BUSINESSEUROPE

CONSULTATION RESPONSE

21 September 2021

**Second phase social partner consultation on the protection of workers from risks related to exposure to chemical agents at work (lead and di-isocyanates) and to asbestos at work**

***Question 1: What are your views on the possible avenues for EU action, potential impacts and the elements set out in section 5 of this document and the analytical document?***

1. As stated in our response to the first phase social partner consultation, where appropriate and based on a number of key conditions, we support the establishment of new limit values or revision of existing limit values within EU Health and Safety legislation, in order to ensure strengthened worker protection. This must be based on sound scientific evidence; the limit value must be technically and economically feasible for employers to implement and to measure; and the proper and timely consultation procedures must be ensured in the Advisory Committee on Safety and Health.

2. We note that the Commission plans to revise the limit values for asbestos and lead and to introduce new limit(s) value(s) in the Chemical Agents Directive (CAD) for di-isocyanates. In this context, the points outlined in our response to the first phase consultation remain valid. Overall, whilst in principle we support a revision of the limit values for asbestos and lead, without knowing the level of the limit values that the commission will propose, it is not possible to assess whether there will be the right balance between effective worker protection and feasibility for employers. As stated by the Commission in the consultation document, the magnitude of the costs and benefits of possible Occupational Exposure Limits (OELs) and Biological Limit Values (BLVs) depends on the specific limit values that are proposed. In this context, it is essential to ensure that the limit values are not too low, thereby preventing companies from implementing and measuring them. On di-isocyanates, more assessment and justification is needed regarding the added value of a BOEL, taking into account the existing requirements under the new REACH Restriction, in the process of being implemented. Further comments regarding each of the three substances is provided later in this response.

3. We remain convinced that a proposal for revision of the CAD and Asbestos Directive should be restricted to the amendment/introduction of limit values for the three substances which are part of this consultation, and not related to other provisions/substances in the directives. As stated by the Commission in its analytical document, the general provisions of the Asbestos Directive remain relevant. Both the Asbestos Directive and CAD work well in terms of worker protection and for employers, as well as being well transposed by Member States. Therefore, there is no need for other changes. Also, this is the best way to ensure an effective and swift legislative process regarding these substances, rather than diluting resources to deal

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with many different aspects at the same time. This is also important in terms of making progress to protect workers from exposure to these substances.

4. We note that the Commission promises "to give due consideration to further suggestions received during the consultation process to improve workers' protection from the risks related to hazardous chemicals at work" and that "where amendments to the legislative framework are relevant they also could be taken into consideration". This very general statement is a concern, as it seems to be an open offer to proceed with other changes to the CAD and Asbestos or even other EU OSH chemical directives, which are not covered in the scope of this consultation. We call for a focused approach which prioritises work on the three substances in question, rather than opening up a broader revision.

5. Of course, we are ready to discuss other relevant OSH chemicals topics with trade unions and governments, where this is appropriate and where there is clear common ground, in particular in the framework of the Advisory Committee on Safety and Health. For example, in addition to proposing a revised limit value for lead, which, as stated by the Commission, is the major reprotoxin, we support the proposal in the OSH Strategic Framework to identify a priority list of reprotoxicants to be addressed, based on the opinion agreed in the Advisory Committee on Safety and Health to set a list of priority substances for an OEL. This will follow work in the ACSH also on Boron and Boron compounds, other key reprotoxins, which have been prioritised for an OEL in the near future.

6. We agree on the importance of a level playing field across the EU when it comes to implementation of the health and safety directives, including in terms of fair competition between companies. It is also important to recognise (as the Commission does) that Member States can always provide for stricter limit values than those set at EU level, bearing in mind that the EU requirements already provide a good level of protection to workers. However, we find that the Commission is over emphasising the heterogeneity of limit values set by Member States, especially for asbestos, as in fact only very few Member States (i.e. France and Netherlands) have lower limit values than the ones set at EU level, taking into account that the analytical methods may differ. This is clear from the table of national limit values provided by the Commission in its own analytical document. Therefore, the argument that a change to the limit value is necessary to ensure fair competition and a level playing field, is not well justified. In those Member States with lower limit values, this also represents a rather small percentage of workers in comparison to the whole EU, i.e. around 17%[1].

