Council of the European Union

Brussels, 18 December 2021
(OR. en)

15008/21

Interinstitutional File:
2020/0262(COD)

LIMITE

SOC 736
EMPL 552
SAN 755
IA 205
CODEC 1644

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	ST 11188/20 - COM(2020) 751 final
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Delegations will find attached a non-paper by Finland on the extension of the scope of the CMD to reprotoxic substances.

NON-PAPER BY FINLAND

Extension of the scope of the CMD to reprotoxic substances – needs for derogations

Chemicals are regulated in the OSH legislation mainly by two directives: the Chemicals Agents Directive (CAD), which applies to all chemical agents and the Carcinogens and Mutagens Directive (CMD), which has been designed to take into account the specific mode of action of carcinogenic and mutagenic substances.

Reprotoxic substances may impair fertility or cause developmental effects. The serious adverse health effects of some reprotoxic substances, combined with the lack of awareness of the risks, justify extra protective measures at the EU level. The more stringent provisions for this group of substances could be set either under the CAD or under the CMD.

If reprotoxic substances were to be included under the scope of the CMD, from the scientific point of view some fundamental differences between the carcinogens and mutagens versus reprotoxic substances should be reflected in the legislation. At the minimum, a distinction should be made between the reprotoxic substances on the basis on whether they exert their effects via threshold or non-threshold mode of action. Furthermore, reprotoxic substances should be derogated from some of the record-keeping requirements.

Threshold vs. non-threshold substances

For a majority of chemical substances it is possible to identify a safe level of exposure (threshold) below which toxicity/adverse effects do not occur. Based on identified threshold level, it is possible to set an occupational exposure limit value (OEL), which can be consider to protect workers against adverse health effects (health-based value). The CAD is designed to reflect the existence of safe threshold level of exposure. In particular, if a protective health-based occupational exposure limit value (OEL) has been set for a substance, it is not required to reduce the exposure below this limit.

The CMD has been specifically designed for substances for which it is not possible to identify a safe level of exposure (a.k.a. non-threshold substances). In case of these substances, for any level of exposure, however low, risks of adverse effects cannot be excluded. It is not possible to set fully protective limit values for such compounds but the values are associated with varying levels of remaining/residual risk (risk-based value). Because of this, CMD includes a requirement to minimize the exposure to as low level as technically achievable.

This requirement applies even below binding OEL levels in order to still reduce the risk below the residual risk associated with the OEL value.

In contrast to carcinogens and mutagens, reprotoxic substances are mainly threshold substances for which it is possible to scientifically identify a threshold below which there is no reproductive health risk. Based on scientific assessment carried out so far, only few reprotoxic substances are considered to exert their effects via a non-threshold mode of action (e.g. developmental effects of lead). Some of the reprotoxins are endocrine disruptors, for which it is currently unclear whether threshold exists or not. Many substances, which have a CLP classification as category 1A or 1B reprotoxicants exert reprotoxic effects only in high concentrations, which are not relevant for occupational settings. Consequently, for almost all reprotoxic substances a threshold can be identified allowing setting of a health-based limit value and consequently the CMD requirement to minimize the exposure to a level as low as technically achievable even below a health-based limit value can be considered disproportionate.

If reprotoxic substances were to be included under the scope of the CMD, it would be reasonable to include a derogation for the minimization requirement for reprotoxic substances except of those reprotoxicants, which are non-threshold substances. Minimization below the occupational exposure limit value (OEL) should apply to non-threshold substances only. For threshold substances, when a health-based OEL has been set there should be no requirement to reduce exposure below this OEL.

This need for distinction between the threshold and non-threshold reprotoxic substances was also the main message in the "Joint declaration on the legal framework to manage risks related to the use of reprotoxic substances at the workplace" agreed by the trade unions (ETUC and IndustriAll) and chemical industry associations (Cefic and ECEG) in 2018.

It should also be noted that if a general requirement of minimization of exposure even below health-based limit values were to be set under CMD for all reprotoxic substances (as is currently proposed by the EP) this would be in clear contradiction with EU's REACH legislation. Many of the reprotoxic substances are regulated also under REACH and in many cases authorizations and restrictions are based on provisions whereby the substance can be used as long as the exposure level does not exceed the health-based REACH limit value (DNEL) set in in the provisions of the regulation.

There are a few options that can be considered for the derogation for the minimization requirements. Five options are presented below. The first three options would respond to the policy needs more immediately. The fourth option would take more time to include reprotoxins into the CMD but allow more time to carry out the preparatory steps in accordance with the normal procedures that respect the principles of better regulation. The fifth option would address reprotoxic substances by strengthening the requirements of the CAD.

