

European Regulations for Labeling Requirements for Food Allergens and Substances Causing Intolerances: History and Future

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Food allergens and intolerances have been diagnosed by doctors for decades, but have received heightened attention in the last two decades because diagnosis and awareness have increased. Consequently, regulators in many jurisdictions have addressed this topic by introducing labeling requirements for substances causing allergies and intolerance reactions in affected individuals. Mandatory labeling of food allergens allows persons suffering from these to make informed choices. However, regulations in some geographic areas have resulted in significant problems for manufacturers as well as consumers. This has been mainly due to frequent changes and amendments, and it has been difficult for all stakeholders to follow and understand the status quo of legislation. The present paper describes the development of European directives and regulations for the labeling of food allergens and intolerances to substances like gluten over the past decades and provides an outlook of what can reasonably be expected to change in the coming years. It also identifies existing gaps, like a lack of threshold levels for adventitious contamination and consequently a proliferation of precautionary allergen labeling, which neither benefits the consumer nor the food industry in its current form.

One of the major administrative acts of European legislation in the area of food was a Council Directive on food labeling in Europe in 1979 (79/112/EEC; 1). It was the first attempt to harmonize the way food sold to the final consumer was labeled in Europe. Although consumer deception (commonly known as food fraud) was already included in Article 2 [“The labeling and methods used must not ... be such as could mislead the purchaser to a material degree...”], food allergens or intolerances were not considered for labeling.

Ten years later, the first Council Directive mentioning gluten-free foods was published (89/398/EEC; 2). However, the directive was very general with the purpose of harmonizing

laws of the member states relating to foodstuffs intended for particular nutritional uses. This directive lists gluten-free foods in Annex I, but does not provide any definition as to what can be considered as gluten-free.

Eleven years later, when food-labeling Directive No. 79/112/EEC and all its amendments had a major overhaul and were consolidated into Directive No. 2000/13/EC (3), “on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs,” there was no mention of a labeling requirement for food allergens or food intolerances.

In 2002, a general food safety regulation, (EC) 178/2002 (4), was published, and a major component therein is Article 14 on food safety requirements (*see below*).

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.

Although this could be interpreted as sufficient as a labeling requirement for food allergens and intolerance because it can be injurious to health for allergy sufferers to consume offending food, this regulation did not explicitly consider the needs of food allergenic or intolerant individuals. Figure 1 graphically summarizes all the rules mentioned in this regulation.

Food Allergen Labeling

Four years later, in 2003, after consumer advocacy groups had campaigned for several years to require the labeling of food allergens, an amendment to the food-labeling directive from 2000 was passed. Directive No. 2003/89/EC (5) amended Directive No. 2000/13/EC with regards to the indication of the ingredients present in foodstuffs. It was the first directive to be commonly referred to as the “allergen-labeling directive.” In their reasoning, the European Commission (EC) states that this directive was put in place “in order to achieve a high level of health protection for consumers and to guarantee their right to information.” Annex IIIa was added to Directive No. 2000/13/EC to include a list of allergens and substances causing intolerances that required labeling. The list contained the following:

- Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut, or their hybridized strains) and products thereof;
- Crustaceans and products thereof;
- Eggs and products thereof;

