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The New European Community Rules on the Labeling of Allergen Ingredients in Foodstuffs

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I. INTRODUCTION

This article describes the recent reforms in the European Community (EC) legislation on the labeling of ingredients in foodstuffs.¹ The objective of the EC reform is to require complete and precise labeling so that people who suffer from allergic reactions to specific foods or components of food may make informed choices.

Former EC labeling rules did not require the mandatory listing of all ingredients present in a food—a lacuna that can cause problems for people suffering from food allergies and food intolerances. The proportion of the population with food allergies or food intolerances is increasing,² and new allergens constantly are emerging. These allergies not only cause illnesses but also can provoke life-threatening reactions, particularly for the young, the old, and the weak. For these groups of vulnerable people, the lack of detailed information on foodstuff ingredients can be a major handicap (i.e., they are never sure that the product they are consuming does not contain the substance that can provoke the adverse reaction).³ Consumers with allergies and intolerances need complete and precise labeling. The new EC labeling rules, which were adopted in November 2003 and are scheduled to come into effect in November 2005, attempt to fill this regulatory lacuna.

Although the symptoms of both food allergies and food intolerances can be similar, important differences do underlie them. In the case of a food allergy, it is the immune system that reacts to a particular substance; with a food intolerance, it is the body's metabolism that functions poorly.

A food intolerance occurs when the body cannot digest a food or food component properly. A frequently-occurring type of food intolerance is lactose intolerance, caused by the lack of the digestive enzyme lactase, which breaks down milk sugar. The undigested food enters undigested into the blood stream and causes adverse reactions. People with an intolerance often can tolerate small amounts of the food or food component without symptoms. During an allergic reaction, however, the body produces anti-

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¹ Directive 2003/89/EC of the European Parliament and of the Council (Nov. 10, 2003) amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs, 1993 O.J. (L 308) 15.

² According to the European Commission, the allergy associations estimate that eight percent of children and three percent of adults are affected. See Press Release, European Commission, Food Without Fear: New Food Labelling Rules Will Improve Consumer Information on Food Ingredients, In Particular Allergens (IP/03/1310) (Sept. 29, 2003), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/1310&format=HTML&aged=0&language=EN&guiLanguage=en> (last visited July 28, 2005). See also The European Food Information Council (EUFIC), Background On Food Allergy And Food Intolerance, at http://www.eufic.org/en/quickfacts/food_allergy.htm ("the true prevalence of food allergy is about 2% of the adult population. In children, the incidence is higher at 3-7%").

³ European Commission Press Release, *supra* note 2.

bodies that deactivate the allergen to remove it from the body. In simple terms, an allergy is "immunity gone wrong," whereby a normally harmless substance is perceived as a threat and is attacked by the body's immunological defense system. Types of allergic reactions range from diseases of a chronic nature (e.g., atopic dermatitis, urticaria, or digestive symptoms) to life-threatening reactions (e.g., asthma or anaphylactic shock).⁴ Allergies often provoke more toxic reactions than do intolerances.

It is impossible for producers of foodstuffs to know customer-specific allergies or intolerances—individual consumers who have these identified allergies or intolerances must take care of themselves. They are unable to do that, however, unless they have full and complete information about the foodstuffs they are ingesting.

II. THE NEW EC FOOD LABELING RULES

DIRECTIVE 2003/89/EC AMENDING DIRECTIVE 2000/13/EC

Directive 2003/89/EC has made important amendments to the general food labeling rules set out in Directive 2000/13/EC.⁵ The amendments require the labeling of all ingredients present in prepacked foodstuffs. The principal change lies in the abolition of the "25% rule," which initially was introduced in 1979 in Article 6(7) of Council Directive 79/112/EEC⁶—the first EC food labeling rules for prepackaged foodstuffs. Other changes concern the use of category names for groups of ingredients, the inclusion of a list of allergens, specific rules for derivatives, and the extension of the rules to alcoholic beverages.

The new rules are scheduled to come into effect on November 25, 2005. After that, the sale of products that do not comply with the new rules is prohibited, although products placed on the market or labeled prior to this date may be sold while stocks last. EC Member States had to implement this Directive into national law on November 25, 2004, so products complying with the new rules already may be placed on the market.

A. The "25% Rule"

The key amendment to the general labeling rules contained in the new Directive concerns the abolition of the "25% rule." Under that rule, it was not obligatory to label the components of compound ingredients making up less than 25% of the final food product. This rule enabled certain ingredients to be "hidden"—notably allergens—where ingredients of sauces (e.g., eggs, milk, or mustard) were not labeled. Under the new rules, these subingredients will have to be listed.

Article 3 of Directive 2000/13/EC makes mandatory the indication/listing of ingredients on foodstuffs' labels. Article 6(8) allows a compound ingredient to be included in the list of ingredients under its own designation, provided it is followed by a list of its own ingredients. The old "25% rule" limited the scope of the latter obligation to a great extent; the new Directive means that the "25% rule" is no longer applicable, because foodstuff producers must list all subingredients of compound ingredients. This strict obligation is subject to an exception, however;⁷ provided that certain conditions are

⁴ EUFIC Background, *supra* note 2.

⁵ Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation, and advertising of foodstuffs, O.J. (L 109) 29.

⁶ Council Directive 1979/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, O.J. (L 33) 1.

⁷ Art. 1(e) of Directive 2003/89/EC (replacing the second subpara. of para. 8 of art. 6 of Directive 2000/13/EC).

met, ingredients used at less than two percent of the finished product may be exempted. This exception strictly circumscribes the obligation to label all subingredients and ingredients used at less than two percent may be "hidden" where:

- the composition of the compound ingredient is defined in EC law (e.g., jam⁸ and chocolate⁹);
- the compound ingredient is a food for which an ingredients list is not required under EC law (e.g., fermented vinegars, cheese, butter, and fermented milk and cream¹⁰); or
- it concerns a mixture of herbs and spices.

