

FOOD ENZYMES IN THE EUROPEAN UNION

The information required for a dossier submission varies depending on the nature of the food enzyme, intended use, history of consumption and estimated exposure.



Background

Regulation (EC) No 1332/2008 on food enzymes covers enzymes that are added to food to perform a technological function, including use as processing aids. The Regulation establishes a Community List of approved food enzymes, their conditions of use in foods, and labelling requirements. All new and existing food enzymes must undergo an authorisation procedure prior to inclusion on the Community list. The deadline for submitting an application for inclusion of a food enzyme for formal authorisation in the European Union (EU) was March 11, 2015.

Your Challenge

Previously, food enzymes other than those used as food additives were not regulated or were regulated non-uniformly under individual Member State legislation. A new regulation on food enzymes was recently established in the EU in order to harmonise the rules on food enzymes at the level of the European Community (EC), and was entered into force on January 20, 2009, except for labelling provisions, which were applicable from January 20, 2010.

Under Article 17(2) of the Regulation, the industry has 42 months from September 11, 2011 to submit dossiers for both existing and new enzymes. Once the Community List of food enzymes is published and placed into effect, only those enzymes included in the list may be placed on the market and used in foods.

Our Solutions

Intertek Health, Environmental & Regulatory Services (HERS) offers the expertise necessary to provide reliable advice in the area of food enzymes.

Our services include:

- Identification of the appropriate regulatory strategy and data requirements for a submission;
- Conducting a feasibility assessment and providing recommendations for generation of information for identified technical and scientific data gaps;
- Preparing dossiers for submission to regulatory agencies for approval of use of an enzyme in the European Union; and
- Providing stewardship of applications through the complex scientific review by the European Food Safety Authority (EFSA) and regulatory procedures (The European Commission and Member States) to approval.

The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for over 25 years. Our European office is well-positioned to liaise with the European Commission and the European Food Safety Authority on behalf of our clients. Our extensive expertise in food ingredients, additives and enzymes ensures that we help bring your products to market in a timely and efficient manner.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

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