- **Option 1: Minimization based on scientific assessment**

This option would built up on the fact that reprotoxic substances are mainly threshold substances and therefore they should by default be derogated from the minimization requirement. Under this option all reprotoxic substances would be included into the scope of the CMD but the minimization requirement of Article 5 would apply only to those reprotoxic substances *which do not have a threshold and which would be listed in a separate new Annex of the directive*. Substances would be listed into this Annex only if the scientific Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) would have assessed the substance (or a group of substances) and concluded that they exert their effects by a non-threshold mode of action.

The 5.3 should be amended as follows:

3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers *to carcinogens, mutagens or those reprotoxic substances, which are listed in Annex IV* is reduced to as low a level as is technically possible.

In Article 18a, the following paragraph could be added:

"The Commission in close co-operation with the Advisory Committee for Safety and Health at Work (ACSH) and the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) shall identify the key reprotoxic substances and their modes of action and update the list of non-threshold substances in Annex IV accordingly".

It should be considered if a more simple regulatory procedure than ordinary legislative procedure could be used for updating the new Annex IV (e.g. comitology).

(Updating of the limit value for lead and its compounds is currently in progress. Based on the scientific evaluation performed by the Risk Assessment Committee it is possible to conclude that developmental effects of lead are exerted by a non-threshold mode of action. Consequently, it could be possible to add lead and its compounds in Annex IV and the limit value could be set under CMD as well. This could perhaps be done already during the current CMDIV amendment. The Advisory Committee on Safety and Health at Work is foreseen to adopt its Opinion on lead OEL in its November meeting).

- **Option 2: Minimisation by default**

Also in this option all the reprotoxic substances would be included under the scope of the CMD. Also the requirement of minimisation would apply to all reprotoxic substances except of those threshold reprotoxic substances for which a health-based binding OELs had been set at the EU level (a separate new Annex for health-based OELs under the CMD should be considered). For threshold substances with a health-based OEL, the employer should no longer be obliged to bring the exposure as far as possible below the limit value.

The Article 5.3. could be amended accordingly:

"3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible *with the exception that for those substances for which a health-based occupational exposure limit value has been set in Annex V minimization is not required below this limit value"*.

The problem with this option is that in the beginning minimization would apply to all reprotoxic substances. This would include also those 11 reprotoxic substances, which currently have a health-based indicative OEL values (IOELV) set under EU directives. Derogation from the minimization requirement would start to apply only when a limit value would be set under the CMD.

Setting binding OELs (BOELVs) under the CMD is a slow process. Based on the Service Level Agreement between the Commission and the European Chemicals Agency (ECHA) the agency will prepare scientific evaluations for limit values for only five substances per year. This slow pace means that setting binding OELs even for the most widely used reprotoxic substances would take many years even if setting OELs for all other hazardous substances would be set aside (list of priority chemicals for OEL setting was adopted in consensus in the May 2021 meeting of the tripartite Advisory Committee on Safety and Health at Work (ACSH)).

It is difficult to overcome the problems associated with minimization requirement applying to all reprotoxic substances, for which OELs have not yet been set. Transition period that would apply to only this one specific (minimization) requirement/Article of the directive would be problematic.

In order to partly ease out this problem, it could be discussed whether during the current amendment of the CMD it would be possible and appropriate to transfer the current Indicative OELs set for 11 reprotoxic substances under the CAD (Commission directives 2000/39/EC, 2006/15/EC, 2009/161/EU, 2017/64/EU) into the CMD as binding OELs.

- **Option 3: Including only non-threshold reprotoxins under the scope of the CMD**

The third option would be to *include only non-threshold reprotoxic substances under the CMD.* The threshold reprotoxins would remain under the CAD. Whether or not a reprotoxic substance exerts its effects via a threshold or non-threshold mode of action would be determined by the scientific Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). If RAC would conclude that the substance (or a group of substances) exerts its effects by a non-threshold mode of action the substance(s) *would be listed in a separate new Annex of the directive*. This Annex would thus contain all reprotoxic substances which fall under the scope of the CMD and all the requirements of CMD would apply to these substances (except, perhaps, some requirements concerning record-keeping; see below). In practice, the directive should be amended to include a definition of non-threshold reprotoxic substances (Article 2) and a new Annex listing these substances. Article 18a) should be amended as indicated above for Option 1in order to set a requirement to identify the key reprotoxicants and their mode of action.