Moreover, under amended Article 6(5) of Directive 2000/13/EC, the looser rules apply to ingredients used at quantities less than two percent:

- such ingredients will not have to be listed in descending order of weight; and
- the presence of similar or mutually substitutable ingredients could be indicated by use of "contains ... and/or ..." where at least one of no more than two ingredients is present in the finished product.

Whether the listing of "alternative" ingredients with an "or" will be accepted remains to be seen. Of particular interest will be the interpretation of "similar or mutually substitutable ingredients," which permits the indication of alternatives.

B. Category Labeling

The new Directive strictly delimits the possibility of identifying ingredients by the name of the category of ingredients to which they belong (e.g., "cheese") instead of their specific name as required under Article 6(6). This practice was allowed for a number of categories under Annex I of Directive 2000/13/EC. Under the revised Directive, however, it no longer will be permitted to employ category listings for either "crystallized fruit" or "vegetables," as these designations have been deleted under Annex I. Fruits and vegetables have been removed from Annex I because they constitute a category of ingredient capable of producing allergic reactions. EC law, however, continues to permit the use of category names such as "fish," "cheese," "milk proteins," "sugar," "wine," and others, totaling seventeen categories under Annex I of the revised Directive. Also, it should be noted that, although "vegetable or animal oil" may be designated as a category under Annex I, the new rules dictate that their source will have to be indicated for all allergenic ingredients. For example, "peanut oil" or "soya oil" must be specified as such according to the denomination in Annex IIIa of the Directive, and no longer can be labeled as "vegetable oil."

C. Categories of Ingredients Known to Cause Allergies

Under the new Directive, an Annex with a list of twelve allergens and their derivatives has been established. These ingredients will have to appear on the label under their

⁸ "Jam" is defined as "mixture, brought to a suitable gelled consistency, of sugars, the pulp and/or purée of one or more kinds of fruit and water" in Annex I Part I of Council Directive 2001/113/EC relating to fruit jams, jellies and marmalades, and sweetened chestnut puree, O.J. (L 10) 67.

⁹ "Chocolate" is defined as "the product obtained from cocoa products and sugars which, subject to (b), contains not less than 35 % total dry cocoa solids, including not less than 18 % cocoa butter and not less than 14 % of dry non-fat cocoa solids" in Annex I Part A 3.a of Directive 2000/36/EC of the European Parliament and of the Council relating to cocoa and chocolate products intended for human consumption, O.J. (L 197) 19.

¹⁰ These are exempted under art. 6(2) of Directive 2000/13/EC.

specific name, whenever they are used in the production of a foodstuff and are still present in the finished product (even in an altered form). Guidance on each allergenic ingredient on the list and some examples (below, in brackets) are taken from an interpretation published by the United Kingdom (U.K.) Food Standards Agency (FSA).¹¹ Annex IIIa lists the following allergens:

- cereals containing gluten and products thereof (i.e., wheat, rye, barley, oats, spelt, kamut, or their hybridized strains);
- crustaceans and products thereof (i.e., all species, lobster, crab, prawns, and langoustine);
- eggs and products thereof (no species of eggs is specified in the Annex, but “eggs” refers to eggs from laying hens as well as eggs from other birds, such as broiler chickens, ducks, turkeys, quail, geese, gulls, and guinea fowl);
- fish and products thereof (“fish” includes fish from all species of fish and fish products; use of the common species names should be sufficient to indicate the “fish” content of a product, but care should be taken in the use of the term “fish” where its presence might not be appreciated and to ensure that the nature of any exotic fish is made clear);
- peanuts and products thereof;
- soybeans and products thereof (terms such as “soya” or “soy” should be sufficient to indicate the soybean origin);
- milk and products thereof (includes cow’s milk and milk from sheep, goats, and buffaloes, etc. Care should be taken to ensure that unfamiliar dairy products used as ingredients (e.g., fromage frais, Mascarpone, Cantal, and Quark) are clearly labeled by reference to milk; moreover, the presence of the milk sugar lactose also needs to be indicated as “milk sugar” or with some other reference to milk.);
- nuts and products thereof (e.g., almond, hazelnut, walnut, cashew, pecan, brazil, pistachio, macadamia, and queensland nut);
- celery and products thereof (refers both to stick and root celery);
- mustard and products thereof (refers to the mustard plant and other forms that originate from it, such as leaves, sprouted seeds, mustard flour, table mustard, and mustard oils);
- sesame seeds and products thereof (products deriving from it, such as tahini and sesame oil, also would trigger the allergen derivative labeling requirement);
- sulfur dioxide and sulfites at concentrations more than 10mg/kg or 10mg/liter expressed as SO₂ (this additive should be declared by reference to the term “sulfur dioxide” or “sulfite” depending on the chemical nature). Furthermore, depending on the particular sulfite present, the chemical name may be used (e.g., sodium metabisulfite). The use of the category name (such as “preservative,” in the case of SO₂) followed by the E-number (E-220 series), which is permitted only under the additives Directive,¹² appears to be deemed insufficient, according to the U.K. FSA.

No labeling exemptions for the above-listed ingredients are granted because these ingredients are known to trigger allergies or intolerances; any use of the listed ingredients in the production of foodstuffs, therefore, must be labeled.

¹¹ United Kingdom Food Standards Agency (U.K. FSA), Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2004 (Draft) (June 2004), available at <http://www.food.gov.uk/multimedia/pdfs/allergenukguidance.pdf> (last visited July 22, 2005). The U.K. FSA states that this guidance is taken from opinions of the European Food Safety Agency (EFSA), Opinions of the Scientific Panel on Dietetics Products, Nutrition and Allergies [NDA] (last updated Apr. 14, 2004), available at www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html (last visited July 22, 2005).

