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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

In accordance with the guidance on Impact Assessment (doc. 16024/14) delegations will find attached the summary of the replies to the Impact Assessment questionnaire on the abovementioned proposal.

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 at work

Summary of the replies to the Impact Assessment questionnaire

Almost all the delegations considered **the policy context and the legal basis of the initiative** to be clearly explained in the IA.

While all delegations agreed that the **problem definition** had been clearly or to some extent clearly outlined, a number of delegations pointed out some **gaps in evidence**, notably in relation to data on the number of workers exposed and to the causal relationship between cancer and exposure to a specific substance. As a result, it can be difficult to evaluate both health benefits and compliance costs.

The coherence and consistency of the **policy objectives** - the protection of workers' health and safety - were acknowledged by all the delegations. As to the **link with measurable monitoring indicators**, delegations were fully or partially satisfied. However, some delegations pointed at a certain lack of available reliable data, also linked to the long-latency nature of the carcinogenic health risks, which undermine the precision of the indicators.

The **Union's competence and the legal basis** were considered by all to be clearly established, and most delegations were satisfied with the IA analysis on **compliance with the principle of subsidiarity and proportionality**.

Most delegations agreed that the **policy options** and most affected **stakeholders** had been identified. The options favoured by stakeholders in open consultations were considered examined or partially examined by the delegations, but some delegations underlined that no information was provided on this or asked for a more precise explanation as to why some options such as biomonitoring were discarded.

Almost all of the delegations considered that the **impacts** of the proposal had been analysed clearly, or to some extent clearly. The **impacts on competition and competitiveness**, the **impacts on SMEs including microenterprises**, the **social impacts**, the **regulatory costs**, the **impacts on individual Member States** and the **impacts on fundamental rights** were broadly considered to have been explicitly or partially explicitly analysed. Some delegations still stressed that impacts on SMEs should be further assessed, including the impacts on technological processes, working methods and costs as well as the impact on specific sectors that use the substances included in the proposal (funeral/embalming industry, zinc-cadmium circular economy for example). The analysis of the **impacts on third countries** was considered by some to be irrelevant.

The **opinion of the Impact Assessment Board (IAB)** was considered to have been set out clearly, or partly clearly. One delegation indicated that the IAB opinion was not available via the link in the footnote. As to the **monitoring**, most delegations thought that the indicators were clearly or to some extent clearly able to measure the intended effects.

Delegations were also fully, or to some extent, positive on the presentation of the **monitoring solutions** and with the information provided on the impact of the **transposition deadline.**

Finally, almost all the delegations recognised that **the methodological choices, the limitations and uncertainties** were made clear.