In the beginning the requirements of CMD would not apply to any reprotoxic substances but the scope would be extended to cover more substances when RAC assesses the modes of action of reprotoxic substances and those identified as non-threshold reprotoxins would be added to the Annex of non-threshold substances. With regard to lead, RAC has already concluded that developmental effects of lead are exerted by a non-threshold mode of action. Consequently, it could be possible to add lead and its compounds into the new Annex of non-threshold substances and under the scope of the CMD already during the current CMDIV amendment.

- **Option 4: Tasking the Commission for future action under CMD**

A third option would be not to include reprotoxic substances into the CMD in this CMDIV amendment but to include here an article requiring that the Commission shall prepare a proposal on their inclusion by the end of e.g. 2027 taking into account e.g the threshold/non-threshold concept. This would allow setting binding OELs for the most important reprotoxic substances concomitantly.

- **Option 5: Tasking the Commission for future action under CAD**

One more option would be to set additional requirements under the CAD instead of the CMD. In the CMDIV an amendment could be included which would set a duty on the Commission to adopt additional general requirements for reprotoxic substances during the currently ongoing process of updating the CAD for lead. These requirements should specifically address the threshold/non-threshold issue and the related need for exposure minimization in the case where the science demonstrates the non-threshold mode of action. Also the possible needs to set more explicit provisions on replacement, closed system, status of OELs etc. should be addressed.

Binding OELs

Irrespective of the decisions concerning the approach to threshold/non-threshold substances if reprotoxic substances were included under the scope of the CMD it would be appropriate to transfer the indicative OELs that have currently been set for reprotoxic substances under the CAD as binding OELs under the Annexes of the CMD. At the same time, it would be preferable to review the current OEL values and update the values, if considered appropriate.

A following article could be added to the directive:

"The Commission shall, after consulting the ACSH, review the indicative occupational exposure limit values set for 11 substances, which have a harmonized EU classification R1A/R1B and re-set the values as binding occupational exposure limit values under the CMD".

A new separate Annex for binding health-based OELs should be considered in order to differentiate between these limit values which can be considered to be protective and the current risk-based limit values set for carcinogens, which are associated with differing levels of residual risk. (Also for some carcinogens it is possible to identify a safe threshold level and consequently set a health-based, protective OEL. In the future, health-based limit values of such carcinogens could perhaps also be set under this new Annex and the existing health-based OELs of carcinogens could be transferred to this Annex.). Alternatively the limit values could be kept in the same list but then it should be clearly indicated, which limit values are health-based, protective OELs and which OELs are associated with residual risk.

Even if it may be possible to keep the limit values of reprotoxic substances as indicative OELs under the CAD, this would cause some friction between OSH and REACH legislations. Member states have some flexibility in implementation of the indicative OELs into their national legislation. Consequently indicative OELs are not recognized to assure that "risk is properly controlled" according to REACH Article 58(2). Because of this, additional legislation may be considered to be needed and set under REACH thus resulting in overlapping EU legislation (e.g. the case of reprotoxic N-methylpyrrolidone, NMP).

Record-keeping

Due to their typical mode of action the health effects resulting from exposure to carcinogens and mutagens arise as a result of cumulative exposure over long periods of time and the resulting health effects can manifest themselves years or decades after exposure. In order to be able to identify cancer cases developing long after the actual exposure as occupational diseases eligible for compensation, the CMD sets a requirement to keep records of exposed workers and to store the records for 40 years (Art. 15.1.). The same requirement of storing of the records for 40 years applies also to records of the health surveillance of workers exposed to carcinogens and mutagens (Art. 15.1).

In the case of reprotoxic substances, the obligation to store the records of exposed workers for 40 years is not justified because reprotoxic substances do not cause recognized occupational diseases, which would manifest themselves after decades. (Even though a substance can be identified to exert reprotoxic effects in animal studies and human epidemiological studies, it is not possible to confirm a causal relationship between exposure to a substance and a reprotoxic health effect in the level of an individual worker.) It should also be noted that according to the EU's general data protection regulation any record-keeping should be based on identified specified and legitimate purpose. Due to these reasons, a derogation should be applied for reprotoxic substances for article 15.1.

The article should therefore be amended to reflect this e.g.:

"1. *Information concerning exposure to carcinogens and mutagens which is included in* the list referred to in point (c) of Article 12 and the medical record referred to in Article 14(4) shall be kept for at least 40 years following the end of exposure *of carcinogens and mutagens*, in accordance with national laws and/or practice."