¹² Directive 95/2/EC of the European Parliament and of the Council relating to additives, O.J. (L 61) 1.

D. Derivatives From Ingredients Known to Trigger Allergic Reactions

Derivatives from allergenic ingredients may be exempt from the allergen labeling requirement under Article 6(11) of Directive 2000/13/EC where a lack of allergenic potential is shown. This provision was included at the last minute when it became clear how many derivatives from allergen ingredients would need to be labeled as such.

New paragraph 11 of Article 6 of Directive 2000/13/EC sets forth a procedure for granting a temporary labeling exemption of relevant derivatives, which provides the time necessary to prove nonallergenicity through scientific evidence. The legislature has acknowledged that some substances and “products thereof” covered by Annex IIIa are derived from major food allergens, but, nevertheless, may not pose a threat to allergic consumers. Moreover, some substances that are liable to cause allergies may be used in such a way that the finished product would not constitute a risk for people with allergies.

Under Article 6(11), the Commission had to be notified by the producers or manufacturers of the ingredients or substances for which the exemption is sought (by producers or manufacturers themselves or by representative associations of those producers or manufacturers) no later than August 25, 2004. Part of the notification was the submission of studies undertaken to establish whether ingredients or substances derived from ingredients listed in Annex IIIa are likely, under specific circumstances, to trigger adverse reactions.

The Commission has issued Guidelines¹³ for the contents of those notifications under Article 6(11), stressing that the provisional exclusion of ingredients and substances was intended to apply only to “derived ingredients” or substances covered by the listed allergens. Therefore, ingredients listed in the Annex and present in foodstuffs may not be excluded. The Guidelines also added that paragraph 11 relates to derivatives used “under certain circumstances,” therefore including ingredients or substances obtained from processed allergens and present in a foodstuff, as well as those used in the manufacture or the preparation of a foodstuff, and removed, leaving only trace amounts in the final product. Finally, it emphasized that Annex IIIa includes only generic ingredients; so, the temporary list that might be established could contain only generic derivatives and/or derivatives used in generic, well-defined conditions (e.g., use as a processing aid). No notification regarding an ingredient or substance used in the manufacture of a specific foodstuff and/or of a particular brand was accepted.

The EC Commission received twenty-seven applications regarding thirty-four ingredients or products thereof, of which thirty-two fell within the scope of the new labeling rules and on which the Commission consulted with the European Food and Safety Authority (EFSA). According to the first opinions adopted by EFSA on December 2, 2004,¹⁴ the derivatives isinglass (used as a clarifying agent in brewing), refined soybean oil, celery leaf oil, celery seed oil and celery oleoresin, lactitol, mustard seed oil, and fish gelatin (used as a flavor carrier) were not very likely to cause a severe allergic reaction. The risk assessments of EFSA concluded, however, that fully refined peanut oil, wheat gluten used as fining agent in wines, nut extracts used as flavors in distillates, and fish gelatin could trigger an allergic reaction. In many cases, EFSA noted that there was

¹³ Guidelines from the Commission’s services for the contents of the notifications requested by the new paragraph 11 of Directive 2000/13/EC, as amended by Directive 2003/89/EC (Brussels) (Dec. 18, 2003).

¹⁴ These opinions are available at www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html (last visited July 26, 2005).

insufficient scientific data to give a definitive opinion. In the case of isinglass preparations, for example, EFSA required appropriate analytical methods and further studies to determine possible residual levels of parvalbumin (a protein triggering allergic reactions).

On March 21, 2005—about four months later than originally foreseen—the Commission adopted Directive 2005/26/EC,¹⁵ establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC. This temporary exemption was valid pending final results of the notified studies (at the latest until November 25, 2007) and definitively where scientific justifications have been provided. The derivatives on the list have been regarded by EFSA as products or ingredients that are not likely—or not very likely—to cause adverse reactions in susceptible individuals. In certain cases, EFSA concluded that it could not draw a firm conclusion, as no reported cases were mentioned. Consequently, Directive 2005/26/EC lists food ingredients and substances provisionally excluded from Annex IIIa, as follows:

- wheat-based glucose including dextrose;¹⁶
- wheat-based maltodextrins;¹⁷
- glucose syrups based on barley;
- cereals used in distillates for spirits;
- lysozym (produced from egg) used in wine;
- albumin produced from egg used in wine and cider;
- fish gelatin used as a carrier for vitamins and flavors;
- fish gelatin or isinglass used as a fining agent in beer, cider, and wine;
- fully refined soybean oil and fat;¹⁸
- natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
- vegetable oils derived phytosterols and phytosterol esters from soybean sources;
- plant stanol ester produced from vegetable oil sterols from soybean sources;
- whey used in distillates for spirits;
- lactitol;
- milk (casein) products used as fining agents in cider and wines;
- nuts used in distillates for spirits;
- nuts (e.g., almonds and walnuts) used (as flavor) in spirits;
- celery leaf and seed oil;
- celery seed oleoresin;
- mustard oil;
- mustard seed oil; and
- mustard seed oleoresin.

After considering the risk assessments carried out by the EFSA, however, the Commission has not included in the provisional list some substances that applicants have notified together, along with those contained in the list above. These products or ingredients were considered by EFSA to be likely or very likely to trigger an allergic reaction; for that reason, they could not be exempted by Directive 2005/26/EC. Therefore, produc-

¹⁵ Commission Directive 2005/26/EC (Mar. 21, 2005) O.J. (L 75) 33.

¹⁶ And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

¹⁷ See *id.*

¹⁸ See *id.*

ers must comply with the stricter allergen labeling requirements in case that they use, for example, the following substances for the production of certain foodstuffs:

- fully refined peanut oil and fat, which EFSA stated could cause an allergic reaction in peanut allergic individuals;
- lysozym (produced from egg) used in cheese to prevent fermentation;
- acid hydrolyzed vegetable protein from soy;
- hydrolyzed wheat gluten used as a fining agent in wine; or
- some types of fish gelatin used in food.

