BUSINESSEUROPE

RESPONSE

FIRST PHASE CONSULTATION OF SOCIAL PARTNERS UNDER ARTICLE 154 TFEU ON REVISIONS OF DIRECTIVE 2004/37/EU TO INCLUDE BINDING OCCUPATIONAL EXPOSURE LIMIT VALUES FOR ADDITIONAL CARCINOGENS AND MUTAGENS

18 September 2017

- **Do you agree with the issues identified above: are the issues accurately and sufficiently covered?**

1. Employers are committed to effective protection of workers from occupational cancer. Preventing occupational cancers is in the interest of workers, public health, society at large, as well as businesses. Furthermore, setting Binding Occupational Exposure Limits (BOELs) at EU level helps to provide a level playing field for industry and worker health and safety protection across the EU.

2. We therefore support the general direction of the Commission to pursue revisions of annexes 1 and 3 of the carcinogens and mutagens directive, to set additional Binding Occupational Exposure Limit Values (BOELs) for some substances, as long as it us under the following conditions:

    - The process of setting BOELs is based on sound scientific assessment (currently provided by the Scientific Committee for Occupational Exposure Limits – SCOEL), technical and economic feasibility and a thorough assessment of the socio-economic impact (also based on statistical data), as provided for by the tripartite Advisory Committee on Safety and Health – ACSH;
    - Only those substances fitting the scientific criteria classifying them as carcinogens or mutagens in Europe should be added to the relevant annex of the directive. The criteria of the Regulation on Classification, Labelling and Packaging of Substances (CLP) should be taken into account.
    - BOEL-setting is focussed on priority substances. Establishing a BOEL for every Carcinogenic and Mutagenic Agent is not realistic, therefore criteria should be defined to set long-term priorities.

3. These conditions are crucial in allowing for an effective implementation of the limit values by industry which is necessary for a high level of worker protection. Firstly, the involvement of the tripartite ACSH allows for the consultation of those who will enforce and implement the limit values at national level, i.e. employer and worker representatives and national governments. Whilst for some substances the employers, workers and governments may express different views on the limit value for a given substance recommended by SCOEL, the opinions of the Advisory Committee provide a general consensus to guide the Commission in revisions of the directive.

4. Secondly, the members of the ACSH Working Party on Chemicals are legitimately entitled to draft the opinions on individual substances, as they are experts in the field,

BUSINESSEUROPE a.i.s.b.l.
AVENUE DE CORTENBERGH 168 – BE 1000 BRUSSELS – BELGIUM
TEL +32 (0)2 237 65 11 – FAX +32 (0)2 231 14 45 – E-MAIL main@businesseurope.eu
WWW.BUSINESSEUROPE.EU – Follow us on Twitter @BUSINESSEUROPE
EU Transparency register 3978240953-79

well acquainted with the principles of OSH chemical risk assessment and prevention, and with the role of EU OELVs in prevention.

5. Thirdly, prior to these processes, SCOEL, whose members have expertise in occupational hygiene, toxicology, routes of workplace exposure, epidemiology and workplace measurement techniques, provides for a sound scientific basis. The Commission also runs a public consultation on the scientific assessment done by SCOEL, aiming to ensure that all scientifically relevant information is taken into account when adopting a recommendation.

6. All of these processes can take some time however they are crucial in achieving a good outcome. We agree that rapid technological change and scientific developments put high demands in terms of timeliness and quality scientific information. Therefore, as well as ensuring that revisions of the directive are done when necessary, i.e. when the conditions set out previously are met, it would be useful to look at how to make the processes for setting BOELS at EU level quicker and more efficient. It has been made clear that this is possible with the two recent proposals for revision of the directive, where, in addition to other bodies acting in good time, SCOEL also increased its output.

7. Since the Commission's proposals for the first and second wave revision of the directive followed the conditions and procedures set out in the previous paragraphs, and proposed a restricted amendment of annexes 1 and 3, we were supportive overall. This despite the fact that some sectors had concerns regarding specific substances and many of the proposed limit values already create substantial challenges, especially for SMEs and micro-companies.

8. Therefore, we encourage the Commission to continue this approach with any future revisions. In contrast to scientific evidence, proposing a series of substances for inclusion in the annex on the basis of unofficial lists, should be avoided, as should setting an arbitrary numerical target of additional BOELVs without clear criteria of prioritization.

9. We welcome the focus in the Commission's consultation document on the hierarchy of measures included in the directive, which recognises that occupational exposure limit values are not the only way for evaluating and controlling risks of exposure to carcinogens and mutagens at work. OSH legislation also protects workers through risk assessment and prevention measures, including substitution, the setting up of closed systems, collective protection, access to personal protective equipment, instruction and training and health surveillance.

10. Furthermore, guides, examples of good practice and other tools developed by the Commission, Member States, and/or social partners can be valuable instruments to complement and assist in implementation of the directive.

11. When proposing exposure limit values or definitions of process-generated substances, the Commission is now increasingly drawing on various sources of scientific advice, i.e. not only the SCOEL, but also in particular the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). No decisions should

be made about the future roles of SCOEL and RAC in setting OELVs until the pilot phase initiated by the Commission's January 2017 OSH communication[1], has been thoroughly assessed.

12. We remain convinced that retaining the current OELV setting procedures allows for the necessary targeted approach to setting limit values in the area of OSH, as it is based on appropriate expertise from SCOEL in providing the scientific recommendations and crucially on the legitimacy of the government and social partner advice provided through the Advisory Committee on Safety and Health. At the same time, using other sources of scientific information, including RAC, IARC, Member States and scientifically recognised institutions can be useful when studying a substance. There is a need to consider the benefits and disadvantages of different solutions and see how the different processes of deriving OELVs can function simultaneously in an effective and efficient way. There is a need to clarify the different approaches and purposes between EU OSH OELVs and REACH DNELs/DMELs, to avoid confusion and legal uncertainty.

