New Directive 2003/89/EC (1), published on 25 November 2003, has significantly amended Directive 2000/13/EC (2) with regard to the indication of ingredients on food labels and particularly to the mandatory labelling of those ingredients that are considered the most common food allergens. The objective is to provide more comprehensive information for consumers with allergies and to allow them to identify those ingredients and foods that they must avoid. The new legislation will be fully implemented by the end of 2005, once the transposition into national legislation has been completed (i.e. on 25 November 2004) and after the transitional period allowing the industry time to meet the new regulatory requirements (i.e. 25 November 2005).

What are the major changes?

The new regulation on food labelling reinforces the general rule that all substances that have been intentionally introduced in a foodstuff should be indicated under their specific name in the list of ingredients. Before Directive 2003/89/EC was adopted, there were three main exemptions from this principle.

The first exemption concerned (i) alcoholic beverages for which no ingredient list was required, and (ii) those substances that were not considered ingredients and therefore did not have to be declared. These included carry-over additives, processing aids and solvents or media for additives or flavourings. Carry-over additives are ‘passively’ or indirectly transferred with a component to the finished food product where they may be present but serve no technological function. Processing aids are used for technological purposes but are removed after processing and are not present in the finished food product. Only the flavouring itself was declared and not the medium, which could be made of starch from gluten-containing cereals or from peanut derivatives.

The second cause for exemption was the 25% rule according to which it was not necessary to indicate in the list of ingredients the components of so-called compound ingredients when they represented <25% of the finished food. The 25% rule was introduced into Community legislation in 1979 with the aim of avoiding inordinately long lists of ingredients and it only applied to common or well-defined compound ingredients, whose composition was considered to be known to consumers (e.g. in the case of 20% powdered chocolate in a prepackaged cake, the constituents of the powdered chocolate, which is a well-defined compound ingredient, were not indicated). However, food production has become more complex and consumers have increasingly expressed the wish to be better informed about the composition of new foods that are put on the market. The 25% rule was of great concern in terms of food allergies, because many undeclared allergenic ingredients could potentially be present in a finished food product at concentrations that may trigger an allergic reaction.

In the third and last exemption, some defined ingredients could be declared under a general designated category, such as ‘vegetable oil’, ‘starch’ or ‘natural flavourings’, without indicating their specific name or provenance.

In addition, even when they were declared, some ingredients could appear under different names, common or complex scientific names, that might not always be understood and recognized by consumers.

Before this new Directive, the list of ingredients as it appeared on the label was neither complete nor precise and clear. All these shortcomings have been addressed in the new legislation. The main features of the new Directive are as follows:
• Abolition of the 25% rule described above, thereby enshrining the principle that all ingredients should be labelled.
• Maintenance of a limited number of specific exemptions for some categories of compound ingredients (e.g., compound ingredient of well-defined composition, such as chocolate, as well as mixtures of spices) insofar as they constitute <2% of the finished product.
• Publication of a list of ingredients or substances responsible for most cases of food allergy or intolerance, for which exemptions would never be allowed.

In some limited cases, therefore, it will still be possible not to label solvents for flavourings, processing aids, carry-over additives and some compound ingredients, provided that they are not derived from one of the allergens listed in Annex IIIa to the Directive.

All allergenic ingredients mentioned in Annex IIIa, including their derivatives, shall be labelled in all foods, including alcoholic beverages, with clear reference to the specific name used in the list, instead of listing them under a category name.

The following ingredients are covered by these provisions: (a) cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, (b) crustaceans and products thereof, (c) eggs and products thereof, (d) fish and products thereof, (e) peanuts and products thereof, (f) soya beans and products thereof, (g) milk and products thereof (including lactose), (h) nuts, i.e. almond (Amygdalus communis L.), hazelnut (Corylus avellana), walnut (Juglans regia), cashew (Anacardium occidentale), pecan nut [Carya illinoensis (Wangenh.) K.e.Koch], Brazil nut (Bertholletia excelsa), pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia) and products thereof, (i) celery and products thereof, (j) mustard and products thereof, (k) sesame seeds and products thereof, and (l) sulphur dioxide and sulphites at concentrations > 10 mg/kg or 10 mg/l expressed as SO2.

The new legislation states that the list of allergens shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge. This update will be done after the European Food Safety Authority (EFSA) has been consulted and has given an opinion, on the basis of scientifically grounded requests from Member States or patient associations. The directive specifies that the first re-examination shall take place no later than 25 November 2005.