E. *Extension of Rules on Allergen Labeling to Alcoholic Beverages*

A further innovation in the amended Directive 2000/13/EC is the effects the allergen-labeling obligation will have on the alcoholic beverages industry. Contrary to what was the case prior to amendment of the EC food labeling rules, the alcohol industry is, in many cases, no longer exempted from the obligation to label ingredients.¹⁹ Thus, all ingredients on the list of allergens will have to be declared, so that, for instance, sulfite present in wines will have to be indicated. Sulfite is the only additive on the list of twelve allergens and is used as preservative in many foodstuffs, including wine, beer, and cider. Therefore, under Article 6(3a) of Directive 2000/13/EC, the label shall include the word "contains" followed by the name of the ingredient. The obligation to label certain derivatives from allergen ingredients appears to affect the whole industry, because Annex IIIa includes "cereals containing gluten and products thereof," "sulfur dioxide and sulfites," and "fish and products thereof." Where other ingredients listed in Annex IIIa are used as carriers or solvents in additives or processing agents, they need to be listed except where they appear on the Commission's exemption list, which is yet to be published. To be included in this exemption list, the brewing industry, together with the suppliers of isinglass, has submitted a 475-page notification to the Commission proposing the temporary exemption for isinglass used as a clarifying agent in the production of beer.²⁰ Commission Directive 2005/26/EC finally included, in view of EFSA's risk assessment, isinglass preparations used as fining agent in beer, cider, and wine as one of the substances provisionally excluded from Annex IIIa of Directive 2000/13/EC. In relation to other substances used in the production of alcoholic beverages, however, such as hydrolyzed wheat gluten used as fining agent in wines, the EFSA's panel considered that wines and musts treated with hydrolyzed wheat gluten could trigger an allergic reaction. Therefore, this substance needs to be labeled as of November 25, 2005.

III. ARE THERE STILL GAPS IN EC LAW?

The changes to the EC food labeling legislation described above are important and appear to improve the situation of persons suffering from food intolerances and aller-

¹⁹ The determination of rules for the labeling of ingredients for alcoholic beverages has been the subject of debate since 1982 when the Commission made its first proposal that was only adopted in part in relation to alcoholic content, however, by Directive 86/197/EEC splitting off of the proposal dealing with the list of ingredients. The Commission has made an amended proposal for a Directive of the European Parliament and of the Council amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation, and advertising of foodstuffs for sale to the ultimate consumer, COM/99/0339 final-COD 97/0027, O.J. C177E/11, which has as its aim to determine the procedure for adopting labeling rules for the ingredients of alcoholic beverages, which originally was stipulated for in Article 6(3) of Directive 79/112/EEC.

²⁰ British Beer and Pub Ass'n, Technical Circular No. 391 (Sept. 1, 2004).

gies. There are still cases, however, where manufacturers of food products are allowed not to provide information about all ingredients, such as in the case of the new 2% rule whereby subingredients of compound ingredients used at less than two percent of the finished product may be exempted from full listing.

Furthermore, other areas are left unregulated by Directive 2000/13/EC as amended by Directive 2003/89/EC such as food supplied by mass caterers and restaurants, foods sold loose, fancy confectionary, food in small packages and indelible marked bottles, and accidental traces of allergens and substances not included in Annex IIIa. The absence of Community legislation does not mean that these do not have the potential to create harmful effects on consumers suffering from allergies or intolerances.

Before addressing further gaps in the labeling law, it should be noted that EC food labeling legislation takes more than food allergies and intolerances into consideration. There are other health disorders for which EC law provides that certain warnings need to be indicated on food labels. For the sake of completeness these rules are described briefly below.

These rules are provided in Directive 94/54/EC on the compulsory indication on the labeling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC.²¹ Foodstuffs containing aspartame have to be labeled with "contains a source of phenylalanine," foodstuffs containing more than ten percent added polyols have to be labeled with "excessive consumption may produce laxative effects," and on confectionary containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the licorice plant *Glycyrrhiza glabra* at concentrations of 4 g/kg or above, the following message must be added after the list of ingredients: "contains licorice-people suffering from hypertension should avoid excessive consumption."

Furthermore, Commission Regulation 608/2004/EC on the labeling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols, and/or phytostanol esters²² provides that there shall be a statement that the product is intended exclusively for people who want to lower their blood cholesterol level, as well as a statement that patients on cholesterol lowering medication should consume the product only under medical supervision.

A. Food Supplied by Mass Caterers and Restaurants

The foods delivered to customers by mass caterers and restaurants do not fall under the scope of the general food labeling directive and, hence, are exempted from ingredient listing—the general labeling rules only apply to foodstuff to be delivered to ultimate consumers and mass caterers. Mass caterers and restaurants, therefore, are spared from the obligation to identify allergens of food they sell loose or prepacked for direct sale. This lacuna continues despite the fact that a significant proportion of food allergy incidents, including deaths, can be traced to foods sold loose or foods sold prepacked for direct sale in places such as catering establishments. Because the Directive does not cover this important category, it remains a matter of national law that sufficient information is conveyed to the consumer.

²¹ O.J. (L 300) 14, as last amended by Commission Directive 2004/77/EC as regards the labelling of certain foods containing glycyrrhizinic acid and its ammonium salt, O.J. (L 162) 76. Directive 79/112/EEC was the predecessor to Directive 2000/13/EC.

²² See arts. 2(3) and (4) of Regulation 608/2004/EC. Phytosterols, phytosterol esters, phytostanols, and phytostanol esters reduce serum cholesterol levels but also may reduce the α -carotene levels in blood serum, O.J. (L 9) 44.

