], whereas the OSH RA is intended to include workplace and task specific information in a comprehensive way. ES can provide useful information for OSH RA, however it is important that they meet the needs of the OSH practitioners. The position paper on *Cefic's views on the interplay between REACH & OSH legislation* provides a general overview on the two risks assessments (*please see section 1*).

Key points:

- REACH and OSH risk assessments can co-exist in the workplace and can complement each other. Information in the main body of the SDS can be used by the OSH practitioner to generate workplace RA, more general information on OCs and RMMs either in the main body of the SDS or in the annex (ES) along with consistent use of standard phrases can help to facilitate this.
- Hierarchy of control should be considered when defining OCs and RMMs for Exposure scenarios under REACH to align with OSH regulatory requirements.
- Removal of duplication of effort in the workplace can be obtained by using OSH RA to confirm obligations under REACH article 37(4) and for RMMs and OCs in ESs to demonstrate compliance with OSH legislation.
- Communication up and down the supply chain and between REACH and OSH practitioners/experts is essential for efficient and effective provision of safe use information to workers.

With this in mind, Cefic would propose the following points for improvement of the interface:

- **Extended Safety Data Sheets (eSDS):** companies' experts on REACH & OSH will continue to work together to improve the eSDS. The first three points below show elements that will be further explored:
    - To perform an OSH RA, **key information[7] of eSDS should be easily identifiable** as SDS and ES are a key tool for OSH practitioners. Considering the complexity of all this information, **digital communication** of SDS and ES information down the supply chain would allow the development of tools and applications to convey more targeted information for the user

[5] EU OSH legislation ensures the minimum requirements to protect the workers' health, while REACH aims to safeguard people and the environment from unintended effects of chemicals. However, as the focus of the paper is on workers protection, the environment is not addressed in the paper.

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

[7] Key information expected: phys-chem properties (vapour pressure, dustiness, granulometry…), classification and hazard profile, DNEL/OEL, CPE, PPE, guidance on safe use, Operational Conditions (temperature, pressure…)

under OSH. For instance, the sections in the main part of safety data sheets contain essential information for the preparation of risk assessments at the workplace, especially information on hazards (section 2), first aid (section 4), firefighting measures (section 5), accidental release (section 6) and specifications for risk management measures (RMM) (section 7 and 8). Risk based advice for specific worker activities from the Exposure Scenarios, such as maximum duration and ventilation requirements will support more detailed safe use advice.

- **Consistent use of the harmonised language (*via* standard phrases[8]) in eSDS**. This would facilitate better use in the OSH RA and is essential for digital communication. Improving consistency among sections of the eSDS would allow an easy identification of essential pieces of information for carrying out the OSH risk assessment and translation. Moreover, for OSH practitioners, it would be helpful to include general measures that apply for all exposure scenarios in the main body (SDS) and refer to exposure scenarios for further complementing measures that might be applicable.
- **Taking better into account the hierarchy of exposure control** when defining RMM in the context of REACH and consequently in the calculation models for defining safe use conditions[9]. This would ensure better alignment between REACH measures and the OSH hierarchy of controls. For example, the ongoing project "*ESIG GES/SWED alignment*[10]" aims to develop *Specific Worker Exposure Determinant (*SWED*)* codes considering the hierarchy of control as much as possible.
- The development of **close-to-practice exposure scenarios** along the supply chain. This would require a strengthening of the exchange between the registrant and downstream users, where appropriate. If knowledge about relevant tasks or workplaces is not available within the company, an exchange with key customers or sector organizations can be useful or necessary to map exposure scenarios in the supply chain that closely reflect real practice. "Use maps"[11] (use descriptions generated by a sector group) are an example of such an exchange, which contributes to more practical input data for the preparation of exposure scenarios.

- **OSH-REACH Risk Assessment (RA) processes**
  - The development of practical EU guidance can support consistency of the implementation of regulatory OSH requirements across all EU countries and will hence improve the interplay between the two RA. Furthermore, roles and responsibilities of OSH and REACH actors should be clarified based on their specific expertise and effective instruments.

