
Protecting workers against carcinogens substances

The industry view on the IV amendment to the Carcinogens and Mutagens Directive on Benzene Occupational Exposure Level

4th December 2020

FuelsEurope and Petrochemicals Europe, representing the EU Refining industry and the Petrochemical sector, essential actors in the chemicals' supply chain **support the Proposal for the fourth amendment to the Carcinogens or Mutagens at Work Directive** (CMD, 2004/37/EC) as adopted by the European Commission on 22nd September 2020¹. This amendment introduces the revised Occupation Exposure Level (OEL) for benzene aiming at protecting citizens - particularly the workers – exposed to carcinogens. Welcoming the ***Commission efforts to beat cancer***, underlined also by the Commission's political guidelines², we acknowledge the continuous and long lasting EU efforts to reduce cancer incidence and the objective of adapting the Occupational Health legislation according to the latest scientific findings.

We **support the revised OEL value of 0.2 ppm for benzene** as it is in line with the research that scrutinised nearly 100 publications and studies on benzene toxicology. The studies concluded that a safe level of exposure where no health effect is detected could be set at 0.25ppm; we however accept an additional safety factor for 0.2 ppm³.

For the refining and petrochemical industry sector, lowering the OEL from the current level of 1ppm to the revised value of 0.2 ppm for benzene will have a **substantial positive impact on the EU worker protection**. At the same time, it will require important investments to adapt installations to the highest standards. To realise this, the involved sectors are preparing industry guidelines with recommendations to achieve the substantially improved OEL for benzene. We welcome the attention for the feasibility of the new OEL through the inclusion of a **transitional period** of 4 years after entry into force of this Directive⁴.

Considering the key **importance of the health effect** in order to protect the workers, we welcome that the Commission retained the tri-partite Advisory Committee on Safety and Health at Work (ACSH) priorities for **new or revised scientific evaluations of OELs** based on scientific evidence and a thorough assessment of the technical feasibility and socio-economic impact. Long-standing collaboration in the preparation of the revision of the OELs has been fundamental to achieve an **acceptable OEL** for both workers and employers. We strongly believe that this approach must be perpetuated with involvement of Occupational Safety and Health experts, timely consultation of industry and other stakeholders, and through the existing procedures involving the ACSH including the WPC.

To conclude, we are of the opinion that a **predictable and stable regulatory framework** is needed to unlock investments necessary to amongst others implement the revised OEL for benzene, to secure strategic autonomy in the EU for essential chemicals, to reinforce continued innovation and to protect EU workers.

¹ COM(2020) 571 final referring to the 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