In the United Kingdom, for example, Regulation 4(3) of the Food Safety (General Food Hygiene) Regulations 1995²³ places a continuous responsibility on food business proprietors to identify hazards in their food business and to operate with adequate safety measures to protect consumers (a process of hazard analysis). This responsibility appears also to apply in relation to potentially allergic consumers of food supplied by mass caterers. A food hazard is described by these regulations as anything that has the potential to cause harm to the consumer. Food allergens (e.g., peanuts) can cause a significant hazard to as many as one in 200 people. Furthermore, the U.K. FSA has published advice for catering establishments on how to cater for food allergy sufferers, foods to watch out for and steps that can be taken, setting out how catering staff can help customers by reading food labels and being aware of allergenic ingredients.²⁴

At the Community level, the new food hygiene rules,²⁵ adopted on April 29, 2004 that will enter into force on January 1, 2006, have the potential to create a similar responsibility, as for the first time the adherence to Hazard Analysis and Critical Control Points (HACCP) principles is mandatory for all food business operators (with the exception of primary producers) of food.

Article 5 of Regulation 852/2004/EC introduces the following HACCP principles.

1. Food business operators shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles.
2. The HACCP principles referred to in paragraph 1 consist of the following:
 - (a) identifying any hazards that must be prevented, eliminated, or reduced to acceptable levels;
 - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
 - (d) establishing and implementing effective monitoring procedures at critical control points;
 - (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
 - (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
 - (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

²³ Statutory Instrument (1995) No. 1763.

²⁴ *Be Allergy Aware* is a leaflet published on the web by the U.K. FSA. It is available at <http://www.food.gov.uk/multimedia/pdfs/allergyleaflet.pdf> (last visited July 26, 2005).

²⁵ Regulation 852/2004/EC of the European Parliament and of the Council on the hygiene of foodstuffs enters into force not earlier than Jan. 1, 2006, O.J. (L 139) 1.

Catering establishments and restaurants fall under the EC hygiene legislation if they fall under the definition of "food business operators." Under Article 2(2) and (3) of Regulation 178/2002/EC²⁶ "food business" is defined as "*any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.*" "Food business operator" is defined under Article 2(3) as "*the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.*" According to these definitions, mass caterers and restaurants undoubtedly fall under the definition of food business operator, to which the new EC hygiene law applies. Therefore, catering establishments and restaurants will have to apply the HACCP principles.

Under the new EC food hygiene rules, business operators are responsible for identifying hazards according to the HACCP principles outlined above. It is useful to look at the definition of a "hazard" to analyze whether allergens could fall under that definition. Under Article 3 No. 14 of Regulation 178/2002/EC, "hazard" is defined as "*a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.*" An allergic reaction to a food may well fall under this definition. In view of the above definitions, restaurants and catering establishments appear to have a responsibility to inform customers about allergenic ingredients or, in the alternative, simply avoid using ingredients known to cause reactions.

Beginning January 1, 2006, all food business operators shall put a system of hazard analysis in place to avert hazards or, where it is too late, to provide for corrective actions. It is important to note that while catering establishments and restaurants are spared from allergen labeling obligations under the EC labeling rules, the new food hygiene rules appear to push the latter to produce and distribute food that may contain ingredients known to cause allergic reactions with caution.

Although it may be argued that HACCP principles do not establish a duty to actively alert customers about allergenic ingredients, it should not be forgotten that food business operators have the direct responsibility under Article 14 of Regulation 178/2002/EC to ensure that only safe food is placed on the market and that unsafe foods are withdrawn from the market. Under Article 14, food is "unsafe" where "*it is injurious to health or unfit for human consumption.*"

Mass caterers may be particularly affected by Article 14 because when a determination is being made as to whether any food is unsafe, regard is held to "*the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning avoidance of specific adverse health effects from a particular food or category of foods.*"²⁷ For a person with a food allergy, dishes containing a food they react to are "unsafe," even though they are safe for most other people. This means that businesses will need to make sure they give people with food allergies the information they need to determine whether a food they react to is in a particular dish.

B. Foods Sold Loose or Prepacked for Direct Sale

Article 14 of Directive 2000/13/EC allows Member States not to apply EC labeling rules in the case of food sold loose or prepacked for direct sale as long as the consumer

²⁶ Regulation 178/2002/EC of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, O.J. (L 31) 1.

²⁷ Art. 14(3)(b) of Regulation 178/2002/EC.

receives sufficient information. Therefore, for foods sold loose (e.g., meat from a butcher or vegetables from a greengrocer), no allergen-labeling requirement applies.

There are, however, national initiatives. Germany is considering, for 2005, adopting a law making the labeling of allergen ingredients on foods sold loose or prepacked for direct sale mandatory. Initial proposals to require the labeling of all ingredients on such products however, were withdrawn. In the United Kingdom, the British Nutrition Foundation, in an effort to ensure that the consumer receives sufficient information, made Recommendations in 2001 to the U.K. FSA on how it could improve information for foods sold loose.²⁸ In this report, the British Nutrition Foundation acknowledged that consumers consider allergy concerns to be the most important. Therefore, the priority lies in the identification of measures to tackle these concerns. Thus, the good operating practices with regard to allergens, followed by some establishments, have been welcomed. This good operating practice has been divided into a four-strand approach: 1) provision of information on raw materials from suppliers; 2) good operating practice for "back of house" (good practice when preparing an allergy sufferer's meal); 3) training of staff; and 4) dialogue with consumers with food allergies. Some retailers already have special procedures in place for display products containing allergens such as notices on service counters. A project undertaken by the British Nutrition Foundation, however, showed that only a minority of loose food sellers complied with the recommendations.

