



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.05.1996
COM(96) 229 final - COD 426

OPINION OF THE COMMISSION

pursuant to Article 189 b (2) (d) of the EC Treaty,
on the European Parliament's amendments
to the Council's common position regarding the

proposal for a
EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC)

on novel foods and novel food ingredients

AMENDING THE PROPOSAL OF THE COMMISSION

pursuant to Article 189 a (2) of the EC Treaty

Introduction

On 7 July 1992 the Commission presented a proposal for a Council Regulation on novel foods and novel food ingredients. (COM(92)295 final - SYN 426).

Further to the opinion of the European Parliament delivered on 27 October 1993, the Commission prepared an amended proposal which was submitted to the Council on 1 December 1993 (COM(93) 631 final - COD 426).

On 23 October 1995 the Council adopted a common position by qualified majority.

On 12 March 1996, the European Parliament adopted 6 amendments to the common position adopted by the Council on 23 October 1995 in respect of the Commission proposal for a Regulation of the European Parliament and of the Council on novel foods and novel food ingredients.¹

Objectives of the Regulation

At present, within the European Union, foodstuffs can generally be placed on the market without any pre-marketing assessment or authorisation.

Recently, a new range of raw materials, processes and technologies, including but not only modern biotechnology and genetic modification techniques have emerged. These innovations aim for example at improving the nutritional and dietary aspects of foodstuffs, at promoting greater technical efficiency in production processing or distribution, at reducing the risk of microbiological contamination or at growing crops by using fewer pesticides. In order to ensure consumer protection and to avoid the creation of trade barriers in the internal market, it was felt necessary to create a Community procedure for the placing on the market of "novel foods" resulting from these innovations and to provide for a safety assessment and for precise labelling provisions. The proposal is therefore of major importance, from the point of view of consumer protection and information as well as for smooth functioning of the internal market and the diffusion of new technologies in the agri-food sector. The Commission believes that there is general agreement between the institutions about the urgent need for Community legislation on this issue.

¹ OJ n° C 190, 29.7.1992, p.3

Opinion of the Commission

In accordance with paragraph 2 (d) of Article 189b of the EC Treaty, the Commission gives the following opinion on these amendments.

The Commission agrees with Parliament that the Regulation should be brought into force as soon as possible, and it can therefore give a favourable opinion on **amendment 48** which reduces the period for implementation of the Regulation from 12 months to 90 days;

The Commission understands the concern expressed by the Parliament in **amendment 53** to ensure that food additives, flavours and extraction solvents meet the same level of safety as novel foods, and shares this principle. However, it cannot give a favourable opinion on the wording of amendment 53 since it implies that the exclusion is conditional, requiring specific action to be taken. The Commission would point out that the framework Directive on food additives (89/107/EEC)² and the Common Position agreed by the Council on 22 December 1995 on a proposal for a regulation of the European Parliament and the Council laying down a Community procedure for flavouring substances intended for use in foodstuffs³ already provide for the same level of safety as for novel foods, including compulsory consultation of the scientific Committee for Food on matters likely to affect public health. In respect of extraction solvents, Directive 83/344/EEC⁴ already provides for a similarly high level of protection of public health.

Amendment 54 provides that the labelling rules of Article 8 apply to novel foods and novel food ingredients which are the subject of the simplified notification procedure. In isolation, this amendment presents no difficulty, since it simply clarifies the intention of the Common Position which is to apply a single coherent set of labelling rules to all categories of novel foods. However, this amendment must also be seen in conjunction with **amendment 55** which deletes the word "significant" in Article 8 (1) (a) of the Common Position so that labelling of novel foods will be required in all cases where a novel food is different from the conventionally produced food. It should be recalled that labelling of significant differences is the mirror-image of the application of the internationally recognised scientific principle of "substantial equivalence" on which the Regulation is based. Under the common position, an operator would therefore know that if he can provide evidence that the food or food ingredient is clearly substantially equivalent, then the notification procedure could be used and the product would not

² OJ n° L 40, 11.2.1989, p. 27

³ OJ n° C 59, 28.2.1996, p. 37

⁴ OJ. n° L 157, 24.6.1988, p.28

require any specific labelling. With the new formulation of Amendment 55, the operator cannot be certain that his substantially equivalent product does not present negligible differences. Therefore, the notification procedure may become unusable in practice.

The Commission understands the concern of Parliament to ensure that consumers are informed of all differences between novel foods and conventionally produced foods. Nevertheless, the application of a criterion that would lead to special labelling requirements even for novel foods which are substantially equivalent is likely to give rise to practical difficulties. Particularly in the case of fruit and vegetables, climatic and geographical factors such as soil types may have noticeable effects on the properties of the final product. For example, climatic variations from year to year result in differences in the final crop. In such circumstances it may be difficult to decide what are the precise parameters to be used in determining whether a novel food differs from its conventional counterpart. In order to provide meaningful information for the consumer, the Commission considers that a product should only be labelled when it presents characteristics which fall outside of the range of natural variations and which may affect the composition, the nutritional value or effects or the intended use of the products. The Commission is therefore unable to accept these 2 amendments and considers that all possibilities should be explored in order to outline the concept of difference so that it provides more legal certainty for economic operators.

The current text of the common position provides that the presence of a genetically modified organism does not need to be indicated on the labelling when this presence is solely due to agricultural characteristics and does not modify the characteristics of the foodstuff itself. This exemption would cover, for example, corn which is genetically modified to increase insect resistance. **Amendments 51 and 52** have the effect of deleting this exemption. The Commission does not share the point of view of Parliament that the presence of genetically modified organisms should be indicated on the labelling of the foodstuff concerned in all cases, even when this presence has no effect on the properties of the foodstuff. The purpose of food labelling is to inform consumers about the characteristics of the food. Information about methods of production and agronomic properties is required only where these have an effect on the finished product. Moreover, the introduction of such a provision would make it necessary either to establish separate distribution systems for foods containing GMOs -which would be extremely difficult to implement from practical point of view- or to provide for systematic labelling in all cases that the produce may contain GMOs. Particular problems arise in respect of imports, since none of the Community's major trading partners provide for labelling in such cases, and GMO produce will usually be mixed with conventional produce before shipment to the EU.

In addition, amendment 51 requires the labelling of "an organism genetically modified by genetic engineering methods". The Commission considers that this formulation implies legal uncertainty, because the concept used is not sufficiently precise and does not correspond to an already existing definition. A clear definition for GMO's is provided by Directive 90/220/EC and this is why it is proposed to use it also for labelling of novel foods.

On the basis of this analysis, the Commission has incorporated one amendment (n° 48) in its modified proposal. The Commission would, however, emphasise that there is general agreement on the urgent need to establish a satisfactory regulatory framework for novel foods at Community level. To this end the Commission will participate constructively with the institutions in the remaining stages of the institutional decision-making procedure using all available possibilities with a view to resolving the outstanding problems identified above.

**Amended Proposal for a
Regulation of the European Parliament and of the Council
on novel foods and novel food ingredients**

(presented by the Commission pursuant to Article 189 A (2) of the EC Treaty)

Current Proposal

Amended proposal

Article 15, 1st paragraph

This regulation shall enter into force 12 months following the day of its publication in the Official Journal of the European Communities.

This regulation shall enter into force 90 days following its publication in the Official Journal of the European Communities.

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DOCUMENTS

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