COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.09.2001
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2001/0199 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs

(presented by the Commission)

EXPLANATORY MEMORANDUM

(1) In the White Paper on Food Safety, the Commission announced its intention of proposing an amendment to the Labelling Directive 2000/13/EC, especially with regard to the current possibility of not indicating the components of compound ingredients which form less than 25% of the final product.

(2) Directive 2000/13/EC of 20 March 2000 (OJ L 109 of 6.5.2000) consolidated Directive 79/112/EEC and its many amendments into a single text. Article 3 establishes that the list of ingredients must appear on the label of foodstuffs, and Article 6 specifies detailed rules for indicating ingredients, providing, among other things, for derogations or simplified indications.

(3) Article 6, paragraph 8, allows a compound ingredient to be included in the list of ingredients under its own designation, provided it is immediately followed by a list of its own ingredients; however, such a list is not compulsory where the compound ingredient constitutes less than 25% of the finished product (the "25% rule"), except in the case of additives.

(4) The question of additives is dealt with in Article 6, paragraph 4, which specifies the cases where additives are to be regarded as ingredients and thus included in the list. According to this provision, additives which are used as processing aids and additives contained in an ingredient of the foodstuff but serving no technological function in the finished product do not have to be mentioned on the label.

(5) As far as rules on simplification are concerned, it is possible by virtue of Article 6, paragraph 6, to indicate an ingredient incorporated into a foodstuff merely by the name of the category to which it belongs (e.g. "oil" together with the adjective "vegetable" or "animal" as appropriate; "crystallised fruit", "fish", etc.).

(6) The result of these provisions is that the consumer is often badly informed about the exact composition of purchased foodstuffs.

(7) The Commission believes it is advisable to provide more information on the composition of foodstuffs by abolishing the 25% rule applicable to compound ingredients.

(8) The 25% rule was introduced into Community legislation more than 20 years ago with the objective of avoiding inordinately long lists of ingredients. It is based on the principle that the consumer knows the composition of compound ingredients and can therefore deduce, for example, that jam added to biscuits is prepared with fruit and sugar.

(9) However, food production has become more complex and people eat a lot more processed foods. In the past few years, consumers have repeatedly expressed the wish to be better informed about the foodstuffs they purchase, and specifically about their composition, even if full ingredient labelling will inevitably make ingredient lists longer. Furthermore, the many recent food scares have reinforced this need for information.

(10) Already in 1997, when the Green Paper on the general principles of food law in the EU was published, Member States' comments on this issue where unanimous. They all asked for a change to the current rule. It must be noted that some Member States, before joining the EU, did not have the 25% rule in their legislation, without this causing specific problems in terms of the legibility of the ingredient list on labels of food products purchased by consumers.

(11) The question of the 25% rule must be examined not only in the context of better information for all consumers, but also with regard to food allergies, an issue which comes under food safety and health.

(12) Indeed, the number of people suffering adverse reactions to certain foods seems to be increasing. These can take various forms, ranging from reactions leading to illness and reduced quality of life to life-threatening allergic reactions. The dose of food allergen required to induce an immunological reaction varies, but in many instances it can be very low, in particular in the case of life-threatening allergies. Often the only treatment is total avoidance of the allergen. It must therefore be ensured that the legislation enables the people concerned to obtain such information.

(13) For some consumers who suffer from allergies or intolerances to certain substances, the lack of detailed information is a handicap in that they are never sure that the product they are buying does not contain the allergen they must not ingest.

(14) In its report on adverse reactions to foods and food ingredients dated 22 September 1995, the Scientific Committee for Food (SCF) stated that the incidence of food allergy is such as to affect the lives of many people, causing conditions ranging from very mild to potentially fatal. The SCF acknowledged that common food allergens include cow's milk, fruits, legumes (especially peanuts and soybeans), eggs, crustaceans, tree nuts, fish, vegetables (celery and other foods of the Umbelliferae family), wheat and other cereals. It also noted that adverse reactions to food additives may occur and that food additive avoidance is often difficult since not all food additives may be included in labelling.

(15) Furthermore, the study of nutritional factors in food allergies and food intolerances, carried out in 1997 under the agriculture and agro-industry R&D programme, clearly stated that "common food allergens such as milk, eggs, soya and wheat are constituents of a wide variety of prepared foods, and in most cases labelling is incomplete and often misleading. This can have devastating consequences for a food-sensitive person. In fact almost all persons who died from food anaphylaxis had a history of allergic reactions to the food allergen responsible for the death, but they were unaware that the allergen was present in the food they ate. **Therefore, it is imperative that all processed foods sold in the European Community countries be clearly labelled with the list of the ingredients and of the starting materials**". (Chapter 10, Prof. C. Ortolani, Head of the Department for Prevention, Diagnosis and Treatment of Allergic Disease, Niguarda Hospital, Milan, and Prof. E. A. Pastorello, Professor of Allergology and Clinical Immunology, University of Milan Polyclinic).