C. Fancy Confectionary?

Article 15 of Directive 2000/13/EC allows Member States to impose less stringent rules for the labeling of certain fancy confectionary products. This constitutes a gap in EC law, as people suffering from certain allergies and intolerances will not be provided with sufficient information to avert the potential risk of adverse reactions, where Member States choose to apply this Article literally. Thus, in the United Kingdom, for example, the Food Labelling Regulations 1996²⁹ exempted flour confectionery products packed in crimp cases or in wholly transparent packaging from most of the labeling requirements. This exception has been deleted in the Food Labelling Regulations 2004.³⁰ Moreover, the U.K. FSA has published Guidance Notes on the Food Labelling Regulations 2004³¹ that state, among others, that the agency is exploring options for making sure that in situations of foods sold loose, foods sold prepacked for direct sale, or certain confectionary products, the consumer is still provided with adequate information.

D. Small Packages and Indelibly-Marked Bottles

Article 13(4) exempts small packages (packages whose largest surface is less than ten square centimeters) and indelibly-marked bottles from the new allergen labeling requirements of Directive 2003/89/EC. It is up to the Member States to adopt detailed rules to enable the purchaser to obtain sufficient information in the case of small packages and indelibly-marked bottles. In the United Kingdom, the Food Labelling Regulations 2004

²⁸ See BRITISH NUTRITION FOUND., PREPARATORY WORK ON IMPROVING INFORMATION IN CATERING OUTLETS AND FOR FOODS SOLD LOOSE (LSA 13/258), FINAL REPORT COMMISSIONED BY THE FSA, available at www.foodstandards.gov.uk/multimedia/pdfs/bnfreport.pdf (last visited July 26, 2005).

²⁹ Statutory Instrument 1996 No. 1499.

³⁰ Food Labelling (Amendment) (No. 2) Regulations 2004, Statutory Instrument (2004) No. 2824.

³¹ U.K. FSA, Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2004 (Draft), available at <http://www.food.gov.uk/multimedia/pdfs/allergenukguidance.pdf> (last visited July 26, 2005).

aimed at implementing the new ingredient listing rules of Directive 2003/89/EC, which amends Directive 2000/13/EC, covers food in small packages and certain indelibly-marked bottles, both for products originating in the United Kingdom and those from other Member States. Therefore, the latter food products would have to comply with the new allergen labeling requirements under U.K. law,³² although these are exempted under Article 13(4) of Directive 2000/13/EC.

The United Kingdom notified the Commission on June 22, 2004—in accordance with the notification procedure of draft technical regulations concerning products under Directive 98/34/EC and Article 19 of Directive 2000/13/EC—of its draft food labeling Regulation in respect to the measures it intends to apply to prepacked food contained either in indelibly-marked glass bottles intended for re-use (and having no label, ring, or collar) or in small packages.³³ Because the Commission had not issued a negative opinion, the “standstill” period ended on September 23, 2004, (i.e., three months after the notification date) so the United Kingdom may take the envisaged measures. The author is not aware of similar notifications from other Member States.

E. Impurities and Minor Traces of Allergens

The new allergen labeling rules apply only to the deliberate use of allergens in the production or manufacture of foodstuffs, where the allergens are still present in the finished product. Accidental trace levels of allergens, which could severely affect allergy sufferers, are not regulated under Directive 2003/89/EC.

In order to alert end-users that an allergen may be present in the final product due to cross-contamination, a number of manufacturers and retailers have used “may contain” labeling on their products. In addition to alerting the allergic consumer about possible contaminations and, more importantly, warnings that the product might contain a particular allergen, the labeling appears to be made with the intention to escape the possibility of liability.

Cross-contamination can arise where different products are made in the same production line. Thus, an ice cream manufacturer who produces vanilla ice cream on the same production line as pistachio may anticipate the possibility that, despite thorough cleaning of all machinery prior to switching product, there might be a risk of cross-contamination and, therefore, may choose to include on the vanilla ice cream label an indication that “this product may contain nuts.”

End-users have criticized this type of voluntary labeling as unnecessarily restricting consumers’ choices and undermining valid warnings.³⁴ Many allergic consumers find it unacceptable that manufacturers continue to make “allergen-free” products in an allergen-contaminated environment. Thus, full segregation of production lines seems to be the only feasible solution to guarantee an allergen-free product. The latter solution should be read in parallel with the EC hygiene rules. Under the HACCP principles (i.e., risk assessment obligations), food business operators are obligated to ensure that allergen-free products are not manufactured in contaminated environments.³⁵

In general, it appears that too little is being done in the area of unwanted allergen traces; clearer, more helpful consumer information is needed.

³² Regulations 4 and 26 of the Food Labelling Regulations 1996, as amended.

³³ See Notification, registered on the European Commission’s TRIS (Technical Regulations Information System) website, at <http://europa.eu.int/comm/enterprise/tris/pisa/app/search/index.cfm> (last visited July 26, 2005).

³⁴ Guidance Notes to the Food Labelling (Amendment) (No. 2) Regulations 2004, *supra* note 31.

³⁵ U.K. FSA, “MAY CONTAIN” LABELING—THE CONSUMER’S PERSPECTIVE (May 2002).

F. Substances Not Included in Annex IIIa

Annex IIIa lists only the major allergens, omitting food substances that may cause an allergic reaction. The Institute of Food Science and Technology (IFST) has stated that 170 foods have been documented as causing allergic reactions.³⁶ For practical purposes, the new EC rules concentrate on the major allergens. Some consumers feel, however, that important allergens have been left out, such as lupine³⁷; molluscs; chestnuts and pine nuts (which are not “nuts” as listed in Annex IIIa); and quorn (made from a vat-grown fungus *fusarium venenatum*, and used as a meat substitute), which also caused serious allergic reactions.

According to Article 6(11) of the amended Directive 2000/13/EC, the list in Annex IIIa shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge. The first re-examination shall take place at the latest on November 25, 2005.

