



Association of Manufacturers and Formulators of Enzyme Products

AMFEP/07/16

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Amfep Statement

The Scope of the EU GM Food and Feed Regulation (EC 1829/2003)

This document replaces [Amfep/06/27](#) of 13JUN2006

Introduction

Genetically modified food and feed are regulated in the EU in the GM Food and Feed Regulation (EC)1829/2003.

Recital 16 of this Regulation states that: "...processing aids which are only used during the food or feed production process are not covered by the definition of food and feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation..."

On September 24, 2004 the Standing Committee on the food chain and animal health (section on genetically modified food and feed and environmental risk) clarified the scope of the Regulation further by stating that:

"food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation 1829/2003".

In its report on the implementation of Regulation 1829/2003 (COM(2006) 625 final) from 2006-10-25, the EU Commission further explains about fermentation processes that "when a GM micro-organism is used as a processing aid the food and the feed resulting from such production process are not to be considered as falling under the scope of the Regulation".

Amfep Statement on the scope of the EU GM Food and Feed Regulation

Amfep is satisfied that a final clarification has now been reached concerning the status of food and feed produced by fermentation using genetically modified micro-organisms.

Based upon this clarification Amfep concludes that in the case of enzymes this means that:

Food and feed enzymes are outside the scope of the GM Food and Feed Regulations and thus do not have to be GM-labelled when:

- 1). They are used as processing aids, AND/OR
- 2). They are produced by fermentation using a genetically modified microorganism (GMM) in accordance with the requirements in the contained use directive (90/219EEC as amended by 98/81/EC) and consequently do not contain the GMM.

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