Conference call on Benzene OEL – Minutes of the Meeting

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Participants:
- [European Commission, DG EMPL]
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[European Commission, DG EMPL] explained the issue of complying with the Occupational Exposure Level (OEL) of 0.05 ppm recommended by the Risk Assessment Committee (RAC) in March 2018, and he explained the refining industry’s commitment in protecting the health and safety of employees. [European Commission, DG EMPL] underlined that we have analysed existing studies on OEL, and our experts came to conclusions on a safe level of occupational exposure which is different from the one recommended by RAC. Taking into consideration the process, which will lead to the final decision, [European Commission, DG EMPL] asked how we could contribute to the process.

[European Commission, DG EMPL] added that we worked further on the toxicological side of the findings, highlighting the challenges in terms of economic and technical feasibility.

[European Commission, DG EMPL] added that our work focused on RAC recommendation of 0.05 ppm and, starting from that level, we focused on the quality of the studies, developing our findings based on the consideration of new studies, as well as the ones analysed by RAC. According to our assessment, the residual risk is negligible below 0.25 ppm.

Furthermore, [European Commission, DG EMPL] said that teams of industry experts and experts in toxicology experts analysed in detail all the studies taken into account by RAC for setting the benzene OEL and ranked them according to their scientific relevance/reliability. Some studies are less reliable because of the presence of other pollutants, and some studies were found to contain errors. Analysing the high-quality studies showed that blood effects (hematoxicity) and genetic effects (chromosomal aberrations and micronucleus formation) were seen at and above 2 ppm (per 8 hours) exposure. A credible no effect exposure for these effects is 0.5 ppm (per 8 hours) based on projection from the levels causing effects and on the confirmed no effect levels identified. This supports an Occupational Exposure Limit of 0.5 ppm / 8h. Industry experts then applied a further two-fold reduction in exposure to take into account bone marrow sensitivity to give an Occupational Exposure Limit of 0.25 ppm / 8h. The study is currently under peer review and it will be published on a scientific journal.

[European Commission, DG EMPL] said that the Working Party Chemicals (WPC) would discuss the opinion on 29/30 April, underlining the relevance of the independent scientific evaluation performed by RAC, which would not be discussed or changed if there is not a new opinion. She added that a safe OEL does not take into account socio-economic evaluation. However, the possible impact is considered in view of finding an agreement on an OEL. She mentioned also the role of the European Parliament in the Ordinary Legislative Procedure who will be entitled to make further amendments.

Moreover, [European Commission, DG EMPL] mentioned the Impact Assessment, which will be prepared by the European Commission after June’s final opinion by the Advisory Committee for Safety and Health. The impact assessment will take the information from the ACSH, and will run through inter-service consultation.
with DG ENV and DG GROW. The European Commission representative said that the Impact Assessment can be quite long and suggested us to have a look at the previous one. In the assessment there will be a cost-benefit analysis. The opinion of workers, employers would be considered in the ACSH and the Commission will follow the advice of the ACSH to prepare the Impact Assessment, which will support the legislative proposal for amending the Carcinogens and Mutagens Directive.

stated the need of having access to all the available information from existing studies. Referring to the Consultant who was appointed by the Commission to conduct a study "collecting most recent information for a certain number of substances in view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work" he said that would be important for the industry to engage with the study contractor in order to provide them additional relevant studies on which they will consider to base their conclusions.

asked what is going to happen after the WPC.

said that the WPC will provide a draft opinion to the ACSH which will take place at the beginning of June.

asked what it will happen if there is no agreement.

replied that normally WPC has to agree because it is in our own interest to go ahead in a reasonable speed. On the other hand, it will be possible that REACH bring forward this substance. She said also that a transition period could be granted if there is a good justification. She concluded that the usual rule is to agree for a stricter provision. She clarified that there are different views, but every stakeholder has been taken into account.

clarified that industry ordered a socio-economic study from Triskellion and that this study has been shared with the consortium doing the study on Benzene. The report of the Consortium shows that there is a huge gap between cost and benefit, underlining that for a 0.05 ppm there is a factor of 100 between cost and benefit. also noted that the derivation of the benzene OEL can be considered as a pilot project for RAC and that several shortcomings have been recognised: that will be corrected in future RAC projects to set an OEL (longer consultation periods, inclusion of additional persons with OEL expertise in the RAC, possibility for a second consultation prior to decision process in case of major changes to conclusions compared to initial position). Despite recognising these shortcomings for the pilot, regrets that RAC is not willing to review the new evidence coming from the industry experts' detailed study and recommends that, in future, the process of setting a new OEL for other substances is not rushed to allow more time to take all evidence into account.

The European Commission's officials concluded that the WPC proposed a value and ACSH are doing the same and there would be likely a transition period.

*End of the call*