[8] ESCom Phrase Catalogue V5.2

[9] REACH recognized exposure assessment models (eg ECETOC TRA, ART) allow to add collective equipment (exhaust ventilation system…) and personal protection equipment without giving the preference to collective protection according the hierarchy principle.

[10] The ESIG GES WG now targets mainly on SWED codes for professional workers, considering only activity based PROCs. When using SWED codes, only the concentration of the substance can be modified in the risk assessment, and therefore ESIG cooperates with DU sectors to understand concentration bands (of solvents) in typical formulations.

[11] Use maps

- Particular attention should be given to if and when improvements or additions of exposure scenarios are required.
  The following situations may be encountered in the OSH/REACH interface in workplaces:
  - *Where ESs are applicable* and exposure mitigation measures from the OSH RA in the plant or on the shop floor are identical or similar to the one recommended in the ES:

    In this case, the OSH RA may be limited to verifying the effective implementation of the RMM mentioned in the ES after having checked that the "real" uses are covered by the extended SDS.

    - Example: handling of a substance/mixture classified as skin irritant. The OSH practitioner in charge of the OSH RA should check: if the real use fits with the one included in the SDS, the classification and verify the adequacy of the SDS/ESs RMM. This includes the suitability of personal protective equipment (PPE). There is usually no need to refine the OSH RA, but it is within the responsibility of the OSH practitioner to assess the situation.
  - *Where RMMs in the ES deviate significantly* from the control measures in the plant or on the shop floor:

    In that situation, information included in the SDS/ES should be considered as the starting point for performing OSH RA (hazard assessment and generic RMM/operational conditions (OC)), The OSH RA will apply the RMMs to the specific needs of the task and workplace.

    - Example: performance of the OSH RA should start from the information included in the SDS/ESs (classification, limit values, RMM/OC…). A systematic OSH exposure and risk assessment have to be performed by OSH experts; the conclusion of the OSH RA and the corresponding RMM/OC have to be compared to the ones included in SDS/ESs. This may lead to a refinement of the ES.
  - A workplace risk assessment conducted by an OSH practitioner/expert to ensure safe working conditions at the workplace should be recognised as a sufficient compliance check for downstream user obligations under REACH Article 37(4). If the conditions of use for a substance, or mixture, are not described in the applicable exposure scenario (annex to the extended-SDS) the downstream user should describe control of risks (adequate control) based on control measures implemented at the workplace. Therefore, the OSH risk assessment and its documentation including, *for example* working instructions, standard operating procedures, exposure assessment reports (air monitoring, biomonitoring, …), qualitative assessments based on professional judgement etc. should be recognized as compliant with the user obligations under REACH (Art. 37(4)).
  - The need to further cascade up the supply chain, to the registrant/importer, refinements of the OCs and RMMs for actual workplaces is only necessary in a few cases and appropriate documentation would need to be completed.
- **Communication, information network and common understanding**

- Communication between REACH and OSH experts should be intensified to improve the operational practice. For instance, a better knowledge of relevant tasks might be achieved through e.g. training modules, in-house workshops.
- Intensified collaboration would for example allow that for new ES or updates of existing ones, information coming from the OSH RA (use and task description, exposure assessment, RMM in use…) can be used for the ES building-up.
    - Example: a new use of a classified substance included in a mixture has to be covered by a chemical safety report (CSR), REACH risk assessors should integrate the relevant practical information (use and task description, exposure assessment, RMM in use…) to start establishing a new ESs or refine an existing one.

Appendix

REACH chemical safety assessment for human health:

REACH Regulation requires the registrant to carry out a chemical safety assessment with an exposure assessment as part of the registration process, for substances registered in quantities above 10 tonnes per year and when they meet the criteria to be classified hazardous or being a persistent, bioaccumulative and toxic (PBT)/ very persistent and very bioaccumulative (vPvB).