(16) This same study states in its concluding remarks that, while awaiting the scientific and technological progress which will enable the allergenic potential of foods to be reduced, "the best policy for the EU is to make certain that the user receives correct and detailed information about each type of food and each ingredient in the final product, and that manufacturers respect these requirements".

(17) The Commission believes it is advisable to assist consumers who have allergies or intolerances as much as possible by providing them with more comprehensive information about the composition of products. This would ensure better consumer information in general as to the composition of a food product, while at the same time ensuring the necessary information for those consumers who, for health or ethical reasons, have to, or want to, avoid certain ingredients.

(18) Simply abolishing the 25% rule would mean that all ingredients would have to appear on the label, but some ingredients could still benefit from a derogation under Directive 2000/13/EC. In particular, the possibility of identifying ingredients by the name of the category to which they belong (Article 6, paragraph 6), as well as derogations for the declaration of additives, will continue to apply, and it is also necessary to make provision for procedures to avoid excessively complex legislation.

(19) To ensure that the provisions concerned are fully consistent with the objectives as described above, it is necessary, for certain categories of ingredient capable of producing allergic reactions, including those not yet fully identified, to remove the possibility of using only the name of the category; such is the case with fruits and vegetables. For the categories allowed to include clearly identified allergens, use of the category name only must be possible only if the allergen concerned, which will appear in an appended list, is not present. Finally, one additive – also included in the appended list – will have to be mentioned with no derogations possible.

(20) The list appended to this proposal therefore specifies the allergenic ingredients or substances which must be declared under their specific name in the labelled list of ingredients and which may not under any circumstances be listed using only the name of the category to which they belong. The list also includes one additive which must always be declared, with no possibility of applying the derogation for additives provided for by Directive 2000/13/EC. In addition, the list needs to be updatable quickly whenever necessary; the proposal therefore also introduces a procedure enabling the Commission to amend the list subject to the opinion of the Standing Committee on Foodstuffs. Finally, the Scientific Committee for Food will be consulted with a view to updating its aforementioned 1995 report, in particular as regards new allergens, and additives, processing aids, solvents and bases.

(21) Lastly, in order to achieve the objective of a high level of health protection by improved information on the composition of foodstuffs, it would be inconceivable to exclude alcoholic drinks from the obligation to indicate the presence of an ingredient that is recognised to be an allergen. This obligation is therefore also included in the proposal, without prejudice to the establishment of rules for the labelling of the ingredients of these drinks, which is the subject of a separate proposal that has already been sent to the European Parliament and the Council.

(22) It is therefore proposed that Directive 2000/13/EC be amended to abolish the 25% rule, to establish a list of allergens which will have to appear on the labelling of foodstuffs, and to remove the possibility of using the name of the category for certain ingredients.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

(1) In order to achieve a high level of health protection for consumers and to guarantee their right to information, it must be ensured that consumers are appropriately informed about foodstuffs, *inter alia* through the listing of all ingredients on labels.

(2) By virtue of Article 6 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[4], certain substances need not appear in the list of ingredients.

(3) Certain ingredients contained in foodstuffs are the cause of allergies or intolerances in consumers in the Community, and some of those allergies or intolerances constitute a danger to the health of those concerned.

(4) The Scientific Committee for Food (SCF) has stated that the incidence of food allergies is such as to affect the lives of many people, causing conditions ranging from very mild to potentially fatal.

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1 OJ C
2 OJ C
3 OJ C
4 OJ L 109, 6.5.2000, p. 29.

(5) The SCF has acknowledged that common food allergens include cow's milk, fruits, legumes (especially peanuts and soybeans), eggs, crustaceans, tree nuts, fish, vegetables (celery and other foods of the Umbelliferae family), wheat and other cereals; it has also noted that adverse reactions to food additives may occur and that the avoidance of food additives is often difficult since not all of them are invariably included on the labelling.

(6) The most common food allergens are found in a wide variety of processed foods.

(7) Even if labelling, which is intended for consumers in general, is not to be regarded as the only medium of information acting as substitute for the medical establishment, it is nevertheless advisable to assist consumers who have allergies or intolerances as much as possible by providing them with more comprehensive information about the composition of foodstuffs.