7. Similar can be said regarding the level playing field arguments for di-isocyanates, as only two Member States have introduced a limit value for this group of substances,

[1] Estimate based on figures in report of consortium of consultants created to carry out the impact study on behalf of the Commission (led by RPA, supported by COWI, FoBiG and EPRD) "Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos)"

even though many Member States have different OELs for specific di-isocyanates (TDI, HDI, MDI etc).

8. This also means that changes to the existing limit values for asbestos and lead, and introduction of new limit value(s) for the group of di-isocyanates will have a large impact across EU Member States, both for application, harmonisation and enforcement by governments and implementation by companies. This does not seem to be adequately recognised by the Commission and should be looked at further in the impact assessment.

9. When it comes to finding a balance between sufficient worker protection and economic feasibility for companies to implement a limit value, including the impact on their competitiveness, global comparisons are important. We therefore appreciate that the Commission has provided information on limit values for the three substances/group of substances in question in force in other parts of the world. This shows that in important parts of the world outside Europe (specifically the US, Australia and Canada), the limit value for asbestos is the same as in EU legislation. For di-isocyanates, measures exist in major world regions (China, US, Canada), which are generally in line with the EU median for individual substances or higher. However, unfortunately there is no analysis stemming from this regarding the impact of potentially introducing a more restrictive limit value at EU level in terms of companies' global competitiveness. This should be considered as part of the impact assessment, when deciding on the level of the revised limit values.

10. As stated in the Commission's consultation document, the estimates/calculations of numbers of workers at risk due to exposure to the three substances/ group of substances in question are very diverse, including in some cases, a large magnitude of difference. Also, in the case of di-isocyanates, according to data from the German Berufsgenossenschaft der Bauwirtschaft (German Social Accident Insurance Institution for the construction sector) and BAuA, the number of exposed workers in the construction sector is clearly overestimated in the report of the consortium of consultants (RPA/FOBIG etc) undertaken on behalf of the European Commission[2]. BAuA estimated 1.4 million exposed workers in their REACH restriction dossier, whereas RPA estimated 4.2 million. Unfortunately, the diversity of the estimates/calculations is not adequately taken into account by the Commission, whereas (as stated above), this is a key point made (inaccurately) regarding the different limit values at national level. In order to assess the benefits and effectiveness of the measures, including feasibility for employers, reliable, objective and scientifically grounded information is necessary on numbers of workers exposed. This should be ensured as part of the impact assessment.

[2] Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos)

***Asbestos***

11. In principle, we support a lowering of the existing limit value for asbestos through amendment of the Asbestos Directive, as long as the conditions already highlighted are met. This means that an excessively low limit value would not be the right approach. In principle, we agree with the approach to derive an exposure risk relationship, as suggested by the European Chemical Agency's (ECHA) Risk Assessment Committee (RAC), which expresses the excess risk for lung cancer and mesothelioma mortality (combined) related to different levels of exposure. RAC does not in fact suggest a specific limit value. It is also important to note that where there are already lower OELs, e.g. in Netherlands, implementation is very challenging and is even jeopardizing removal of asbestos in some cases, which negatively affects protection of workers and public health.

12. Taking these considerations into account, we propose that the absolute maximum for a reduction in the limit value should be a factor of 10. Even with such a reduction, the consultant's report (as mentioned previously), shows that there would already be a steep increase in costs and that the costs would be around 100 times higher than the benefits. Furthermore, the report shows that when analyzing the costs for companies as a percentage of turnover, small companies in some sectors, such as specialized construction, or repair and maintenance activities, will be facing costs of more than 10% of their turnover, and in case the limit values were reduced to 0.002 or 0.001 f/cm$^3$, costs of even more than 20% of their turnover. The report also indicates that when expressed in terms of profits or investment, these costs are even greater. This would therefore not meet requirements on cost-benefit, in particular for smaller companies, as well as having a negative impact profit for companies with small profit margins, and on investment.