13. Going forward, whatever approach is decided on, it is crucial that it does not endanger existing EU processes for setting BOELs for protecting workers from exposure to chemicals at the workplace. EU policy makers must respect and clearly distinguish the different procedures which apply to EU OSH chemicals legislation and REACH, as they operate in different regulatory settings. As stipulated in the EU Treaty, legislation protecting workers' health and safety at the workplace is part of social policy, providing EU minimum standards, whereas the EU Treaty base for REACH is internal market harmonisation. The Commission must also respect the public consultation process of scientific documents and give adequate time for this, whichever bodies provide scientific input for OELs. This allows the industry and other interested parties to provide the most up-to-date information.

- **Do you agree with the approach regarding the third and fourth amendment for the establishment and/or revision of binding occupational limit values in Annex III to Carcinogens and Mutagens Directive?**

14. Regarding the third, fourth and even subsequent amendments of the directive, the question of whether specific substances should be included depends on whether they meet the conditions set out earlier in this response and whether the necessary processes have been completed. Since this is already the case for the substances highlighted in the consultation document for the third amendment, and the preparatory work has already been done, overall, we support the Commission's approach. In a sense, this question is not really necessary.

15. However, we take this opportunity to highlight some issues regarding the process for the third amendment, which caused difficulties in particular at the key stage of formulating the draft ACSH opinion in the chemicals working party. Firstly, it should be noted that the scientific opinions issued for some substances were not open for

[1] Commission Communication 'Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health (OSH) Legislation and Policy'.

consultation as would have been the case if recommendations had been made. Secondly, whilst for the first and second amendments, not only scientific information was available, but also information on the socioeconomic impact, for the third amendment, only scientific information on effects to health were available and not enough information on the impact of the proposed values. This information is key to making a judgement on whether the limit values can be implemented by industry and therefore actually protect workers. Also, the information was not provided in a timely way. This should be improved in the future.

16. Regarding the fourth amendment, discussions are already ongoing in the chemicals working party of the ACSH on those substances highlighted by the Commission, as well as others. When it comes to prioritising work on substances for the fourth or further amendments, notwithstanding point 14., we can in general agree to the criteria highlighted by the Commission in its consultation document. However, the criteria of technical and economic feasibility should also be included. In terms of policy considerations, as already highlighted, coordination and exchange of information between REACH and OSH and the Commission departments responsible for them, is also necessary.

17. We also remind the Commission of the benefit of recommending a Biomonitoring Limit Value (BLV), in cases where it is scientifically justified and relevant, which should be evaluated on a case by case basis. For example, this can be the case for metals if there is a risk of ingestion of the substance. Biomonitoring allows for a more comprehensive approach to the protection of workers' health.

- **What other substances/mixtures in addition to (or instead of) the substances indicated above under point 4 should be considered for inclusion in the next amendments of Annex III to the Carcinogens and Mutagens Directive?**

18. We agree with the Commission's approach for periodic revision of Annex III of the directive to continue to establish binding occupational exposure limit values and directly related provisions (e.g. skin notations) for additional carcinogens and to revise existing limit values in light of evolving scientific and technological developments. This should be for those substances which meet the conditions set out at the beginning of this response and which have gone through the necessary processes, combined with the establishment of a long-term vision on how to prioritise substances for inclusion in annex III.

19. In any case, work is already underway to study a number of substances, including those mentioned in the Commission's consultation document. In terms of prioritising the work, it would be useful to have a thorough discussion in the chemicals working party of the ACSH on the conditions highlighted in the Commission's consultation document and other conditions to be met, such as technical and economic feasibility, hazard profile, expected level of exposure, conditions of use and measurement possibilities. As part of this discussion it is also important to take account of the different national approaches regarding implementation of BOELVs.

- **What other processes and/or process-generated substances should be considered for inclusion in Annex I to the Carcinogens and Mutagens Directive?**

20. Processes and process-generated substances to be considered for inclusion in Annex I of the directive, as with other substances, should be those which meet the conditions set out at the beginning of this response and which have gone through the necessary procedures. At the same time, we do not see this in the same way as possible amendments to Annex III of the directive. We believe that further enlarging Annex I would only help to a limited extent in avoiding or reducing exposure, as it is often not clear to which specific substance exposure should be reduced or avoided and to which extent/level. This means that inclusion in Annex I may help generally to raise awareness, but it is not oriented towards effective solutions. This is the case with the substances already included in Annex I and there should be consideration of the possibility to move them, where relevant, to Annex III, if the chemicals which are responsible for the hazard have been identified.

- **Would you consider initiating a dialogue under Article 155 TFEU on any of the issues identified in point 3 of this consultation?**

21. We do not wish to initiate a dialogue under Article 155 TFEU on the issues identified in point 3 of the consultation.

22. The existing legal framework for protecting workers from exposure to carcinogens and mutagens at the workplace is well-developed and the existing processes already involve social partners, including through the Advisory Committee on Safety and Health. As long as this remains the case in the future, we see no need for additional dialogue.

23. We would welcome discussing in an informal way with the trade unions how the existing processes (SCOEL, ACSH) could be made more efficient, how to take account of information on substances from other sources, and how the legislative process through the EU institutions could be made smoother. However, we do not see this as a topic for formal dialogue.

*****