Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Contribution by IMA-Europe on the public consultation

May 2016

IMA-Europe (the European Industrial Minerals Association) represents the European producers of Calcium Carbonates, Dolomite, Andalusite, Bentonite, Borates, Diatomite, Feldspar, Kaolin, Lime, Mica, Plastic Clays, Sepiolite, Silica, Talc and Vermiculite in all non-commercial issues related to the properties and safe use of minerals, from their extraction and processing through to their end-use applications.

Our contribution will focus on questions number 17, 25, 26 and 27 of the public consultation. First, you will find herein below our response to Question 17. Then, we will respond to Questions 25 until 27 jointly.

Question 17:

17. In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

	1	2	3	4	5	I don't know
Hazard identification criteria	○	○	●	○	○	○
Risk assessment and characterisation	○	●	○	○	○	○
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	○	○	●	○	○	○
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	○	○	●	○	○	○
Risk management measures restricting or banning the use of chemicals	○	●	○	○	○	○
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	○	○	●	○	○	○

If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.

Hazard assessment correctly addresses the intrinsic properties of a chemical substance. However, in order to develop an appropriate risk management tool and ensure a proper control of the substance uses, the joint consideration of the exposure and hazard parameters is essential.

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In overall, regulators and stakeholders often lack a broad perspective about the existing vertical and horizontal interlinkages between the different chemical legislations. The current fact that substances are only classified according to their intrinsic properties, lead to a purely hazard-based approach in policy-making. This said, it is therefore very difficult to determine if chemical legislation is appropriate in achieving human health and environmental protection, since exposure and actual risk parameters are not taken into account by regulators.

IMA-Europe wants to highlight that the hazard properties of a substance should be the starting point only for deciding the launching (or not) of risk management measures and that these former ones should be based on exposure aspects in order to ensure a risk-based decision-making. For this purpose, we want to stress the importance of the Risk Management Option Analysis (RMOa) tool developed by regulators but often not used. In this context, we strongly believe that if the RMOa tool was regularly employed whenever searching for an appropriate risk management measure for specific uses of a hazardous substance, the outcome of the process would be more targeted and, therefore, more efficient regarding the guarantee of having a high-level protection system for the environment and the targeted public (consumers, workers, etc.).

Questions 25-27:

25. Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
The EU chemicals legislation framework contains gaps and missing links	○	○	○	●	○
The EU chemicals legislation framework has overlaps	○	○	○	●	○
The EU chemicals legislation framework is internally inconsistent	○	○	●	○	○

26. Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

a) Inconsistencies

IMA-Europe identified some inconsistencies within one of the OSH Directives, which is aimed at protecting workers against health and safety risks from exposure to carcinogens or mutagens at work.

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Issues arising from the Carcinogens and Mutagens Directive (CMD) 2004/37/EC:

- There is a need to distinguish between substances having a threshold limit of effect (i.e. no effect can be observed below the limit) and non-threshold substances (i.e. substances for which a residual risk can be expected at a very low concentration).
- The hierarchy principle of the CMD needs to be redefined. As an example, substitution is not appropriate for chemical agents with a threshold of effect that can be managed as any other substance, provided that exposure is controlled below the defined safe limit value.
- Article 5 on risk management is unclear for some situations and inconsistent with the Chemical Agents Directive (CAD) 98/24/EC. Indeed, whenever a binding OEL value (BOELV) exists under Annex III of the CMD and the requirement to eliminate or reduce exposure "as low as technically possible" applies, the existence and validity of the BOELV may be questioned. It is unclear how far below the OEL the exposure needs to be reduced. In addition, the concept of lowering exposure level as low as technically possible does not take into account economic and feasibility factors. Therefore, the strict requirements of the CMD are not appropriate for less potent (and threshold) carcinogens. In this context, the terminology of reducing exposure levels "as low as reasonably practicable" would be more feasible and appropriate as it would take into account economic factors.

Currently, there is no adequate legislative framework to regulate occupational exposure to threshold carcinogens. Our first choice as a solution to this problem would be to consider the **joining of the Chemical Agents Directive (CAD) and CMD into a single instrument** that would not only define appropriate measures/obligations for all chemicals at work, but also be based on the nature/hazard of the substances.

Another possibility would also be to restrict the scope of the CMD to non-threshold carcinogens and to **regulate threshold carcinogens through BOELVs in the CAD**. Indeed, the CAD, which is based on the concept of risk assessment and risk minimization coupled with its Annexed lists of limit values, would be more appropriate and provide the right and proportional level of intervention to ensure adequate worker protection and prevention to hazardous substances. More particularly, we would advocate for a pragmatic approach where not only it would be acceptable to reduce exposure to the level of the BOELV and not any lower, but also that the substitution and closed systems principles would not apply if exposures are controlled adequately (below the BOELV).

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b) Overlaps

Overlaps between CAD (98/24/EC) and CMD (2004/37/EC) with further recommendation

We consider that there are potential conflicts of implementation and a lack of sliding scale that currently exists between the CAD and the CMD (cfr. Question 26(a)):

a. Integrating the two Directives in a single instrument covering all chemicals at work could be the best option to solve incoherencies and helping for simplification provided the single instrument would define appropriate measures/obligations for the different kinds of substances covered. This unique instrument should provide a system of obligations based on the nature/hazard of the substances. In addition, it would allow to address the risk management of substances for which no effect can be observed below a certain limit (e.g.

27. Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

REACH (EC 1907/2006) and EU OSH Directives

We invite regulatory bodies to recognize workplace legislation, instead of REACH Candidate listing and Authorisation, as the most effective risk management option for substances where there is a need to address a risk limited to the workplace:

a. When authorities identify a risk, but find that it is limited to the workplace, then workplace specific legislation offers, in our view, the most targeted, effective and proportionate regulatory risk management approach. Moreover, it should be ensured that no additional and unnecessary regulatory measures are applied, i.e.:
    i. When the identified risk for all uses of a substance can be more effectively addressed by workplace legislation, the substance should not be included within the Candidate list. In the event of a substance that has already been included in the list but meets the criteria established by the workplace legislation, it should not be prioritised for Authorisation purposes under REACH.
    ii. When the identified risk for some uses of the substance can be more effectively addressed by the workplace legislation, those uses should be exempted from Authorisation under REACH pursuant to Article 58(2) of this former legislation.
b. The setting of EU-wide OELs for substances where a risk is identified at the workplace, is an essential step to achieve better regulation.
c. As mentioned already in Question 17, IMA-Europe stresses the importance of the Risk Management Option Analysis (RMOa) tool whenever searching for an appropriate risk management measure for specific uses of a hazardous substance. We firmly believe that the outcome of the RMOa process would be more targeted and, therefore, more efficient regarding the guarantee of having a high-level protection system both for the environment and human health.

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