# Food enzymes

2006/0144(COD) - 10/03/2008 - Council position

The common position introduced a number of modifications to the text, many of which were based on, and inspired by, Parliamentary amendments tabled at first reading. The Council, on its own initiative, introduced some of the Parliamentary amendments in each of the three sectoral proposals, with a view to harmonising the provisions. The common position incorporates in full, or in principle, 21 of the 33 amendments proposed by Parliament at first reading.

In summary, the main elements of the common position are as follows:

**A single legal base:** accepting Parliamentary suggestions, the Council has decided to retain Article 96 of the TEU as the sole legal base for the proposal agreeing that agricultural aspects are merely incidental and not core to the proposed Regulation's objectives.

**Misleading the consumer:** the provisions relating to misleading the consumer have been integrated into recital 6 of the proposal.

**Protecting the environment:** the Council has modified the proposal so that prior to an authorisation being granted, scientific evaluators should take any environmental impacts into consideration.

**Regulatory comitology procedure with scrutiny:** the Council has agreed to introduce the new regulatory procedure with scrutiny for the adoption of measures that supplement the Regulation.

**Interpretation decisions**: all provisions relating to interpretations have been regrouped into a new single article. Given that they do not supplement the Regulation they have been made subject to the regulatory comitology procedure without scrutiny.

**Transitional measures for products already on the market**: in the common position, the Council has provided for a one year transitional period, from the date of entry into force of the proposed Regulation. Foods lawfully placed on the market or labelled during this year may be marketed until their date of minimum durability or use-by-date.

**Provisions prohibiting the placing on the market of non-compliant food enzymes:** For reasons of clarity, legal certainty and the correct functioning of the internal market, the Council has inserted an article that prohibits producers from placing non-compliant food enzymes on the market. This is consistent with the proposals concerning flavourings and food additives.

**Authorisation of enzymes falling within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed:** the Council agrees, subject to some redrafting, that the two authorisation procedures for any substance can be carried out simultaneously.

**Labelling:** Labelling provisions have been streamlined and reinforced. A distinction is drawn between "business to business" labelling and labelling requirements for products intended for sale to the final consumer. Although the order of provisions is different from that proposed by Parliament, the principles underlying the content are the same.

**Amendments not incorporated into the common position:**

**Enzymes added to food for nutritional purposes and digestive aids:** the Council has decided that it is unnecessary to make an explicit reference to enzymes intended for human consumption (such as enzymes used for nutritional purposes or as digestive aids) given that they are excluded from the scope of the proposed Regulation. In fact, the scope of the proposed Regulation only includes enzymes added to food to perform a technological function. Based on this logic, the Council has therefore also decided to exclude cultures that are "traditionally" used in the production of food (such as cheese and wine) and which may incidentally produce enzymes. By deleting the word "traditionally" the scope for exclusion would be enlarged and could result in cultures which, are added to food for the technological function of the enzyme that they produce, not being adequately regulated.

**Enzymes that benefit the consumer:** the Council has decided not include this amendments on the grounds that the proposed Regulation covers enzymes that are added to food for a technological function and hence the use of enzymes in most cases improves the environmental performance of the production process, which brings an indirect rather than direct benefit for the consumer.

**GMOs – Labelling:** given that food enzymes remain subject to labelling provisions defined in Directive 2000/13 relating to the labelling, presentation and advertising of food stuffs, as well as Regulation (EC) No 1829/2003 on genetically modified food and feed, the Council decided to adopt a prudent approach and did not accept amendments that could interfere with the scope of the horizontal Regulations already in force.

**GMOs – Unique identifier:** on the grounds of proportionality and simplification, the Council has deleted any reference requiring enzyme specification in the Community list of food enzymes, since this is considered superfluous.

**Precautionary principle:** the precautionary principle is a general principle that underlies general food law and as a result applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analyses framework, the precautionary principle can only be taken into account within the context of risk management, never in the risk assessment phase – as suggested by Parliament.

**Publication of the opinions of the European Food Safety Authority (EFSA):** given that publication of EFSA opinions is already provided for in Regulation (EC) No 178/2002, the Council considered this amendment superfluous.

**Re-evaluation every 10 years:** the Council considers that a system of continuous observation and re-evaluation provides adequate food safety. An additional review every 10 years would represent an unnecessary administrative burden on producers, users, the EFSA, the Commission and the Member States.

**Decisions submitted to the comitology procedure without scrutiny:** Decisions on whether or not a given substance falls within the scope of the proposed Regulation are interpretive in nature and will not supplement the Regulation. As a result they do not fall within the scope of the regulatory procedure with scrutiny.

**Definition of enzymes:** An additional definition of "enzymes" when "food enzymes" is already defined is not, in the Council's opinion, necessary.

**Specification of the entries of food enzymes in the list:** the Council decided to maintain the phrase "where necessary" when providing for certain specifications. The need for such labelling concerns a restricted number of cases only, where the physical composition of the food has been changed due to the use of a food enzyme. In such cases only should the consumer be informed of the fact.

**Labelling:** although the Chapter of Labelling has been reorganised by the Council, the principles underlying the provision's content remain the same. However, in cases where provisions are already established in other EU legislative acts, they have not been adopted in the common position. For example, Parliament's proposal requiring labels to provide information on the side-effects of enzymes in excessive quantities has not been included on the grounds that the EFSA already took such information into account during the revaluation procedure. Further, information on the technological function of an enzyme, as proposed in one Parliamentary amendment would, according to the Council, be of little use to non-specialists.

To conclude, the Council is of the view that the common position represents a fair balance of concerns and interests that respects the proposed Regulation's objectives.