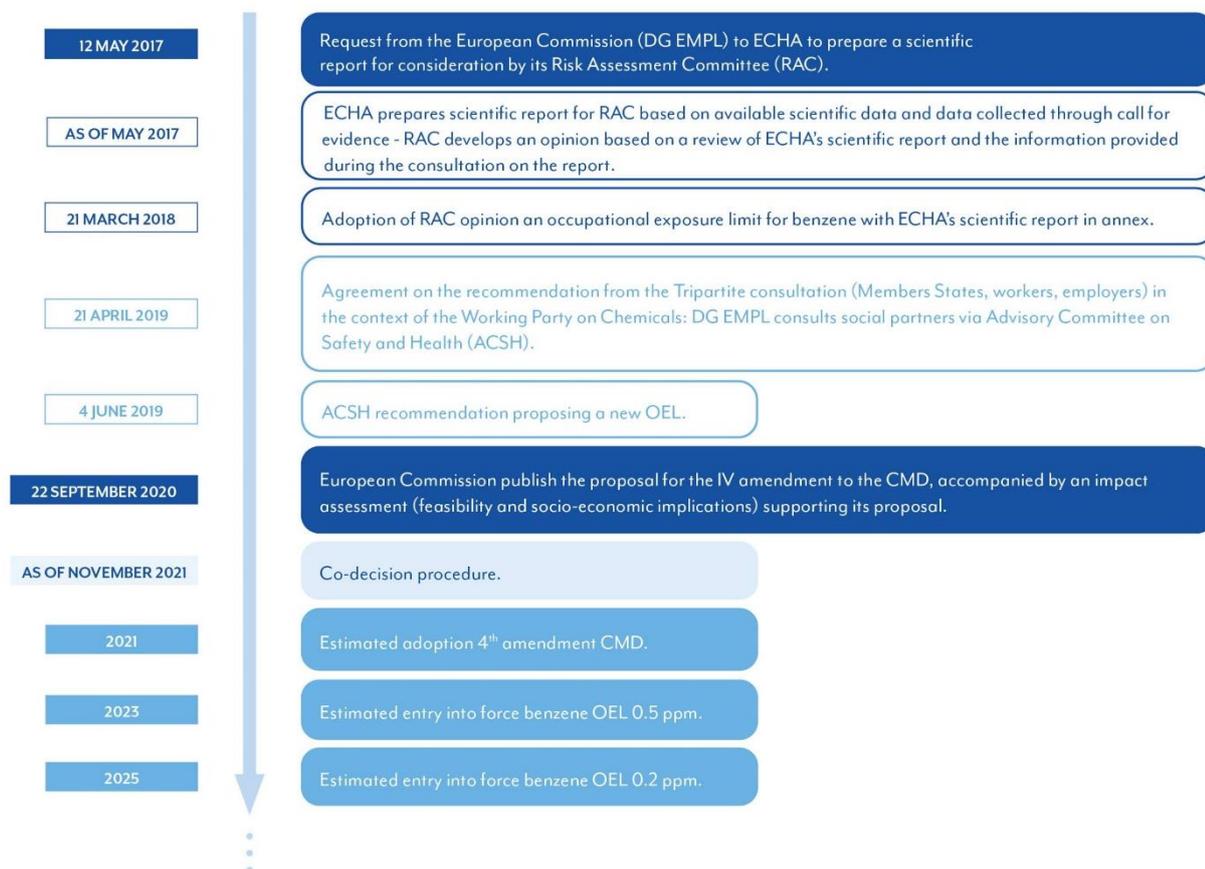
² 'a European plan to fight cancer, to support Member States and stakeholders in improving cancer control and care [...] to reduce the suffering caused by this disease' and for Europe to take the lead in the fight against cancer. Link to the Commission political guidelines: https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

³ Schnatter et al "Derivation of an Occupational Exposure Limit for Benzene Using Epidemiological Study Quality Assessment Tools".

⁴ Notably: From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m³) should apply.

The timeline of the CMD revision

The graph below represents the different steps in the process, which will lead to the adoption of the IV amendment to the CMD and the timeline for implementation of the new OEL for benzene.



ANNEX

Industry contributed to the preparation of the proposal for the fourth amendment to the CMD with a targeted Socio Economic Assessment, which has been performed by an independent consultant (Triskelion⁵). In addition, the following scientific studies published in peer-reviewed journals were used as a reference to support our views:

1. Schnatter et al. 2020. [“Derivation of an Occupational Exposure Limit for Benzene Using Epidemiological Study Quality Assessment Tools”](#). Toxicology Letters, 334: 117-144. This paper focuses on the worker studies on genotoxicity and hematologic toxicity to derive health-based OEL by developing a study on the quality assessment method. -.
2. North C. M. et al. 2020a. [Modes of Action Considerations in Threshold Expectations for Health Effects of Benzene](#). Toxicology Letters, 334: 78-86. This paper focuses on the mode of action for benzene health effects by using highest quality studies identified by quality assessment tool.
3. North C. M. et al. 2020b. Key Event-Informed Risk Models for Benzene-induced Acute Myeloid Leukemia. Toxicology Letters (*under review for publication*). This paper focuses on a method of modelling cancer risk that is closely aligned to the mode of action of benzene.
4. Albertini R. and Kaden D., 2020. [“Mutagenicity Monitoring in Humans: Global versus Specific Origin of Mutations”](#) This paper focuses on identifying sensitivity difference of human mutagenicity biomonitoring assays performed in bone marrow versus peripheral blood. No real evidence was found on the specificity of methods for assessing genotoxicity.

⁵ Socio-Economic Analysis of proposed Occupational Exposure Limit for Benzene:

https://www.petrochemistry.eu/wp-content/uploads/2019/05/SEA-benzene-final_20190314-summary.pdf