CII comments on the "Paper to Inform Joint CARACAL and ACSH/WPC Discussions on the Interface between REACH and OSH"

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Introduction

The CII was set up in 2015 and has since that time been promoting closer collaboration between REACH and OSH experts in industry and authorities. It holds REACH and OSH to be complementary. The CII aims at ensuring that the interface of REACH and OSH is managed in a way that respects the strengths of both legislations and that synergies between the two are unlocked and duplications are avoided.

Therefore, the CII welcomes the organisation of the 1st Joint Meeting of CARACAL and the ACSH / WPC (hereinafter "Joint Meeting"), as well as the background paper, which proved to be a useful basis for constructive exchanges at the meeting. We encourage continuing the discussions in further joint meetings of CARACAL and ACSH / WPC. The CII is organising an informal REACH-OSH Forum, with several sessions per year. It offers this Forum as a potential place where to exchange more informally in between the sessions of the Joint Meeting.

The CII appreciates the opportunity to comment on the background paper. It will firstly address the questions asked in the background paper and then add some further reflections on the topic.

CII Responses to Questions Raised in the Background Paper

Question a)

Do you agree on the analysis of the interface between REACH and OSH legislation presented in section 2?

We believe that section 2 of the background paper in general terms provides a good analysis of the interface between REACH and OSH. We have noted the following:

In the last paragraph of section 2.1 (Legal basis and objectives), we believe there is a mistake, which may be important to correct. The paper states that legal measures under OSH are taken by the co-legislators (as opposed to REACH measures being taken through 'comitology'). It is our understanding that under Article 3 of the Chemical Agents Directive, indicative OELVs are adopted by means of comitology too. Comitology is not a means that is reserved to Regulations like REACH but can also be chosen for technical measures to be adopted under Directives. This consideration is important when in Section 2.4 the paper suggests that REACH Risk Management increasingly takes over from Risk Management under OSH because measures are perceived to be easier to adopt under REACH. We appreciate that the paper notes that this "current practice results in incoherent solutions, overlaps and inefficiency". OSH has delivered many OELVs in the last years and it should not be forgotten that the risk management under REACH has also often

taken a long time. If authorities perceive that the lack of use of comitology for the setting of Binding OELVs is a hurdle, it could be assessed whether to introduce a comitology-procedure also for BOELVs, just like for indicative OELVs, could improve the situation.

In Section 2.4 it is noted that RMOAs are currently considered a voluntary tool. We recall that according to the proportionality principal authorities are bound to consider how to best achieve the regulatory objective, i.e. to identify the most proportionate and adequate Risk Management Option. Therefore, either RMOAs could be turned into a formal (and consistently used) tool or another mechanism for making this adequacy/proportionality assessment should be introduced.

In the analysis of the interface, the role of OELVs as a tool for controlling worker exposure has received strong emphasis. However, other relevant instruments of the occupational health and safety regulations to protect workers are discussed only superficially. A more complete picture would require a more detailed description of the full set of tools, e.g., the hierarchy of control and risk management measures.

Question b)

In case the REACH Candidate List would become a prioritisation tool beyond REACH, should this also be used to prioritise actions under OSH legislation, such as setting binding occupational exposure limits (BOELs)? How should this process be organised and what bodies should be involved? What should be the relationship between the Candidate List and ACSH priority list for future OSH OELs?

With particular regard to OSH (and OELV-setting under OSH), the CII believes that the prioritisation of substances needs to be done by a body that has a holistic view of sources of risks at the workplace, i.e. the ACSH. The ACSH will consider several criteria (e.g. hazard properties, number of exposed workers, occupational disease data, medical survey data, etc.) to prioritize the substances for which an EU-wide OEL should be established. REACH does not comprehensively cover risks at the workplace (to give just one example: it does not cover process-generated substances) and can therefore not take into account all aspects that need to be considered when prioritising. We do, however, believe that REACH can feed into the prioritisation by the ACSH. In this regard, substances that are already on the Candidate List and that pose a risk at the workplace could be prioritised for the setting of an OELV. This is because when these substances were included on the Candidate List (e.g. with a view to subjecting them to authorisation), OELVs were not consistently considered by REACH authorities amongst the regulatory options that could have addressed the concerns. Should it turn out, that uses of substances currently on the Candidate List would better be managed by OSH (incl. OELVs) that should be considered in the prioritisation of substances under OSH.