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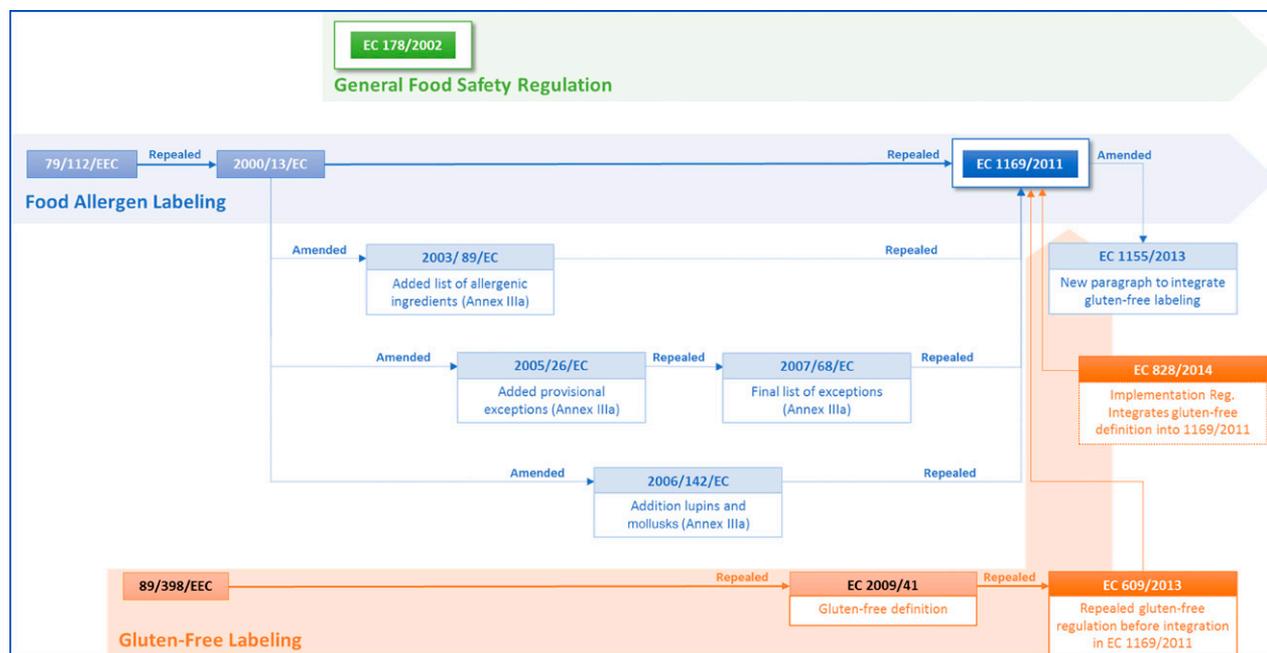


Figure 1. Summary of European labeling rules for food allergens and gluten-free products.

- Fish and products thereof;
- Peanuts and products thereof;
- Soybeans and products thereof;
- Milk and products thereof (including lactose);
- Nuts, i.e., almond (*Amygdalus communis* L.), hazelnut (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nut [*Carya illinoensis* (Wangenh.) K. Koch], Brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), and macadamia nut and Queensland nut (*Macadamia ternifolia*), and products thereof;
- Celery and products thereof;
- Mustard and products thereof;
- Sesame seeds and products thereof; and
- Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/L expressed as SO₂.

The list did not allow for any exemptions, not even for materials known not to contain food-allergy-triggering proteins, like highly refined soybean oil or lecithin fractions. This would render such labeled products potentially harmful to the health of affected allergic consumers, whereas most highly refined or fractionated derivatives no longer pose a threat because all proteins have been removed. Considering that an estimated 20 000 different products containing soy and soy derivatives are sold in supermarkets, this would adversely affect the economy of the food industry and the quality of life of affected individuals alike.

Industry lobbying groups started to push back on this amendment, and, in 2005, a temporary exemption list (essentially an amendment to the amendment) was published in EC Directive No. 2005/26/EC (6). It listed the following temporary exemptions to the amended labeling directive:

Cereals containing gluten

- Wheat-based glucose syrups, including dextrose;
- Wheat-based maltodextrins;
- Glucose syrups based on barley; and
- Cereals used in distillates for spirits.

Eggs

- Lysozyme (produced from egg) used in wine; and
- Albumin (produced from egg) used as fining agent in wine and cider.

Fish

- Fish gelatin used as a carrier for vitamins and flavors; and
- Fish gelatin or isinglass used as fining agents in beer, cider, and wine.

Soybean

- Fully refined soybean oil and fat;
- Natural mixed tocopherols (E306), natural D- α -tocopherol, natural D- α -tocopherol acetate, and natural D- α -tocopherol succinate from soybean sources;
- Vegetable oil-derived phytosterols and phytosterol esters from soybean sources; and
- Plant stanol ester produced from vegetable oil sterols from soybean sources.