(8) The list of allergenic substances includes those foodstuffs and ingredients recognised as causing hypersensitivity and likely to benefit from an exemption under Directive 2000/13/EC. In order to keep up with the development of scientific knowledge, it is important to be able to revise this list rapidly, when necessary. Such revisions should take the form of implementing measures of a technical nature, the adoption of which should be entrusted to the Commission in the interest of simplifying and accelerating the procedure.

(9) In order to provide all consumers with better information and to protect the health of certain consumers, it should be made obligatory to include in the list of ingredients all ingredients present in the foodstuff and, in the case of ingredients known to be allergenic, to declare them by their specific name in all cases, including in alcoholic drinks, allowing no possibility of using the name of the category to which they belong, nor, in the case of additives, any exemption from inclusion in the list of ingredients.

(10) In order to avoid the risk that labelling may become too complex and difficult to read, procedures are needed which make it possible to avoid excessively long lists of ingredients, but without impairing the attainment of the abovementioned objectives. In order to take account of the technical constraints involved in the manufacture of foodstuffs, it is also necessary to authorise greater flexibility with regard to the listing of ingredients used in very small quantities.

(11) Directive 2000/13/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2000/13/EC is amended as follows:

(1) Article 6 is amended as follows:

(a) The following paragraph 3a is inserted:

"3a. Without prejudice to the rules to be established pursuant to paragraph 3, the presence of one or more of the ingredients listed in Annex IIIa in a drink referred to in paragraph 3 shall be mentioned, unless the ingredient(s) concerned is/are included under its/their specific name(s) in the name under which the drink is sold. This indication shall comprise the term "contains", followed by the name of the ingredient(s) concerned".

Where necessary, detailed rules for applying the first subparagraph may be adopted, in accordance with the following procedures:

(a) as regards the products referred to in Article 1(2), of Council Regulation (EC) No 1493/99* under the procedure laid down in Article 75 of that Regulation;

(b) as regards the products referred to in Article 2(1), of Council Regulation (EEC) No 1601/91** under the procedure laid down in Article 13 of that Regulation;

(c) as regards the products referred to in Article 1(2), of Council Regulation (EEC) No 1576/89*** under the procedure laid down in Article 14 of that Regulation;

(d) as regards other products, under the procedure laid down in Article 20(2) of this Directive.

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* OJ L 179, 14.7.1999, p. 1.
** OJ L 149, 14.6.1991, p. 1.
*** OJ L 160, 12.6.1989, p. 1."

(b) The second subparagraph of paragraph 5 is amended as follows:

(i) The fourth indent is replaced by the following text:

"– where fruit or vegetables, none of which significantly predominates in terms of weight, are used in a mixture as ingredients of a foodstuff, they may be grouped together in the list of ingredients under the designation 'fruit' or 'vegetables', immediately followed by a list of the fruit or vegetables present and a phrase such as 'in varying proportions'; in such cases, the mixture shall be included in the list of ingredients in accordance with the first subparagraph, on the basis of the total weight of the fruit or vegetables present,"

(ii) The following sixth and seventh indents are added:

"– ingredients constituting less than 5% of the finished product may be listed in a different order after the other ingredients,

– where ingredients which are similar or mutually substitutable are likely to be used in the manufacture or preparation of a foodstuff without altering its composition, and in so far as they constitute less than 5% of the finished product, they may be referred to in the list of ingredients by means of the phrase 'contains ..... and/or .....', where at least one of no more than two ingredients is present in the

finished product, or 'contains at least one of the following ingredients: …, …, …:', where at least one of no more than three ingredients is present in the finished product."

(c) Paragraph 8 is amended as follows:

(i) The following sentence is added to the first subparagraph:

"However, where the ingredients of the compound ingredient are already listed as single ingredients in the list of ingredients, repetition is not compulsory, as long as an explanatory note, placed near the list of ingredients, clearly informs the purchaser that they are present in the foodstuff as single ingredients and as ingredients of the compound ingredient."

(ii) The second subparagraph is replaced by the following text:

"The list referred to under the first subparagraph shall not be compulsory:

(a) where the composition of the compound ingredient is defined in current Community legislation, and in so far as the compound ingredient constitutes less than 5% of the finished product; however, this provision shall not apply to additives, subject to paragraph 4(c);

(b) for the compound ingredients listed below, with the exception of additives, subject to paragraph 4(c):

(i) preparations of sauces or mustards constituting less than 5% of the finished product,

(ii) mixtures of spices or herbs constituting less than 2% of the finished product;

(c) where the compound ingredient is a foodstuff for which a list of ingredients is not required under Community legislation."

