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REPORT

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	11188/20 + ASDD 1 - COM(2020) 571 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 - Analysis of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 22 September 2020, the European Commission published its proposal for a directive amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ("CMD4") (doc. 11188/20 + ADD1).
2. This proposal is the fourth revision of the basic Directive (CMD). It aims, *inter alia*, at revising or setting limits for occupational exposure to three harmful chemical agents: benzene, acrylonitrile and nickel compounds, complemented by notations, where necessary.
3. On 25 November 2020, Coreper agreed on a mandate for negotiations with the European Parliament (doc. 13404/20).

4. On 25 March 2021, the Committee on Employment and Social Affairs (EMPL Committee) of the European Parliament adopted its Report on the proposal and on 13 April 2021, it approved the decision to enter into trilogue negotiations, confirmed by the plenary on 28 April 2021.
5. The first trilogue took place on 27 May under the Portuguese Presidency.
6. On 10 November, Coreper approved a revised mandate in order to enable the Slovenian Presidency to continue negotiations with the Parliament.
7. At the fourth trilogue, on 15 December 2021, the negotiating teams of the Council and the Parliament reached a provisional agreement, the main elements of which are outlined below.

II. ELEMENTS OF THE PROVISIONAL AGREEMENT

1. Reprotoxic substances

Title and definitions

Reprotoxic substances have been added to the title of the CMD. Consequently, in Article 2, the following definitions have been included: reprotoxic substances, non-threshold reprotoxic substances and threshold reprotoxic substances. In order to identify whether a reprotoxic substance is threshold or non-threshold, a relevant notation will be provided in the appropriate column of Annex III, following the well-established procedure, as soon as there is a scientific assessment at Union level.

Two more definitions have been added to Article 2, namely the definition of "biological limit values" and "health surveillance". This has been done in order to fully transfer provisions related to lead, a reprotoxic substance, from CAD into the CMD. The setting of biological limit values in Annex IIIbisnew for any new substance will follow the procedure in accordance with Article 153(2)(b) TFEU. Furthermore, the provisional agreement limits the two concepts only to substances in the new Annex IIIbisnew, which at this point includes only lead.

Limit values

Since reprotoxic substances would from now on be regulated only in the CMD, adjustments needed to be made in order to ensure legal clarity with respect to provisions already existing under Chemical Agents Directive (CAD). In this respect, limit values established under the CAD have been transferred into the CMD.

Minimisation

The provisional agreement provides for different minimisation requirements for non-threshold and threshold reprotoxins. Following the reiterated request from the Parliament, in this context, reference is also made to those reprotoxic substances which have not yet been identified as threshold or non-threshold.

Article 5(3), which contains the requirement of minimisation of the level of exposure of workers, would apply to non-threshold substances, thus maintaining coherence with what is already foreseen for carcinogens and mutagens. A new paragraph 5(3bis) has been added to introduce a requirement for minimisation of the risk related to the exposure of workers to threshold reprotoxic substances, a concept in line with existing CAD provisions.

On the insistence of the EP, another new paragraph 5(3ter) has been added to provide for minimisation of the risk related to the exposure of workers to those reprotoxic substances which have not yet been identified as threshold or non-threshold. In such a case, when carrying out the risk assessment, the employer shall duly take into account the fact that a safe level of exposure might not exist for such a reprotoxic substance.

Record-keeping

In order to take into account the difference in latency periods between reprotoxic substances on the one hand, and carcinogens and mutagens on the other, the obligation of record-keeping for reprotoxic substances has been set to at least 5 years following the end of exposure.

Recitals

In addition, three recitals have been provisionally agreed to justify the extension of the CMD to reprotoxic substances, the derogation in the minimisation requirement for all reprotoxic substances that are not non-threshold and the inclusion of the biological limit values.

2. Hazardous medicinal products (HMPs)

With regards to hazardous medicinal products, the provisional agreement includes:

- a recital clarifying that certain HMPs contain carcinogens, mutagens or reprotoxic substances and therefore fall under the scope of the CMD;
- a reinforced training obligation, under Article 11, for workers handling the HMPs and a recital justifying this provision;
- a review clause, asking the Commission to prepare guidelines on HMPs and to, where appropriate, develop a definition and establish an indicative list of the hazardous medicinal products that meet the criteria laid down in Article 2. (of this Directive).
- a joint institutional statement, acknowledging the common understanding that hazardous medicinal products which contain carcinogens, mutagens or reprotoxic substances fall under the scope of Directive 2004/37/EC.

3. Risk-based methodology

As part of the overall package, the provisional agreement foresees a review clause asking the Commission to work on the risk based methodology, where appropriate and following the opinion of the Advisory Committee on Safety and Health.

4. Other political issues

In order to secure an agreement on the overall package, and in exchange for Parliament's concessions on some of its key demands, the following compromises were provisionally agreed:

Respirable crystalline silica

The Commission shall start the process of revision of the limit value for respirable crystalline silica in 2022 and, where appropriate, propose its modification in subsequent revisions of the CMD.

Cobalt and its compounds

The Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with relevant stakeholders, propose, where appropriate, a limit value for cobalt.

Action plan for 25 additional substances

Where appropriate, the Commission shall present an action plan to achieve new or revised occupational exposure limits values for at least 25 substances, groups of substances or process-generated substances no later than 31 December 2022 and present legislative proposals, where appropriate, [as prescribed by Article 16 of Directive 2004/37/EC without delay]¹.

On all other issues, the Council's general approach was kept.

III. CONCLUSION

1. The Permanent Representatives Committee is thus invited to:
 - endorse the compromise text provisionally agreed in the trilogue, as set out in the ADD 1 REV1 to this Note,
 - approve the joint statement as set out in ADD 2 to this Note, to be published in the L series immediately after the legislative act; and

¹ Under scrutiny reservation from the Commission.

- mandate the Presidency to inform the European Parliament that, should the European Parliament adopt its position at first reading, in accordance with Article 294 paragraph 3 of the Treaty, in the form set out in the compromise package contained in the Addendum to this document (subject to revision by the legal linguists of both institutions), the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.
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