

Brussels, 16 May 2023

## **AMFEP comments on Spain Draft Royal Decree on Processing Aids used in Food Processing and Production Processes (2023/114/E)**

**The Association of Manufacturers and Formulators of Enzyme Products (AMFEP) welcomes the opportunity to comment on Spain's draft Royal Decree on processing aids used in food processing and production processes (Notification number 2023/114/E).**

AMFEP is an EU-based association created in 1977 and consists of 30 members, representing over 90% of the European and over 80% of the world enzyme market. We overall welcome the efforts undertaken by the Spanish authorities in order to regroup all relevant pieces of legislation into one Decree. However, AMFEP has a very specific concern regarding the placing of enzymes on the Spanish market.

### Placing enzymes on the EU market

Until the EU list of food enzymes is drawn up, national rules on the marketing and use of food enzymes and food produced with food enzymes will continue to apply in EU countries, as per Article 24 of Regulation 1332/2008. In the absence of national law, the placing of food enzymes on the EU market is governed by the provision of Regulation (EC) No 178/2002 on the General Food Law. AMFEP members legally place their products on the market in accordance with the EU rules, and until the establishment of the first Union list, all existing rules remain applicable.

### Pre-market Approval System

At present, only two EU Member States have a pre-market approval system for food enzymes, i.e. France and Denmark. In France, approved food enzymes are mentioned on the list of processing aids, together with the food processes in which they can be used. In Denmark, approved food enzymes are not published on a positive list. The approval for each individual food enzyme is granted directly to the applicant (manufacturer, importer and/or user), specifying for which food application(s) the food enzyme can be used.

### AMFEP concerns regarding the Mutual Recognition principle as applied in Spain

AMFEP is pleased to see that the Spanish decree includes provisions related to the Mutual Recognition principle, which allows enzymes safety assessed and legally placed on other national markets to also be placed on the Spanish market. However, some AMFEP members have reported that enzyme products legally placed on national markets other than France and Denmark cannot be commercialised in Spain.

We are concerned about the strict implementation of the Mutual Recognition principle by the Spanish authorities, which could hinder the free movement of goods within the EU. Enzyme products legally placed on a Member State's market should not be forbidden access to the rest of the EU market. Therefore, we recommend the Spanish authorities to ensure that enzyme products legally placed on the markets of other Member States are allowed to be sold in Spain. This should also apply to food products legally manufactured with the help of enzymes legally placed on any Member States market and entering the Spanish market.

### Conclusion

AMFEP is committed to promoting cooperation on regulatory and safety aspects of enzymes. We believe that the mutual recognition principle is a fundamental component of the EU's internal market, and we strongly recommend the Spanish authorities to ensure its proper implementation in the final version of the decree.