



AMFEP-FEDIMA position on OEL (Occupational Exposure Limit) proposals for fungal alpha-amylase in The Netherlands

AMFEP strives to place safe products on the market and give safety guidance to downstream users so that enzymes are handled safely along the supply chain. AMFEP always welcomes authorities' initiatives to protect workers' safety. Occupational exposure limits (OELs) are regulatory risk management tools that can assist in identifying the most appropriate control strategy for specific substances.

Based on scientific research and more than 40 years of experiences throughout the collaboration between AMFEP and a number of industries, AMFEP concludes that the risk for workers is well managed if enzyme exposure is below 60 ng/m³(1).

Presently in The Netherlands a process is ongoing to establish an OEL for fungal alpha-amylase, which is meant to be used throughout the baking industry as well as in other industries. Three values for such OEL have been proposed:

- 0.9 ng/m³ proposed by The Dutch Health Council as a level of exposure at which they suggest there is an additional 1 percent risk of sensitization to fungal alpha-amylase,
- 10 ng/m³ proposed by the sector of industrial bakeries as the value this sector of the baking industry would be able to comply with,
- 60 ng/m³ proposed by the sector of bakery ingredients suppliers and AMFEP, based on scientific arguments

The OEL of 0.9 ng/m³ as suggested by Health Counsel has been commented in the Substance Evaluation Report for alpha-amylase issued by the European Chemicals Agency (ECHA).

<https://echa.europa.eu/documents/10162/a7e7c131-ab90-40e3-a754-577a60da5680>

In this evaluation report it is mentioned that the Health Council of the Netherlands in an earlier publication (2008) concluded that the uncertainties in the studies which are forming the basis for the proposal of 0.9 ng/m³ were too substantial to permit estimates about what value to assign to an OEL. As no new data has been added since then, this conclusion by the Health Council of the

Netherlands should be still valid and the limited data in the studies therefore cannot be sufficient for suggesting any value for an OEL.

The OEL proposal of 10 ng/m³ has been suggested by the sector of industrial bakeries based on a study measuring exposure levels to alpha-amylase conducted at a number of production facilities within this sector. The study showed that using the specific measuring strategy of this study, exposure data were obtained which might make it possible for this specific sector to comply to an OEL of 10 ng/m³.

However, OELs must not be set because a part of the sectors involved in the supply chain can possibly comply. They should solely be set based scientific reasons regarding the workers' safety across the entire supply chain. The sector of industrial bakeries are end-users; therefore, enzyme exposures in this sector are to be expected lower than enzyme exposures in sectors of upstream users like the baking ingredient providers as well as the manufacturers of the substance. It has been demonstrated in a similar study that higher exposure levels indeed are present at upstream users of alpha-amylase, and that the upstream users would be unable to comply with an OEL of 10 ng/m³. The arbitrary OEL suggestion of 10 ng/m³ is not based on any scientific dose-response relationship, but solely based on practical exposure data covering only a part of the complete value chain, we therefore conclude that this proposed OEL value should be abandoned. More importantly, as shown below, workers would be protected if exposure is kept below 60 ng/m³.

The OEL set at 60 ng/m³ was proposed by the sector of bakery ingredients suppliers and enzyme manufacturers. This value is based on scientific data combined with more than 40 years of experience throughout a number of industries and is expected to provide a safe working environment for the entire bakery industry, just as it is already currently doing so in other industries.

Several studies on the dose-response relationship have been conducted (2,3) and in a peer reviewed paper (1) an overview is given of studies leading to the establishment of the acceptable exposure limit for enzymes in terms of the DMEL value (Derived Minimum Effect Level) of 60 ng/m³ for occupational exposure. This limit is adopted by the European Chemicals Agency (ECHA), and it is valid for all enzymes including fungal alpha-amylase for all industries throughout EU.

In conclusion, the OEL proposal of 60 ng/m³ meets the basic science-based requirements for establishing an OEL where workers' risk is well managed, and it is already showing its feasibility throughout EU in terms of a DMEL value. Hence AMFEP and FEDIMA strongly propose that this limit is also adopted as the OEL for fungal alpha-amylase in the Netherlands.

References:

- 1) D.A. Basketter, C. Broekhuizen, M.Fieldsend, S. Kirkwood, R.Mascarenhas, K. Maurer, C. Pedersen, C. Rodriguez, H.E Schiff. 2010. Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH. *Toxicology* 268, 165-170.
- 2) D. A. Basketter, F. H. Kruszewski, S. Mathieu, D. B. Kirchner, A. Panepinto, M. Fieldsend, V. Siegert, F. Barnes, R. Bookstaff, M. Simonsen & B. Concoby. 2015. Managing the Risk of Occupational Allergy in the Enzyme Detergent Industry. *Journal of Occupational and Environmental Hygiene*, 12: 431–437
- 3) A. I. Larsen, C. R. Johnsen, J. Frickmann, et al. 2007. Incidence of respiratory sensitisation and allergy to enzymes among employees in an enzyme producing plant and the relation to exposure and host factors. *Occup Environ Med* 64: 763-768