13. Additionally, at very low limit values, new analytical methods would be needed, changing from rather easy to perform optical microscopy to technically complex high-end electron microscopy. The consequences of this need to be taken into account by the Commission in its further work. For example, whilst this would allow for detection of smaller/thinner fibres, on the other hand electron microscopy is much more sensitive to other typical workplace related exposures (e.g. general dust), which could cause problems for reliable detection of asbestos. Also, it would take at least one year for laboratories to implement the new methodology and undertake quality controls, etc. This step is needed before any sample is taken, as for the time being, there are not enough laboratories in each Member State that are able to provide this service. There are also steep cost increases when shifting to electron microscopy. Finally, for most of the analyses so far, information on exposures, is based on use of optical microscopy, so this could lead to conflicting analyses.

14. In view of other suggestions that have been made regarding the Asbestos Directive, we reiterate that broader changes to the directive are not necessary, as it works well and is well transposed and implemented at national level. Also, the lowering of Binding Occupational Exposure Limit Values (BOELVs) automatically implies the adoption of stricter preventive measures, to achieve the lower level of exposure, thereby bringing substantial improvements to workers' health.

***Lead***

15. We agree in principle on the need to lower the existing Binding Occupational Exposure Limit Value (BOEL) and Binding Biological Limit Value (BLV) for lead in the CAD, as long as the conditions already highlighted are met. This means avoiding excessively low limit values.

16. Employers are fully committed to equality and non-discrimination at the workplace, including in terms of protecting their workers from health and safety risks at work. However, we do not believe this is the place to deal with such issues, as EU occupational safety and health (OSH) legislation inherently aims to provide the same level of protection for all workers in a non-discriminatory way, even if this may be achieved through different tailored protective measures, particularly at the workplace. More specifically, limit values are not designed for specific groups, but for overall worker protection. It is also important to recall that pregnant and breastfeeding workers are afforded an extra layer of protection through the Pregnant Workers Directive, in which lead is in fact already listed as a substance that such workers must not be in contact with or exposed to. Also, the EU OSH Framework directive already obliges employers to take account of people with specific risks.

17. We agree, as recognized by the consultants (as mentioned previously) and RAC, that since there is not a clear correlation between levels of lead in air and blood, that employee blood lead concentrations should be recognized as the main exposure metric in assessing occupational exposures to lead.

18. The current binding biological limit value (BLV) for inorganic lead is 70 µg Pb/100 ml blood. All the potential BOEL and BLV limits included in the consultant's report (as already referred to) are significantly lower than these existing values in the CAD. The RAC opinion, adopted in 11 June 2020, recommends a BLV equal to 15 ug Pb/100 ml blood for lead and its inorganic compounds. Whilst the affected sectors are committed to achieving limits that are protective of health, they would need sufficient time to implement the necessary changes to achieve such a goal.

19. The current airborne binding limit value for inorganic lead and its compounds in the CAD is 0.15 mg/m³. RAC has recommended an occupational exposure limit value for inhalable fraction of lead and its compounds of 0.004 mg/m³, but this is derived indirectly based on lead blood levels by way of a modelling tool. Also, the RAC recommendation conflicts with the results of the consultants (as mentioned previously) that effectively low lead blood levels appear to be achievable despite associated high lead air concentrations. This needs to be taken into account by the Commission, by taking a very cautious approach regarding a possible change to the airborne limit value in the CAD.

20. Taking into account all these aspects, we propose a pragmatic implementation of new BOEL and BLVs with staged milestones, allowing for a gradual reduction that aims to ultimately deliver the health-based BLV proposed by RAC. This should be combined with a commitment that other regulatory actions are unnecessary. This would lead to a substantial decrease of the limit value, whilst taking into account the

needs of industry for time to implement. The milestones should be phased over a period of approximately 10 years to address the points raised in previous paragraphs, bearing in mind that even such a period would be difficult to implement in some circumstances.

21. The issue of timing is compounded by the fact that blood lead levels in workers reflect both current and past exposures and that significant time will be required following implementation of upgraded risk management measures to eliminate lead already stored in the body (as the main storage is within the bone and elimination is very slow). This means that it will not be possible to comply with the BLV in certain cases. This aspect needs to be taken into account in implementation, for example by introducing a footnote in the CAD, as well as a commitment to provide guidance to employers and workers in the future to support targeted medical surveillance of workers who have been exposed for long periods before the new limit value came into force. This commitment for guidance could be introduced in annex II of the directive.