The CII does, however, not consider the Candidate List to be an appropriate tool for prioritising substances for regulatory action. The Candidate List currently serves purposes that can count as Risk Management Measures (e.g. communication in the supply chain). It also pushes for the substitution of the substances on that list. Therefore, the decision what to prioritise should be taken before new substances are included on the Candidate List. This would also be in line with ECHA's Integrated Regulatory Strategy.

We suggest enhancing informal collaboration between REACH and OSH experts at an early stage (e.g. when an RMOA is being conducted). When REACH authorities identify concerns for the use of a substance at workplaces, they may want to involve OSH experts to do a joint assessment of the level of concern / risk. This will help to find a common assessment what the priority of regulating the substance at the workplace is. On the basis of such a common assessment, the chance will be enhanced that the substances prioritised for OELV-setting will meet expectations of both, OSH and REACH authorities. This, in return, increases transparency, predictability and legal certainty for authorities and companies.

Question c)

Should workers' exposure in industrial and professional uses remain part of the REACH authorisation and restriction processes, in a similar way as applied today? In that case, how can the choice of instruments be made more consistent?

The CII takes the position that REACH and OSH can be complementary for managing risks at the workplace. We believe that both, Authorisation and Restrictions, can play a relevant role in chemicals management at the workplace.

We do, however, believe that Authorisation and Restriction have not always been used appropriately for doing so. The REACH revision offers an opportunity to make some amendments, in particular to (1) the Authorisation tool, (2) to DNELs, and (3) to introduce a formal tool to make choices on proportionate risk management. This would help avoiding overlaps, confusion and the undermining of OSH.

The starting point for our proposed approach

While both REACH and OSH apply at the workplace, OSH is the legislation that is particularly dedicated to workers protection and it takes a holistic view on workplaces. Under OSH, comprehensive workplace-specific risk assessments are conducted, which cannot be replaced by REACH Exposure Scenarios. This role of OSH should be respected. Where OSH provides specific tools (e.g. OELVs), they should be considered as lex specialis and thus take precedence over other more generic tools.

REACH can be used to inform risk management under OSH. REACH risk management options may also be used, where OSH does not provide sufficient tools to address a concern. For example, although OSH contains the substitution principle as a first priority in the hierarchy of controls, the CII acknowledges that for uses where an alternative is available, authorisation can be effective in helping the market transition to using the alternative. REACH Restrictions could be used to ban uses, where no time is needed for the market to transition to the alternative. We, however, urge that before pushing for such substitution it needs to be fully assessed whether the alternative substance is indeed safer (not only from a chemicals management perspective) and does not trigger negative trade-offs for other policy objectives (e.g. circularity, climate change) that would overall lead to socio-economic losses rather than gains.

Issues with the current approach

Already the current approach on risk management under REACH should have taken into account OSH more consistently and effectively:

- OSH has not always been taken into consideration, when REACH authorities identified risks at the workplace. The CII believes that where workplace risks were identified, OSH should have been consistently considered, and been accepted as the legislation particularly designed to address risks at the workplace and thus taking precedence. REACH Risk Management should have then been used as a complementary instrument, where particularly justified.
- Restrictions like the one for NMP and DMF have mimicked OELVs but did not follow the procedure that the legislator had foreseen for setting limit values at the workplace. There is a similar issue with the use of reference-DNELs in Authorisations.
- Although case-law of the European Court of Justice implicitly allows the granting of exemptions from authorisation for uses, for which an OEL is in place, no such exemption based on Article 58(2) has been granted to this date.
- The CII has been calling for establishing criteria on when to use OSH (supported by OELVs) to manage risks at the workplace and when other risk management measures should be used to support OSH. We welcome that REACH authorities and the ACSH have made proposals for

such criteria. The CII encourages continuing this debate in a more systematic fashion and refers herewith to its proposals with regard to criteria (include link).