(d) The following paragraph 10 is added:

"10. Paragraph 4(c)(ii) and (iii), the first indent of the second subparagraph of paragraph 6, , and the second subparagraph of paragraph 8 shall not apply to the ingredients listed in Annex IIIa.

Annex IIIa may be amended in accordance with the procedure referred to in Article 20(2)."

(2) In Annex I, the designations "crystallised fruit" and "vegetables", and the corresponding definitions, are deleted.

(3) Annex IIIa, the text of which is set out in the Annex to this Directive, is inserted.

Article 2

Member States shall bring into force, by 31 December 2003 at the latest, the laws, regulations and administrative provisions necessary to:

– permit, as from 1 January 2004, the sale of products that comply with this Directive;

– prohibit, as from 1 January 2005, products that do not comply with this Directive; any products which do not comply with this Directive but which have been placed on the market or labelled prior to this date may, however, be sold while stocks last.

They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

"ANNEX IIIa

Ingredients referred to in Article 6(3a) and (10)

Cereals containing gluten and products thereof

Crustaceans and products thereof

Eggs and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk and dairy products (including lactose)

Nuts and nut products

Sesame seeds and products thereof

Sulphite at concentrations of at least 10 mg/kg"

IMPACT ASSESSMENT FORM

IMPACT OF THE PROPOSAL ON BUSINESSES, WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs)

TITLE OF THE PROPOSAL:

Directive of the European Parliament and of the Council amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs

DOCUMENT REFERENCE NUMBER:

SANCO/2389/2/2000

THE PROPOSAL

1. The aim of the proposal is to make it obligatory to list all the ingredients present in foodstuffs, so as to provide consumers with comprehensive information and allow people suffering from allergies to check for the possible presence of allergens in products.

IMPACT ON BUSINESS

2. Who will be affected by the proposal?

   – The agri-food industry.

   – Approximately 25 000 firms, most of them with more than 20 employees.

   – Firms in all Member States.

3. What measures will businesses have to take to comply with the proposal?

   List on their product labels all the ingredients used in manufacturing the product.

4. What economic effects is the proposal likely to have?

   – on employment: none

   – on investment and the creation of new businesses: none

   – on the competitive position of businesses:

   No changes will be needed to the labelling of foodstuffs which do not contain a compound ingredient constituting no more than 25% of the finished product or of foodstuffs whose manufacturers already list all ingredients.

   Only the labelling of complex products which contain one or more compound ingredients will have to be changed to comply with the proposed legislation.

For these products, the list of ingredients is therefore bound to be longer, but it is not possible to anticipate precisely how much larger the labelling surface would have to be.

However, in most of these cases, the increase in size should not be substantial, as:

– additives which need not be mentioned in the labelling under existing legislation will have to be mentioned in future only if they are manufactured using products likely to cause allergies or intolerances;

– it is possible to avoid repeating the mention of the same ingredient.

In one example submitted to the Commission by a manufacturer, the labelling of a complex prepared meal containing several compound ingredients would increase from a list of 31 ingredients under the present provisions to a list of 34 ingredients under the proposed legislation, with the constituents of compound ingredients being pooled in order to avoid repetition.

The cost of labelling complex foodstuffs should therefore not be affected significantly in the majority of cases.

Even though changes will be few in number, the labelling of certain products will still have to be modified, entailing costs for the companies concerned.

These costs are very difficult to quantify, as they depend on the number of products whose labelling would have to be modified. The cost of producing a labelling layout varies between EUR 1 000 and 2 000.

Nevertheless, the Commission feels that these costs can reasonably be expected to have only an extremely marginal effect, if any, on the competitiveness of businesses, for the following reasons.

The additional labelling obligation will not enter into force until after a transitional (transposition) period, and it will be possible for all stocks of products placed on the market or labelled before the date of implementation of the measure still to be sold, even if their labelling does not comply with the Directive.

This transitional period will for example allow companies to bring product labelling into line with the new provisions in conjunction with an already planned change to labelling for other reasons. It is in fact quite common for labels to be changed independently of changes to legislation.

Labelling which provides total transparency by listing all ingredients can only boost the confidence of consumers, including those who suffer from allergies and play safe by not purchasing products if they are not sure which ingredients they contain.

The obligation to list all ingredients, in force in other countries such as the USA, can therefore constitute a positive factor in commercial terms.

Technical adaptations are envisaged in order to provide for flexibility in terms of the listing of ingredients used in very small quantities.

5. There is no need or justification for special arrangements for small or medium-sized enterprises.

CONSULTATION

– Confederation of the Food and Drink Industries: agreement

– Association of Cider and Fruit Wine Industries: agreement.

– Confederation of European Spirits Producers: did not comment.

– EUROCOMMERCE : agreement.