IV. LIABILITY FOR FAILURE TO COMPLY WITH RELEVANT LEGISLATION ON ALLERGEN LABELING

The foregoing description of the new rules raises the question of the liability facing those food business operators in Europe who do not adhere to the new labeling rules. EC food labeling legislation relates to the intentional use of the listed allergens and does not cover accidental traces of allergens. Liability questions are not dealt with in the legislation, and enforcement of the allergen labeling requirements is left to the Member States.

Under Regulation 44 of the U.K. Food Labelling Regulations 1996,³⁸ it shall be an offense to sell food that is not marked or labeled in accordance with the provisions of Part II (general labeling requirements) of the Regulations. The new allergen labeling requirements provided under the 2004 amendment are part of these general labeling requirements. This offense can carry a penalty of up to £5,000.³⁹ It will be a defense to prove that the food concerned was marked or labeled before November 25, 2005, and that the matters constituting the alleged offense would not have constituted an offense under the Food Labelling Regulations 1996 if the amendments made by the Food Labelling Regulations 2004 had not been in operation when the food was sold.⁴⁰ In Germany, Article 10 of the Food Labelling Regulation⁴¹ and Article 54 of the Food Code⁴² provide

³⁶ The Institute of Food Science and Technology (IFST), Information Statement (June 23, 1999) (issued through IFST's public affairs and technical and legislative committees), available at www.ifst.org (last visited July 26, 2005).

³⁷ A legume, closely related to peanuts, which is widely used in foods such as bread, pasta, and biscuits, and has resulted in severe reactions. A study showed that nearly half of 24 European patients with peanut allergy also suffered from lupine allergy. Reported at www.abc.net.au/science/news (last visited Jan. 11, 2005).

³⁸ Statutory Instrument (1996) No. 1499.

³⁹ According to Article 44 of the Food Labelling Regulations 1996, the person that violates that provision is “liable on summary conviction to a fine not exceeding level 5 on the standard scale.” The Standard Scales for fines are set up under section 37(2) of the Criminal Justice Act 1982. Level 5 currently provides for a maximum fine of £5,000.

⁴⁰ A new paragraph is inserted in Regulation 50 (transitional provision) by the Food Labelling Regulations 2004.

⁴¹ Lebensmittelkennzeichnungsverordnung on Dec. 22, 1981 [1981] BGBl I 1625, consolidated Dec. 15, 1999 [1999] BGBl I 2464 (last amended Nov. 10, 2004) [2004] BGBl I 2799.

⁴² Lebensmittel- und Bedarfsgegenständegesetz of Aug. 15, 1974 [1974] BGBl I 1945, consolidated Sept. 9, 1997 [1997] BGBl I 2296 (last amended May 13, 2004) [2004] BGBl I 934.

for fines of up to •15,000 for cases in which foodstuffs that are not labeled at all, or that are not labeled in the way prescribed by law, are put into circulation with intent or negligence.

Further to the case of simple failure to comply with the legislation, there certainly are other scenarios where a food producer may be found liable for the harm products may cause to allergenic consumers. This is the case for failure to advert to the presence of an allergen in a product where it normally would not be expected to be found, or for labeling or verbal statements to the effect that a product is free of a particular allergen when the allergen is present due to either cross-contamination or another cause.⁴³

V. NO EXCEPTIONS FOR SMALL PRODUCERS AND PRODUCERS OF QUALITY PRODUCTS

The new food hygiene rules set out in Regulation 582/2004/EC, in Article 1(2)(c), exempt producers of small quantities of primary products (i.e., those supplied directly to final consumers or to local retail establishments) from the strict new food hygiene provisions; there is no exception for small producers or quality products from the allergen labeling rules.

The new rules also apply to all manufacturers of prepackaged foodstuffs whose products received protection under the Community schemes for Protected Designations of Origin (PDO), Protected Geographical Indications (PGI),⁴⁴ or Traditional Specialty Guaranteed (TSG),⁴⁵ except where the products already are exempted from the listing of ingredients (e.g., vinegar, cheese, butter, fermented milk, and cream under Article 6(2) of Directive 2000/13/EC).

VI. COMPARISON TO EC LAW: RECENT DEVELOPMENTS IN U.S. LAW

The United States has taken a significant step in food labeling reforms. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA),⁴⁶ which amends the Federal Food, Drug, and Cosmetic Act (FDCA),⁴⁷ has been adopted and will come into force on January 1, 2006. Similar to the new EC rules, under U.S. law it will be mandatory for food manufacturers to identify in plain, common language the presence of any of eight identified major food allergens. U.S. law does not go as far as the EC rules, as it does not include cereals other than wheat; celery; mustard; sesame seeds; and sulfur dioxide and sulfites at concentrations of more than 10mg/kg or 10mg/litre (expressed as SO₂), into their list of allergens that need to be clearly identified. The eight potential allergens listed in the amended U.S. legislation under FDCA section 201(qq)(1) coincide with those in Annex IIIa of Directive 2003/89/EC. Moreover, under FALCPA section 3(4),

⁴³ For further analysis of liability questions in the field of food allergens under EC product safety and defective product liability rules and U.K. law, see Bernard O'Connor & Leesha O'Driscoll, *The Liability of Food Producers for Undeclared Allergens*, 1(3) FOOD ALLERGY & INTOLERANCE (2000).

⁴⁴ Council Regulation 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (July 14, 1992) O.J. (L 208) 1, as amended by Council Regulation 535/97 (Mar. 17, 1997), O.J. (L 83) 3, and Council Regulation 692/2003 (Apr. 8, 2003), O.J. (L 99) 1.

⁴⁵ Council Regulation 2082/92 on certificates of specific character for agricultural products and foodstuffs (July 14, 1992), O.J. (L 208) 9.