- Not only the lack of criteria for choosing the appropriate risk management option is an issue. Also the lack of a dedicated procedure / step in the process when these criteria should be applied is a problem. We believe that an RMOA or comparable tool would be the right way to achieve this. Choosing an appropriate Risk Management Option by means of an RMOA at an early stage can prevent delays in the implementation of risk management measures (Cobalt Salts are a good example of how it is the absence of an RMOA that leads to delays) and consequently speeds up the whole regulatory intervention. The lack of clarity about the elements, which should be checked in an RMOA has caused an inconsistent use of this tool. We therefore believe that also this issue would need to be addressed.

<u>CII proposal for a way forward, including aspects to be addressed in a REACH Revision:</u>

Many of the issues mentioned above could already be addressed without a change to the legal text of REACH. The CII suggests using the opportunity of the REACH Revision to make legislative changes, that make it even easier to find the right practical balance between risk management at the workplace through OSH and REACH. We believe that our proposal better exploits the specific strengths of both pieces of legislation and synergies between them:

- Reform of the authorisation regime:
  - The authorisation regime could be properly reformed, i.e. by giving authorities the option not to include a (group of) substance(s) with all its/their uses, but to rather identify specific uses of a (group of) substance(s) on Annex XIV. Those would be uses, for which an assessment has shown that a safer and more sustainable alternative is becoming available on the market. Authorisation could serve as flexible transition period for the market, maintaining the push to moving towards the use of this alternative. Where authorities see that other uses of the same (group of) substance(s) are socio-economically desirable, because no safer or more sustainable alternative exists, they would help prevent stigmatisation of those uses of the substance, which may be safe and/or essential.
  - If the authorisation-process were not to be revised in the way suggested above, it would be important to revise Article 58(2). The wording should become clear and concrete when an exemption should be granted. The reformed Art. 58(2) could permit exemptions for specifically identified uses, where authorities in the phase of identifying the most appropriate Risk Management Option concluded that OSH (supported by an OEL) is the most proportionate way forward. Exempting those uses from authorisation would be in line with the intended regulatory outcome. This could be achieved by giving authorities broader discretion in choosing the uses that they intend to exempt from authorisation.
  - Finally, there should be a mechanism to remove substances from Annex XIV and the Candidate List. If, despite the initial expectation, certain uses of a substance turn out to have no alternatives and both, industry and authorities, would need to go through repeated AfAs, regulatory priorities would lie elsewhere and the removal of substances from both Annex XIV and the Candidate List would enhance the relevancy of the tools.
- Reform of DNELs/DMELs (and – briefly touching on a related topic – PNECs) under REACH:
  - Article 2(4) of REACH states that the Regulation shall apply without prejudice to Community workplace and environmental legislation. In the CII's opinion, the current approach towards DNELs and PNECs is not in line with this principle. The derivation of DNELs and PNECs does not consider feasibility and socio-economic aspects. Nevertheless, sometimes REACH authorities state that – where for a substance there are both a DNEL and an OELV – enforcement should focus on the lower one. This effectively means that DNELs are undermining Binding OELVs, although the legislator specifically intended for these limit values to consider feasibility and socio-economic aspects. The same is valid for

PNECs undermining EQSs. The background paper appropriately recognises the "high degree of legitimation" of OELVs and that where there is co-existence between diverging OELVs and DNELs, there is a potential confusion for companies and enforcement authorities.

  - To resolve this issue, the CII suggests explicitly clarifying in REACH that where a European OELV (or EQS) has been set this value takes precedence over the DNEL/DMEL (or PNEC) derivation under REACH. Evidently, OELVs should be kept up to date, considering any new information that would justify adopting a stricter OELV.
  - Considering this suggestion for a revision of REACH is of particular importance in light of the idea to introduce Toxicological Reference Values (TRVs) into CLP (the background paper acknowledges that such TRVs may "aggravate potential inconsistencies"). In the background paper, the Commission acknowledged that "there may be situations where practical constraints may require clarification of the applicable limit values, as well as practical solutions/derogations, in particular for processes for which respecting DNELs/DMELs will be very difficult in practice." The reform idea suggested above would help resolve this issue in a systematic manner.

- As REACH overlaps with several other pieces of legislation in terms of risk management, the identification of the most proportionate risk management measure cannot be limited to measures that can be adopted under REACH. The CII suggests that a procedural step needs to be formally introduced, in which not only the risk is identified, but in which the proportionate choice in terms of Risk Management Options is made. This could be done by formally introducing the RMOA or a tool serving the same purpose and named differently into REACH. Within this procedural screening step, criteria that would be developed for making choices of RMOs could be applied on a case-by-case basis and more consistency in the REACH-OSH interface could be achieved.

