



Amfep-Fedima statement

Date: 1 September 2015

Re. Dutch Health Council amylase report: Fungal alpha-amylase (derived from the fungus *Aspergillus oryzae*) - Health-based recommended occupational exposure limit

Fungal alpha-amylases are used for flour correction, helping mills and bakery ingredient companies to ensure consistent bread quality. The addition of a fungal alpha-amylase, in amounts recommended for the baking industry, corrects the deficiencies in the flour without changing its baking quality. Key benefits are 1) standardizes flour with a lower cereal alpha-amylase content, 2) ensures a fine and uniform crumb structure and 3) helps gas production in hydrolyzing damaged starch producing maltose during the yeast fermentation and 4) ensures prolonging oven rise.

Enzymes are proteins. Similar to other protein allergens such as in flour and pollen, enzymes may in some circumstances cause respiratory sensitization when inhaled by individuals exposed repeatedly to sufficiently high airborne concentrations of enzyme dust or aerosols. Allergy symptoms are similar to hay fever: persistent sneezing, runny nose, watery eyes, breathing difficulties and coughing. We would like to emphasize that enzymes including alpha-amylase are not associated to food allergy or to allergy resulting from skin contact.

The safety concern assigned to potential respiratory sensitization raised in the Dutch Health Council amylase report is only related to workers. There is no concern for respiratory sensitization due to enzymes in consumers.

Amfep (The association of Manufacturers and Formulators of Enzyme Products) as well as Fedima (The European federation of manufactures and suppliers of ingredients to the bakery, confectionery and patisserie industries) have been aware of this safety risk for workers and are providing safety stewardship to companies using enzyme products. Our experience for more than 40 years has proven that enzyme can be safely used in working places.

However, we have observed that authorities have put increasing focus on occupational asthma in general. Today there is no Occupational Exposure Limit (OEL) for alpha-amylase. In November 2014 the Dutch Health Council published the report "Fungal alpha-amylase (derived from the fungus *Aspergillus oryzae*) - Health-based recommended occupational exposure limit" in which a very low OEL is proposed.

Amfep contacted the Dutch authorities in December 2014 and addressed that Amfep is very concerned about the OEL proposal by the Dutch Health Council report, and is also concerned about the content in the amylase report as well as on the consultation process prior to issuing the report. Obviously, the industry was not properly involved in the review process of the Dutch Health Council amylase report, and moreover the OEL proposed in the report is very low and seems hardly achievable.

Amfep and Fedima are striving to get closely involved, and Amfep and Fedima members will join the further processes for OEL setting in the Netherlands.