Milk

- Whey used in distillates for spirits;
- Lactitol; and
- Milk (casein) products used as fining agents in cider and wine.

Nuts

- Nuts used in distillates for spirits; and
- Nuts (almonds and walnuts) used (as flavor) in spirits.

Celery

- Celery leaf and seed oil; and
- Celery seed oleoresin.

Mustard

- Mustard oil;
- Mustard seed oil; and
- Mustard seed oleoresin.

In the meantime, it appears that two additional products have been identified that can trigger allergic responses: lupins and mollusks and products thereof. Swiftly, another amendment to the amendment covering these two products was published:

Directive No. 2006/142/EC (7). The justification for adding lupins to the list of ingredients requiring labeling was attempted with variable success by the risk assessment authorities. According to a publication in German by the Federal Agency for Risk Assessment from 2011 (8), “19 severe cases of lupin allergy are described in the literature.” More cases of fruit allergies have been described in the literature, and no fruits have been added to the list of substances that require labeling as potentially allergy-triggering. Notwithstanding the number of cases reported in the literature for lupin, the major reason for the aforementioned was phylogenetic proximity to peanut and soy. As in the case of lupin, closely related plant species often trigger allergic reactions (cross-reactivity), i.e., a person known to be allergic to peanuts may also develop an allergic reaction when consuming lupins or soya. Therefore, the requirement to label lupins could be considered a precautionary measure.

In the meantime, the countdown for the temporary exemptions in the amendment of Directive No. 2005/26/EC continued. In 2007, a final list of permitted exemptions was published in Directive No. 2007/68/EC (9), amending aforementioned Annex IIIa of Directive No. 2000/13 as follows:

1. Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut, or their hybridized strains) and products thereof, except

- wheat-based glucose syrups, including dextrose;
- wheat-based maltodextrins;
- glucose syrups based on barley; and
- cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

2. Crustaceans and products thereof.

3. Eggs and products thereof.

4. Fish and products thereof, except

- fish gelatin used as carrier for vitamin or carotenoid preparations; and
- fish gelatin or isinglass used as fining agents in beer and wine.

5. Peanuts and products thereof.

6. Soybeans and products thereof, except:

- fully refined soybean oil and fat;
- natural mixed tocopherols (E306), natural D- α tocopherol, natural D- α tocopherol acetate, and natural D- α tocopherol succinate from soybean sources;
- vegetable oil-derived phytosterols and phytosterol esters from soybean sources; and
- plant stanol ester produced from vegetable oil sterols from soybean sources.

7. Milk and products thereof (including lactose), except

- whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; and
- lactitol.

8. Nuts, i.e., almonds (*A. communis* L.), hazelnuts (*C. avellana*), walnuts (*J. regia*), cashews (*A. occidentale*), pecan nuts [*C. illinoensis* (Wangenh.) K. Koch], Brazil nuts (*B. excelsa*), pistachio nuts (*P. vera*), macadamia nuts and Queensland nuts (*M. ternifolia*), and products thereof, except

- nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

9. Celery and products thereof.

10. Mustard and products thereof.

11. Sesame seeds and products thereof.

12. Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/L expressed as SO₂.

13. Lupin and products thereof.

14. Mollusks and products thereof.

It is very notable that exemptions for fining agents for wine, namely egg and milk, had been withdrawn, whereas fish proteins as fining agents are still permitted. Also, oils and seed oils for celery and mustard have been withdrawn from the labeling exemptions list and are now again required to be labeled as allergens.

In 2011, after no less than 3 corrections and over 40 amendments, the old 2000/13/EC directive—and all its amendments and amendments to amendments, e.g., 2007/68/EC—were repealed in favor of a new consumer-oriented labeling regulation (EC 1169/2011; 10). The list of allergens and intolerances has been transferred from Annex IIIa of Directive No. 2000/13/EC to Annex II of new Consumer Information Regulation (EC) 1169/2011.

This new regulation clearly indicates that the list of allergens in this annex may not be final and can be changed (either to include new allergens or to exempt other products) as new evidence comes to light. In Article 21, Section 2, the text reads, “In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the Commission shall systematically re-examine and, where necessary, update the list in Annex II by means of delegated acts, in accordance with Article 51.”