22. We agree with RAC that there is no scientific information available to establish a limit value for organic lead compounds. Also, due to the ban on leaded fuels, there is no need for such an OEL.

***Di-isocyanates***

23. We note that the Commission intends to add new BOEL(s) for di-isocyanates in the CAD. Whilst there may be some benefits in terms of worker protection, it is not clear whether these will really add to what is already ensured through the REACH restriction. The Commission also acknowledges that according to the ECHA restriction background document, occupational exposure to di-isocyanates depends on different factors. It is important to note that RAC has concluded that the existing REACH restriction "is the most appropriate EU wide measure to prevent new cases of respiratory sensitization […] by implementing harmonized training for the workforce". Whilst the Commission in its consultation document recognizes that the REACH restriction and the more recently introduced training requirements already provide protection for workers, it unfortunately does not explain what a new BOEL would add to this or why further measures are necessary, despite us requesting this already in the first phase of the social partner consultation.

24. At this stage, it is therefore important to see whether existing measures as part of REACH restriction or general OSH legislation are already effective and to analyse whether and under what circumstances, a new BOEL would actually be complementary to this. This should include fully considering how the implementation of mandatory trainings will reduce exposure, bearing in mind that measures stemming from this, e.g. improvement in wearing PPE appropriately, better ventilation and awareness raising, will no doubt further lower cases of exposure and enhance workers' health. We urge the Commission to undertake more assessment on these aspects and to clearly justify the proposal for a new BOEL.

25. It is also important to bear in mind that the REACH restriction only entered into force recently and its effects still have to be reported by Member States. The consultant's report (as mentioned previously) actually stated that the "impact of the REACH Restriction on exposure concentrations is unknown".

26. It is also not clear whether introducing a BOEL in the CAD would ensure a balanced approach between worker protection and additional burdens/costs on employers. The consultant's report revealed a high degree of uncertainty regarding the benefits of introducing a BOEL. In particular, an excessively low limit value must be avoided, as this is likely to cause implementation problems, as the analytical methods currently available would not allow for detection at very low levels. Moreover, the consultant's report highlighted that introducing the new limit values for di-isocyanates would mean that, "the cost of compliance consisting of risk management measures, monitoring and administrative burden would fall heavily on small companies and medium sized companies at all OEL options", which would be unacceptable.

27. We believe a stepped approach is necessary. This means that introduction of an OEL should only follow the assessment of existing measures and an analysis of added/complementary benefits, as requested above. Since the consultant's report shows that high exposures lead to a much higher likelihood of asthma cases (Table 4-66), if an OEL is to be set, it should aim at tackling this problem, by preventing peak exposures, which are strongly linked to asthma cases. In this case, it would need to be a pragmatic STEL OEL at the level of the EU median of national OELs. This would significantly reduce peak exposure in addition to the REACH restriction, which would be a major improvement for workers' health. This approach would also create a level playing field, whilst limiting the burdens/costs on employers to implement. In contrast, there is no need to adopt a lower limit value than the EU median, as this would not have an additional impact on peak exposure.

28. Given that Member States are required under the REACH Restriction to report to the Commission by 2025 on "any established training requirements, the number of reported cases on occupational asthma and occupational respiratory and dermal disease, any national occupational exposure levels and information on enforcement activities", we believe that any potential further steps to review a new OEL should only take place after having this essential information. This represents an opportunity to assess the real-life impact of the already adopted REACH restriction, ensuring a framework which fully protects workers while optimising the cost-benefit ratio of the measures.

29. Since medical surveillance is of key importance for respiratory sensitizers, which is the case with di-isocyanates, we also suggest adding some provisions in Annex 2 of the CAD regarding medical surveillance for higher exposure applications. Medical surveillance could prevent sensitized workers from being further exposed to di-isocyanates and inform companies of potential health risks in the workplace. In this context, it is important to bear in mind that this is the first time the CAD will address respiratory sensitisers, and since this is a precedent it should be discussed carefully.

***Question 2: Are the social partners willing to enter into negotiations with a view to concluding an agreement with regard to any of the elements set out in section 5 of this document under Article 155 TFEU?***

30. In this case, we believe that the ACSH is the right place for dialogue between social partners, jointly with governments on the next steps of the process. We therefore do not see a need to enter into negotiations on the elements set out in the consultation document.