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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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 **(first reading)** - Adoption of the legislative act = Statements

Commission Statement - Hazardous medicinal products

The Commission highlights the importance of protecting workers from the adverse health effects that occupational exposure to certain hazardous medicinal products can have.

In this regard, it is acknowledged that certain hazardous medicinal products which contain one or several substances meeting the criteria for classification as carcinogenic (categories 1A or 1B), mutagenic (categories 1A or 1B) or reprotoxicant (categories 1A or 1B) in accordance with Regulation (EC) No 1272/2008, fall under the scope of Directive 2004/37/EC.

Commission Statement – Action plan and legislative proposals

The obligations imposed on the Commission in Article 18a (new) regarding the presentation of an action plan and the presentation of a legislative proposal cannot go against the institutional prerogatives of the Commission and its right of initiative deriving directly from the treaties.

Article 18a (new) refers to Article 16 of Directive 2004/37/EC, which lays down an obligation to set limit values on the basis of the available information, including scientific and technical data, in respect of all those substances for which this is possible. In implementing this provision, the Commission is also invited to present the action plan referred to in Article 18a (new). For reasons of transparency, this action plan will consist of a listing of the next 25 new or revised substances to be scientifically evaluated. The evaluations of the listed substances will form part of the established procedure including consultation of social partners, the opinion of the ACSH and impact assessment preparing any necessary legislative proposals in due time.

Statement by Austria, Bulgaria, Cyprus, Estonia, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Slovakia, Denmark, Romania

Austria, Bulgaria, Cyprus, Estonia, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Slovakia, Denmark, Romania support any measure to increase the safety and health of workers. In this context, the progress is welcomed that has been made not only in setting new and stricter limit values for carcinogens but also in extending the scope of the Directive to reprotoxic substances.

However, it is regrettable that such substantial changes were made without involving the Advisory Committee for Safety and Health at Work. It would have been desirable to analyse in detail which article or provision should apply or not apply to reprotoxics. That concerns in particular the minimal requirements on health surveillance.