# JOINT DECLARATION ON THE LEGAL FRAMEWORK TO MANAGE RISKS RELATED TO THE USE OF REPROTOXIC SUBSTANCES AT THE WORKPLACE

The current EU OSH legislation dealing with occupational exposure to chemicals consists of two directives, the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD):

- The CAD applies to any hazardous chemical present at work - including reprotoxic (R) substances;
- The CMD applies solely to substances meeting the criteria for classification as carcinogenic (C) or mutagenic (M) Cat. 1A or 1B according to the regulation on classification, labelling and packaging (CLP).

Both sets of legal requirements are similar, but not identical.

For some time now, a debate has been running on whether it would be justified to move to one set of legal requirements for managing CMR substances at the workplace. The Commission has committed to proposing a way forward in 2019.

## Our view on the way forward

We support an update of the current legal framework leading to a more effective and efficient approach compared to what we have today. In our view one EU directive covering carcinogens (C), mutagens (M) and reprotoxicants (R)[1] at the workplace would be a solid basis for harmonized EU wide minimum requirements.

Such a directive could strengthen the current system, bring legal coherence and better alignment of chemical legislation at the EU level, as well as facilitating a more level playing field across Member States in Europe in terms of protecting workers' health.

## Main features of a CMR directive

The CMR directive would be de facto a new directive reflecting enhanced and modernized requirements for managing CMR substances[1] at the workplace. It would build upon the current CM directive and incorporate principles of risk management related to CMRs as set by other Union legislation or national legislation.

As a general principle, exposure to CMR substances[1] shall be avoided in line with the prevention hierarchy as set by the current CM Directive. Where this is not possible, risk management measures:

- must ensure that the risk from using the substance is adequately controlled, i.e. the exposure is below a level where health risks cease to exist or
- ensure that the level of exposure of workers is reduced to as low a level as is technically possible for those CMR substances[1] where a 'no-risk level' cannot be defined.

Whether or not a safe level would exist is to be determined throughout the process of setting EU wide binding exposure limits. This implies the need to obtain exposure limits for at least the most prevalent CMR substances[1]. As a starting point existing indicative OELs for reprotoxicants could be implemented as binding ones, with a clear indication whether they are health based or not. To facilitate future updating / setting of binding OELs, a comprehensive set of criteria is needed to identify and prioritise CMRs entering the process. These criteria should take into account a mid to long term view.

These main features of a CMR directive are further elaborated in the annex, which is an integrated part of the declaration.

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[1] Meeting the criteria for classification as carcinogenic (C), mutagenic (M) or reprotoxic (R) Cat. 1A or 1B according to the regulation on classification, labelling and packaging (CLP).

## From a short to a medium term change

Incorporating reprotoxic substances in the current CM directive is on the short term the most efficient solution. As many Member States do not have an integrated legal framework, retaining a separate framework – a CMR Directive - will facilitate transposition requirements and enforcement by Member States.

Discussions on a complete overhaul of the current OSH legislation for chemicals are in our view the next step once agreement has been reached on how to move forward with managing CMR-substances.

## Signatories

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# Annex

## Key features of a CMR directive

1. The same legal requirements should apply to Carcinogens (C), Mutagens (M) and Reprotoxic (R) substances meeting the criteria for classification in category 1A & 1B under the CLP regulation[2].
2. The hierarchy of prevention and control measures applies to all CMR substances cat. 1A & 1B.

   These substances should be replaced as far as technically possible (art. 4.1). If that is not possible, the company should use closed systems (art. 5.2), and if that is not possible as well, the employer should ensure that exposure is reduced to a level as low as technically possible, except where some conditions are met (see point 7 hereunder).
3. Binding occupational exposure limit values (Binding OELs) should be set for all relevant CMRs cat. 1A & 1B.
   Especially binding OELs are a useful tool for the design of control measures and reduction of exposure when elimination/substitution and the use of closed systems are not technically possible.
4. A distinction should be made between threshold and non-threshold CMR-substances.
   Threshold substance means that, using the available scientific data, it is possible to define a clear exposure threshold below which exposure to the substance causes no adverse effects (with all endpoints considered after short-term or daily exposure over a working lifetime). Non-threshold substance means that for any level of exposure, however low, risks of adverse effects cannot be excluded[3].

   Whether or not a safe level would exist is to be determined throughout the process of setting EU wide binding exposure limits. The Scientific Committee for Occupational Exposure Limits or the Risk Assessment Committee of the European Chemicals Agency should be entrusted of advising whether a substance has a threshold, or a non-threshold mode of action. Information available through other regulatory processes or performed by national committees should be taken into account.
5. If a threshold mode of action exists a health-based limit value should be derived, if not an exposure-risk relationship respectively should be provided. In the latter case the derived OEL should be qualified as risk-based and accurate information should be provided on the associated residual risk.
6. The outcome of the scientific assessment should be subject to public consultation and sent to Advisory Committee on Safety and Health for further evaluation and adopting an opinion on a recommended OEL in line with the current legal provisions.
7. The exposure minimization principle (i.e. the obligation to further reduce the exposure below the binding OEL) should only be mandatory to non-threshold substances. When a binding health-based OEL has been set (i.e for a carcinogen or a reprotoxic substance) and when it is proven by exposure measurements that this OEL is complied with, there should be no regulatory need to reduce further the exposure.
8. The eleven substances with an EU harmonised classification R1A/1B for which indicative OEL have been set under CAD should be transferred in Annex III of CMD. Inorganic lead and its compounds - for which binding limits values have been set under CAD - should also be transferred in Annex III of CMD and be revised.
   These measures should be easy to implement since almost all EU Member States already have OELs for all these substances in their national legislation at levels equal or stricter compared to the EU value.

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[2] Regulation (EC) No 1272/2008

[3] for example lead compounds are to be considered non-threshold substances due to their neurotoxicity and not due to reprotoxicity.

## Annex

### Comparing key features of the CMR directive with the scenario's to be assessed by the Commission

According to the ongoing stakeholder consultation[4], the Commission is assessing several scenarios to regulate the use of carcinogenic, mutagenic and reprotoxic substances (CMRs) at the workplace.

We believe that our proposal is close to what is considered as scenario 3 in the Commissions assessment but is not identical to it. The scenario 3 as suggested by the Commission foresees differentiated requirements for reprotoxic substances depending on their mode of action (threshold/non-threshold). In our view, the idea of differentiated requirements depending on the mode of action should also apply to CM substances.

Scenarios 4 and 5 could delay the adoption of a necessary prompt and simple legislative action to align the workers' protection legislation with the other EU chemical legislations. Delaying further EU action could prompt some Member States to take action at national level as it was recently the case in Belgium who decided to include reprotoxic substances 1A and 1B in the scope of its national CMD legislation with the full application of the existing CMD requirements. This means that we now have six EU countries (representing 38 % of the EU workforce) with reprotoxic substances treated with more stringent provisions compared to EU rules. This situation will further complicate the operations of EU companies facing different legal occupational safety and health (OSH) requirements in different EU countries.

[4] http://rpaltd.co.uk/reprotoxic-substances-consultation