Question d)

Should measures to increase workers' protection in REACH be strengthened? Could setting specific risk management measures (ensuringthat certain exposure levels are observed at the workplace) as conditions in authorisation decisions and derogations from restrictions play a useful role? OR: should REACH go further and open for the possibility to set occupational exposure limits for specific uses? In the latter case, how can the specific expertise of social partners and occupational safety and health experts be better integrated in REACH?

As mentioned above, the CII holds it inappropriate to set binding limit values under REACH, where the legislator has specifically assigned the derivation and adoption of limit values to OSH. We do not support the setting of limit values that would be specific for certain uses. Different limit values for different uses would lead to less clarity and confusion. We acknowledge that sometimes compliance with a given OELV (which applies to all of industry) can be harder to achieve in some sectors. The appropriate mechanism to deal with these issues is however not to set different limit values for different sectors using the same substance, but rather to take that into account, when transition periods for compliance with the OELV adopted under OSH are determined.

The CII also notes that under REACH it is often assumed that operational conditions (OCs) and risk management measures (RMMs) in Exposure Scenarios and Authorisations do (or at least should) reflect the OCs and RMMs at all sites in the EU that perform the (authorised) use. While the CII acknowledges the usefulness of REACH Exposure Scenarios as an element to consider when managing risks at the workplace, it emphasises that any REACH-OCs and RMMs are largely based on a substance-specific perspective. REACH does not take into account all aspects that need to be considered for a site-specific risk assessment under OSH. Due to site-specific circumstances (e.g. other substances used or present at the same site) the REACH-recommended OCs and RMMs

may not be best suited in each and every site in the EU with that use. The CII holds it to be unrealistic to expect REACH exposure scenarios to reflect all different site-specific risk assessments for uses that are conducted across the EU. What should matter for enforcement in the end is whether with the site-specific OCs and RMMs the exposure is reduced below the given limit value (i.e. the EU-wide OELV or in the absence of an EU-wide OEL the DNEL set by the registrants). In addition, in particular for SMEs, OSH-related information is not communicated effectively via REACH information tools, since they tend to be rather complex.

Question e)

Should workers' protection in industrial and professional uses be done primarily under OSH legislation? Should relevant uses currently addressed by REACH authorisation in future be addressed under OSH legislation (option 3 for the reform of REACH authorisation and restriction processes)? How can the capacity of OSH legislation to deal with a wider range of chemical risks be improved?

On the balance between regulatory risk management via OSH or REACH

Indeed, the CII believes that workers' protection in industrial and professional uses should be done primarily under OSH legislation. As indicated above under Question c), the CII does not call for transferring all responsibilities for risk management at the workplace to OSH. However, we do agree that for most risks identified at the workplace, OSH provides an appropriate way of managing the risks effectively. REACH Risk Management can play a supporting role where alternatives that are demonstrated to be safer and more sustainable are (becoming) available. In summary, it should first be considered whether an issue can be sufficiently addressed by OSH. Regulatory risk management under REACH can then be used in a complementary fashion, where OSH cannot address the risk appropriately.

With regard to uses of hazardous substances (as such or in mixtures) by professional users, the CII acknowledges that users of these substances and mixtures need adequate expertise, which depends on the severity of the concrete hazard and risk. Therefore, it may be proportionate to ban consumer uses of substances with certain hazards or mixtures containing these substances. This reasoning does, however, not apply to professional users of substances and mixtures. Where such a use occurs, professional workers are usually specifically trained and the professional use is rather comparable to industrial uses.

When it comes to articles containing hazardous substances it cannot be assumed that the presence of the substance leads to a risk for the professional user. Where such a risk could arise for professional workers, this would be sufficiently covered by OSH. The CII therefore objects to the idea raised in the Chemicals Strategy for Sustainability to address professional users by means of Art. 68(2)-based restrictions and subjecting these uses to hazard-based bans, with exemptions for essential (or safe) uses only. OSH should continue to manage these professional uses, except where OSH is demonstrated not to be able to address the risks and thus targeted risk management options under REACH (Authorisation or Art. 68(1)-based restrictions) could play a role.