The new regulation also provides more specific information about how the labeling of food allergens in the ingredient list has to be done. The allergen needs to stand out from the ingredient list. Article 21, Section 1(b) states, “the name of the substance or product as listed in Annex II shall be emphasized through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background color.” Also, allergens need to be labeled with reference to the product listed in Annex II, e.g., “contains milk” instead of “contains casein” [Article 21, Section 1(a)]. Additional labeling clarifications are listed in the Commission Notice of 13.7.2017 (11).

The regulation adds the requirement for labeling information for non-prepackaged foods and foods served/sold by mass caterers. In practice, it means that from the day the consumer information regulation entered into force (December 13, 2014), all restaurants, bakeries, etc., must provide information on allergic ingredients, at least upon request (Article 8, Section 6).

Although this regulation is regarded as positive by many consumer and patient advocacy groups, it does not address one of the more significant problems: cross-contamination or carry-over of allergens during production processes. This regulation, as well as the previous food allergen-labeling directives, exclusively concerns ingredients. In practice, there is no regulation in place that addresses at what level of carry-over or cross-contamination an allergen, which is not part of the ingredient list, needs to appear on the label. Although Article 36.6(2) of Regulation No. 1169/2011 foresees that the Commission shall adopt implementing acts to ensure that information on the possible and unintentional presence in the food of substances or products causing allergies or intolerances does not mislead or confuse consumers, this has not happened at the time of the writing of the present paper. This is a very difficult situation for food producers and affected consumers alike. The Australia-based Allergen Bureau developed, with the help of

experts, a risk-based labeling threshold scheme for the accidental carry-over of allergens. The Voluntary Incidental Trace Allergen Labelling (VITAL) scheme (12) is widely used by the industry, but not legally binding. Several requests have been placed with the European Food Safety Authority (EFSA) to provide guidance for the labeling of trace contamination with allergens, e.g., by using the values established by VITAL. By the time the present paper is published, no threshold values for allergen trace-level contamination will have yet been established in European legislation.

Food Allergen Labeling in Wines

Wine production in Europe is highly regulated. Regulation (EC) 606/2009 (13) lists the authorized practices in wine production, which includes the clarification of wine. The list of agents that can legally be used for clarification of wine include in the latest consolidated version of the regulation (May 25, 2016) the following:

- edible gelatin
- plant protein from wheat, peas, and potatoes
- isinglass
- casein and potassium caseinates
- egg albumin
- bentonite
- silicon dioxide as a gel or colloidal solution
- kaolin
- tannin
- chitosan derived from *Aspergillus niger*
- chitin-glucan derived from *Aspergillus niger*
- yeast protein extracts

In addition to these fining agents, the use of lysozyme is permitted to a maximum of 500 mg/L.

Regulation (EC) 607/2009 (14) specifies in Article 51 what must appear on the label when substances causing allergies or intolerances are involved. In the consolidated version (July 1, 2013), the text reads, “For the purposes of indicating the ingredients as referred to in Article 6(3a) of Directive No. 2000/13/EC, the terms concerning sulphites/sulfites, milk and milk-based products and eggs and egg-based products that must be used are those listed in part A of Annex X.” Egg and milk were not originally included in the regulation and only added through implementing Regulation (EC) 579/2012 (15), Article 1(1).

It is interesting to note that Regulation (EC) 607/2009 in its 2013 consolidated version still refers to repealed Regulation (EC) 2000/13 instead of current Regulation (EC) 1169/2011. However, as is common in these cases, all references to the repealed act shall be construed as a reference to the repealing act.

From the food allergen-labeling perspective, and as described previously, egg and milk used as fining agents for wine production were included among the exceptions listed in 2005/26/EC. This was triggered by several requests from organizations dealing with wine and wine production.