As part of this assessment, registrants develop exposure scenarios for the uses of the substance that are identified (SDS section 1.2). When they supply the substance, they provide relevant exposure scenarios (in general as an attachment) to downstream users to achieve safe use of the substance.

Exposure scenarios are generic by nature to cover potentially a large number of workplaces along the supply chain, and across different sectors. As such, the ES is unlikely to meet the requirements of a local risk assessment and cannot be tailored to the specificities or exposure determinants at an individual workplace. On the other hand, the OSH legislation requires that the risk assessment must be workplace and task specific.

In REACH regulations, the risk is calculated as a risk characterisation ratio (RCR) which compares the assessed exposure (either obtained from models or actual measurements) to the derived no-effect level (DNEL). If the RCR is < 1 then the risk is adequately controlled.
Modelled exposure is derived using models such as ECETOC TRA and ART. The ECETOC TRA model specifically uses process categories (PROCs) to define generic activities or tasks, whilst ART uses set descriptions for activities giving rise to exposures. Safe use is demonstrated by varying the input data in the respective model. Only the parameters specific to the model can be varied.

OSH risk assessment process

The requirement for a risk assessment, as defined by the Chemical Agents Directive (CAD) & Carcinogens and Mutagens Directive (CMD) directives, is to prevent or minimise exposure to hazardous chemicals in the workplace based on a risk assessment for the tasks being undertaken. Each Member State has to transpose the provisions of the CAD/CMD in their national legislation.

The OSH practitioner determines for each task the exposure to the substance, either individually or in combination (if appropriate), by using qualitative or semi-quantitative criteria (control banding) and quantitative data generated from measurements. The risk assessment, for the task at hand, must consider the hazards from all substances used and those hazards generated by the task (process generated

hazardous chemicals). The assessment might include also professional judgement. Exposure models are rarely used. Hazard banding, on the other hand, is regularly used when no limit values are available.

When OELs are available, once the assessor completes the exposure assessment, the result is compared with the Occupational Exposure Limit (OEL) value. If the measured value is:

- below the OEL, the risk is controlled.
- above the OEL, suitable and tailored exposure controls must be applied to ensure compliance with OELs.

Hazard identification

Both risk assessment processes use hazard information based on the classification, labelling and packaging regulations (CLP) and limit values (OEL and/or DNEL). **It is recommended that the expert conducting the OSH RA uses the information found in the main body of the supplied SDS as the basis for the workplace risk assessment**. A simple check of the classification can be performed by OSH people in case of doubts or inconstancies between different suppliers.

Reference values used in the risk assessment processes

In REACH, DNELs (Derived No Effect Level) are generated for each substance and are derived from toxicological data as part of the chemical safety report. DNELs are developed by the registrants for long-term inhalation exposure, short-term inhalation exposure and for dermal exposure. They are calculated for human health (workers and consumers).

There are a limited number of EU-OELs available to be used as reference values: EU wide BOELS (Binding OELs) and other OELs set by national states or based on IOELVs (Indicative OELs); it means risk assessment is mainly based on tools specialised in OSH RA (control banding, for example) and professional judgement. When OELs are available, they are usually developed for long and short-term inhalation exposure. Occupational exposure limits (OELs) are values developed based on sound scientific evidence and impact assessments

In addition, biological guidance values (BGV) and biological limit values (BLV) are developed for biological indicators. The number of BGV/BLV is very limited, although biological limit values are in particular helpful for assessing all relevant routes of exposure including dermal exposure. They are typically managed by occupational physicians.

When recent scientifically sound health based OELs (EU or national) are available, they can be used as equivalent to the DNEL $_{\text{inh workers}}$ in the context of REACH for the calculation of an RCR. When no OELs are available, DNEL $_{\text{inh workers}}$ can be used as for example in Germany as a value to show adequate exposure control or input data for the hazard assessment especially in control banding tools.

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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 1.2 million jobs and account for 17% of world chemicals production.