Enhancing the capacity of OSH

The CII struggles with understanding the last part of Question e), i.e. how the capacity of OSH legislation to deal with a wider range of chemical risks can be improved. OSH already addresses more chemical risks (e.g. of process-generated substances) than REACH does.

The question may be intended to relate to the amount of substances for which an OELV can be set per year. In this regard, the CII would like to emphasise two points: (1) Regulatory risk management under REACH is not necessarily faster than under OSH, as many restriction- and authorisation-cases demonstrate. (2) In the last years, OSH has delivered a considerable amount of OELVs for substances and groups of substances. Yet, the number of substances for which an

OELV could be assessed if useful to have, is long and we understand and support considerations on how to facilitate the process of setting OELVs.

One limiting factor in this context is that RAC can only deliver 5 scientific assessments that feed into the OELV-setting process. Sometimes it is suggested that the resources of RAC suffice for only five OELVs, but it would have resources for further work on Restrictions under REACH. If that were to be the case, authorities would – out of budget considerations – be driven to rather adopt a limit value through REACH than OSH. We therefore welcome that the background paper suggests that the creation of a separate legal basis for ECHA aims inter alia to give more flexibility to ECHA in allocating resources to different legislative areas than REACH and CLP. Another aspect regarding the RAC capacity to delivering scientific opinions that can serve as the basis for setting OELVs (besides the above budget considerations) is the need to ensure that sufficient OSH experts serve on RAC to manage to deal with increased numbers of scientific opinions.

The CII notes that the main reason for transferring OELV-setting under REACH is that comitology would apply. We point out that under the CAD, indicative OELVs are adopted by means of comitology. Should authorities – after having assessed all options to streamline and improve the current process foreseen for binding OELVs under OSH – consider that the current procedure for setting OELVs is too burdensome, we would support exploring the change of the procedure for setting binding OELVs under the CMRD. If there were a need to reconsider existing BOELVs, this update should be implemented under the OSH procedure and not under a REACH restriction procedure (e.g. DMAC).

Question f)

Would a more systematic approach in ECHA assessment of priority substances help to speed up and render more systematic the preparation of harmonised measures such as BOELs under OSH legislation?

For this question we refer to our responses to Questions b) and c) above. To summarise, we would support an early step in the process that would systematically analyse whether there is a risk, where the risk occurs and how the risk can be addressed in the most proportionate way. Although not consistent, so far RMOAs have been the most promising tool to fulfil this role. Where REACH authorities identify concerns relating to the workplace, they should obtain the perspective of authorities specialised in OSH, as this will help assign a properly considered priority for further action.

Question g)

How could incentives for substitution be strengthened under OSH legislation?

As outlined above, the CII acknowledges that REACH Risk Management Options are particularly strong in pushing for substitution. On that basis, the CII supports that REACH RMOs continue to be used where it has been assessed that there is an alternative available which is safer and more sustainable.

The OSHA (Occupational Safety and Health Administration) hierarchy of controls is a system used in industry to eliminate or reduce exposure to risk in the workplace and is implemented within Europe. These are the five controls ranked from most to least effective:

1. Elimination
2. Substitution
3. Engineering Controls
4. Administrative Controls
5. Personal Protective Equipment (PPE)

Substitution already has a prominent role under OSH hierarchy of controls. Thus, if the approach suggested by the CII under Question c) above was implemented, there would not be a need to further strengthen the substitution pressure under OSH.

Further reflections:

- The above also needs to be seen in light of the objectives of the European Green Deal and the Chemicals Strategy for Sustainability
- The clarification of the roles of and synergies between REACH and OSH legislation for exposure and safe use of substances at the workplace can play an important role in contributing to the achievement of these goals, in particular in relation to the concepts of essential use, application of the general risk approach and safe and sustainable by design chemicals, that are currently discussed

The Cross-Industry Initiative (CII) for better regulation in chemicals management *was set up between December 2014 and March 2015 as a coalition aimed at streamlining the management of chemicals. It is currently comprised of over 60 organizations: sectoral associations at the EU and national level as well as companies. Our members represent manufacturers as well as downstream users of chemicals, large companies and SMEs. The remit of the CII targets exclusively cases in which the potential risks posed by chemicals are limited to the workplace environment.*