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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Revision of Directive 2004/37/EC on carcinogens, mutagens and reprotoxic substances at work (sixth batch) *- Summary of replies to the Impact Assessment questionnaire*

In accordance with the guidance on Impact Assessment (doc. 6270/18), delegations will find attached a summary of the replies to the questionnaire on the Impact Assessment accompanying the abovementioned proposal.

ANNEX

Summary of replies to the Impact Assessment questionnaire

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All delegations responding to the Impact Assessment (IA) questionnaire considered that the policy context was explained clearly and that the legal basis of the initiative was clear and appropriate. All but one responding delegation (which agreed partly) believed that the existence, scale and consequences of the problem are clearly demonstrated and the analysis of the problem is supported by evidence. Delegations were split relatively evenly on whether any gap in evidence is acknowledged, with comments touching upon the lack of data on respiratory tract toxicity caused by welding fumes and the lack of reliable data causing difficulties to establish a direct causal relationship between exposure to a specific carcinogen and cancer cases.

All delegations (except for one partly in agreement and one not responding) considered that an appropriate methodology was applied and that the methodological choices, limitations and uncertainties were set out clearly. All responding delegations agreed that the IA set out clear policy objectives, which correspond to the identified problems and are consistent with the broad EU policy strategies. While most delegations considered that the objectives are linked to measurable monitoring indicators, a few believed this to be only partly true. Comments in this regard concerned the reliability, quality and availability of data on the proposed indicators, which might lead to imprecise measurements of the indicators as well as less defined sector-specific metrics.

All responding delegations believed that the Union's competence is clearly established. All delegations fully agreed that the IA analyses whether the proposed action is consistent with the principles of subsidiarity and proportionality – except for one delegation partly in agreement when it comes to the subsidiarity principle, and two delegations partly in agreement regarding the proportionality principle. All but two responding delegations found that the IA takes into account action already taken or planned at EU or Member State level.

Delegations found that the IA identified several options to meet the objectives, among which "further harmonisation" was selected by most respondents. All delegations responding to this question deemed that the most affected stakeholders were identified and the IA contains elements on how public and stakeholder consultations informed the policy options. Most delegations considered that reasons were given for discarding options that were favoured during consultations, whereas a few believed this to be partly true, and one delegation disagreed, remarking that an overview of proposals from the consultation that were discarded was not provided.

All but two responding delegations believed that transparent criteria were used to determine the impact of different policy options, with one delegation considering the evidence in the IA insufficient to discard the option of setting an occupational exposure limit for Isoprene. All respondents agreed fully or partly that the impacts of the different policy options were set out in a comparable format, that both the short-term and long-term costs and benefits of the policy options were taken into consideration and that the impact on affected public and stakeholders was clearly analysed for each policy option.

Most delegations were satisfied that the economic impacts (on competition, consumers, competitiveness, SMEs, including microenterprises, administrative burdens and compliance costs, digital aspects and futureproofing), the social impacts, the environmental impacts and the impacts on individual Member States, regional or local authorities were sufficiently assessed, based on appropriate data/evidence. A few delegations however did not consider this to be true, in particular regarding consumers, digital aspects, environmental impacts and the impacts on individual Member States, regional or local authorities.

Regarding competition, one delegation pointed to the impact on certain sectors in case it would not be possible to use respiratory protective equipment to comply with the proposed cobalt limit value. One delegation noted the impact on consumers in the smoked food industry and the competitiveness of SMEs and microenterprises when it comes to the retained polycyclic aromatic hydrocarbons option. One delegation considered that the IA failed to take into account the complexity and heterogeneity of welding procedures when it comes to assessing the impacts on competitiveness and the administrative burdens and compliance costs. Three delegations remarked that effects at regional or local level are not assessed and that the socio-economic impact analysis is conducted primarily at EU level, not at individual Member State level.

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While a majority of respondents were of the opinion that the comments and recommendations of the Regulatory Scrutiny Board were considered in the IA report, some believed this to be only partly true. Two delegations questioned whether the effectiveness of adding welding fumes to Annex I of the Directive for better prevention has been sufficiently demonstrated.

The respondents were mostly in agreement that the proposed indicators will enable the intended effects to be measured and that operational monitoring and evaluation arrangements are proposed. Five delegations however partly agreed regarding the proposed indicators, and difficulties regarding the availability of data on working conditions and substances present in workplaces, and regarding the comparison of healthcare costs and lack of standardization in exposure monitoring strategies across the EU, were noted. All delegations were satisfied that those responsible for monitoring and compliance are identified, and all but one responding delegation agreed fully or partly that the IA addressed the impact of the proposed transposition deadline for Member States.

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