It should be emphasized that this regulation on labelling only applies to allergenic foods/ingredients that have intentionally been introduced in a food. It does not apply to residual amounts of allergens that could unintentionally occur because of cross-contact or cross-contamination in the food chain or during processing, although the consequences may be similar in terms of risk for allergic consumers.

Does the regulation go too far?

The drawing up of the above-mentioned list in Annex IIIa gave rise to extensive discussions within the Council and the European Parliament and with stakeholders. One major controversial point was the inclusion of all derived products in the list of ingredients subject to mandatory labelling. As examples, the rule, if implemented as such, would impose the labelling of starch or glucose syrup produced from wheat, as well as egg white or fish gelatine used as clarifying agents in beer or wine. Refined oil produced from peanut, soya bean, nuts and sesame should also be labelled as such, the generic term vegetable oil no longer being permitted.

The European Commission asked the Scientific Committee on Food, then the EFSA, to give advice on (i) the scientific basis for the identification of allergenic food ingredients for foodstuff labelling purposes and (ii) the possibility of determining threshold doses and identifying factors, including food processing, that might eliminate or reduce the allergenicity of a food ingredient.

The opinion of the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies was adopted on 19 February 2004 (3). It confirms that a review of the scientific literature provided evidence that each of the ingredients listed in the Annex has the potential to cause allergic reactions in sensitive individuals. It also supports the legal provision that this list should be regularly updated and that revision should also be prompted by new scientific evidence but, as yet, no specific criteria have been defined for the purpose of identifying new allergens.

Furthermore, the opinion of the EFSA also states that in no case is the available evidence sufficient to establish a threshold dose below which allergic reactions are not triggered. Processing may decrease or increase the allergenic potential of foods, but no evidence or consideration can reliably predict what the effect will be. The possibility that specific derivatives of the most common food allergens might not trigger an allergic reaction needs to be evaluated on a case-by-case basis before any exemption from labelling can be authorized.

It has been argued that extensive refining processes in particular cases may ensure the elimination of the allergenic component and thus guarantee the absence of risk. For such cases, new paragraph 11 of Directive 2000/13/EC (2) establishes a procedure allowing for a temporary labelling exemption of relevant derivatives, thus allowing time for applicants to gather the scientific evidence needed to confirm this assumption.

To this end, the Commission may be notified until 25 August 2004 of studies currently being conducted to establish whether ingredients or substances derived from ingredients listed in Annex IIIa are likely or not, under specific circumstances, to trigger adverse reactions. The purpose of the procedure is to raise the possibility of exempting specific derived ingredients or substances from
mandatory labelling, first provisionally and then definitively, provided relevant scientific justification has been provided. Only derived ingredients or substances are covered and likely to be subject to notification. It is also specified that the notification only concerns derivatives used ‘under specific circumstances', i.e. on a case-by-case basis. This procedure includes ingredients or substances obtained from processed allergens and present in a foodstuff, and also those used in the manufacture or preparation of a foodstuff and then removed, such as processing aids.

The notification procedure is open to the producers or manufacturers of the ingredients/substances for which exemption is requested, or to the producers or manufacturers of foodstuffs including such ingredients/substances in their production process, or to representative associations of those producers or manufacturers.

After consultation with the EFSA, and no later than 25 November 2004, the Commission shall adopt a list of those ingredients or substances, which shall consequently be provisionally excluded from AnnexIIIa and thus exempted from labelling, pending the final results of the notified studies, or at the latest until 25 November 2007 (i.e. 4 years after the adoption of the Directive). The definitive status of those derivatives will then be decided on the basis of the results of the studies, and after an opinion has been obtained from the EFSA.

It is noteworthy that the objective is to provide allergic consumers with relevant and comprehensive information, without thoughtlessly and unnecessarily increasing the obligations on food companies or providing information that may unjustifiably worry consumers. If ingredients or substances temporarily benefit from a labelling exemption until the end of 2007, although the new provisions will be fully implemented by the end of 2005, the safety of consumers with allergies shall not be at stake. It will then be critical to restrict the exemptions to ingredients/substances for which a sufficient weight of evidence is available to suggest that they are unlikely to trigger adverse reactions in sensitive individuals, and then only if the applicant is in the process of conducting appropriate studies to furnish scientific conclusions on the absence of allergic potential.

This notification procedure is now underway and the deadline for the adoption of the provisional list mentioned above is 25 November 2004.

The views in the article are the authors’ own and do not necessarily reflect those of the European Commission.

References