⁴⁶ Food Allergen Labeling and Consumer Protection Act of 2004, Title II of Pub. L. No. 108-282, § 741 (Aug. 2, 2004) (codified in scattered sections of 21 U.S.C. and 42 U.S.C.).

⁴⁷ Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, § 201, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. § 321 (2004)).

food labels in the United States will have to indicate the presence of major food allergens used in spices, flavorings, additives, and colorings, all of which previously were exempted.

Similar to Article 6(11) in the amended Directive 2000/13/EC, section 3(6) of FALCPA provides that any person may petition the Secretary of Health and Human Services to exempt a derivative from the allergen labeling requirements. The Secretary has 180 days after the person has submitted scientific evidence that such food ingredient does not cause an allergic reaction that poses a risk to human health, to issue its final decision. To avoid unintentional contact with major food allergens, the new U.S. law empowers the U.S. Food and Drug Administration to conduct inspections and to issue a report within eighteen months to ensure that the food manufacturers comply with practices to reduce or eliminate cross-contact of a food with any major food allergens that are not intentional ingredients of the food.

VII. CODEX ALIMENTARIUS RULES ON THE LABELING OF ALLERGEN INGREDIENTS

Allergen labeling has been addressed at international levels through the Codex Alimentarius Commission and the Food Agriculture Organization/World Health Organization's Food Standards Program.⁴⁸ In the Codex Alimentarius, which is a collection of internationally-adopted food standards, the Codex General Standard for the labeling of prepacked foods⁴⁹ addresses allergens. Section 4.2 of the Codex General Standard establishes the general rule to list ingredients on the label in descending order of weight. This rule is subject to the "five percent exception," where a compound ingredient constituting less than five percent of the food does not need to be labeled, except where it is a food additive serving a technological function. Section 4.2.1.4 of the Codex General Standard lists foods and ingredients that are known to cause hypersensitivity and, therefore, always need to be declared, similar to Annex IIIa of Directive 2003/89/EC.

Similar to the U.S. scheme, the Codex does not go as far as the new EC rules, having left out mustard, celery, and sesame seeds on the list of ingredients and foods that are known to cause hypersensitivity.⁵⁰ Thus, EC law provides for stricter labeling for more substances than the Codex Alimentarius.

VIII. COMPATIBILITY OF THE EC RULES WITH THE WORLD TRADE ORGANIZATION AGREEMENTS

The question is whether these stricter Community rules may be incompatible with the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and/or the Agreement on Technical Barriers to Trade (TBT). Although food labeling rules normally are assessed under the TBT Agreement under the objective of disseminating consumer information (and not the protection of human health), the

⁴⁸ See generally http://www.codexalimentarius.net/web/index_en.jsp (last visited July 26, 2005).

⁴⁹ The Codex General Standard for the Labelling of Prepacked Foods was adopted by the Codex Alimentarius Commission at its 14th Session (1981); subsequently revised by the 16th and 19th Sessions (1985 and 1991, respectively); and amended by the 23rd and 24th Sessions (1999 and 2001, respectively).

⁵⁰ A footnote to section 4.2.1.4. provides that "future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)."

labeling of ingredients known to cause allergies may well address both objectives. In this case, the SPS Agreement would apply because Annex A1 to the SPS Agreement provides that:

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, ... labeling requirements directly related to food safety.⁵¹

Article 3(1) of the SPS Agreement provides the following:

To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

For food safety, Annex I(3) to the SPS Agreement defines international standards, guidelines, and recommendations as those established by the Codex Alimentarius Commission.

Because there are Codex Alimentarius rules in the General Standard for the labeling of prepacked foods (which address the issue of labeling of substances that are known to trigger allergic reactions), the Community has to be able to justify scientifically its stricter standard to comply with Article 3(3) of the SPS Agreement, which allows that "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification."

In another aspect, however, the Codex seems to go further than the European Community or the United States when it states, under section 4.2.2, that when it is not possible to provide adequate information on the presence of an allergen through labeling, the food containing the allergen should not be marketed. This may apply to accidental cross-contamination of allergen-free foodstuffs with allergen-contaminated foodstuffs through the use of the same production line. This could be understood to mean that, where manufacturers are not certain of a possible contamination with a certain allergen, it is their responsibility to remove that product from the market. This would provide a positive signal to consumers, who would no longer need to second-guess labels in their choices of allergen-free food consumption.

IX. CONCLUSION

Having described the general picture of the new EC labeling rules and their effects on both consumers and food manufacturers, it can be said that the European Community has made a good start at filling the labeling lacuna. On the other hand, serious grounds for criticism of the new EC labeling rules remain. These issues include the new "2% rule" set out in the amended Directive 2000/13/EC; food supplied by mass caterers and restaurants; foods sold loose; fancy confectionary; food in small packages and indelibly-marked bottles; accidental traces of allergens in foodstuffs; and the fact that a number of substances known to trigger allergies were not addressed in the amendment to Directive 2000/13/EC.

⁵¹ The Agreement on Sanitary and Phytosanitary Measures is available at www.wto.org (last visited July 26, 2005).

Consumers suffering from allergies or intolerances may still suffer because important sources of their adverse reactions have not been regulated. The U.K. FSA has shown a positive attitude in closing these loopholes at the national level by publishing Guidance Notes to catering establishments; by including small and indelibly-marked bottles in the allergen-labeling obligation; and by alerting food manufacturers to the dangers of accidental cross-contamination of allergens. Hopefully, the new EC food hygiene rules, which enter into force on January 1, 2006, will make food business operators more cognizant of consumer's needs through the obligation to integrate a system of hazard analysis into food management. Until then, it is the task of the Member States to publish voluntary codes of manufacturing practice and advisory labeling so as to increase consumer confidence in the areas not covered by the new EC labeling rules.