The preliminary findings of EFSA stated that the data provided did not allow the prediction of the likely occurrence of allergic reactions from egg and milk (and products thereof). Consequently, after revising this list, they were not retained on the exclusion list in Commission Directive No. 2007/68/EC. All wines in the European market must comply with labeling requirements since July 1, 2012, according to Commission Regulation (EU) 1266/2010 (16) and declare egg and milk if

the casein (β -lactoglobulin also recommended) and ovalbumin content is higher than 0.25 mg/L.

Yet, further clarification was requested from EFSA after a new request by the International Organization of Vine and Wine on the use of ovalbumin/egg white and casein/caseinates/milk products in 2011. In all cases, EFSA concluded that, “wines fined with casein/caseinate/milk ovalbumin/egg white products - may trigger adverse reactions in susceptible individuals under the conditions of use proposed by the applicant” (17). Therefore, to date, no permanent exemption from the requirement to label the presence of milk- and egg-based proteins in wines is in place.

Gluten

The first definition of what can be labeled as foods for people who are intolerant to gluten was labeling Regulation (EC) 2009/41 (18) “concerning the composition and labeling of foodstuffs suitable for people intolerant to gluten.” This regulation defines gluten [following Codex Alimentarius Standard 118 (19) to a large extent] as “a protein fraction from wheat, rye, barley, oats or their cross-bred varieties and derivatives thereof, to which some people are intolerant and which is insoluble in water and 0.5 M sodium chloride solution.” It permits the labeling of certain products as “very low gluten” and “gluten-free.”

Foodstuffs can be labeled as “very low gluten” if one or more ingredients made from wheat, rye, barley, oats, or their cross-bred varieties has been specially processed to reduce gluten, and the level of gluten does not exceed 100 mg/kg in the food sold to the final consumer. If such products do not exceed 20 mg/kg gluten, they can be labeled as gluten-free. Oats specially processed to avoid contamination by wheat, rye, barley, or their cross-bred varieties that do not exceed 20 mg/kg gluten can also be labeled as gluten-free. The same applies to ingredients substituting wheat, rye, barley, oats, or their cross-bred varieties and contain <20 mg/kg gluten.

The regulation also allows other “foodstuffs for normal consumption” to be labeled as gluten-free. This begs the question whether it is misleading to advertise products, which the consumer can reasonably expect to not have gluten, as gluten-free. An example is mineral water.

The actual challenge is to demonstrate that a product with a gluten-free claim contains no more than 20 mg/kg gluten. Although supply chain management and documented traceability are crucial components, the ultimate proof is in the analysis; however, laboratories are challenged by assays that do not always deliver consistent results.

Because the list in Annex II not only contains food allergens, but also substances causing intolerances, it is notable that gluten-free labeling Regulation (EC) 41/2009 was not integrated into Consumer Information Regulation (EC) 1169/2011, which was done through, as usual, an amendment and took three legal acts to do so: On June 12, 2013, Regulation (EC) 609/2013 (20) repealed several regulations dealing with food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. It included repealing gluten-free labeling Regulation (EC) 41/2009, effective July 20, 2016. In the reasoning of this regulation, it is explained that the gluten-free labeling regulation was repealed for clarity in conjunction with the labeling requirement of (EC) 1169/2011. The “whereas” text in Section 41 reads as follows:

Currently, the rules on the use of the statements “gluten-free” and “very low gluten” are specified in Regulation (EC) 41/2009. That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in food and sets specific rules for food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients or to substitute such gluten-containing ingredients and other food that is made exclusively from ingredients that are naturally free of gluten. Regulation (EU) 1169/2011 sets out rules on information to be provided for all food, including non-prepacked food, on the presence of ingredients, such as gluten-containing ingredients, with a scientifically proven allergenic or intolerance effect in order to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements “gluten-free” and “very low gluten” should also be regulated under Regulation (EU) 1169/2011. The legal acts to be adopted pursuant to Regulation (EU) 1169/2011, which are to transfer the rules on the use of the statements “gluten-free” and “very low gluten,” as contained in Regulation (EC) 41/2009, should ensure at least the same level of protection for people who are intolerant to gluten as currently provided for under Regulation (EC) 41/2009. That transfer of rules should be completed before this Regulation applies. Furthermore, the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between a food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients and other food that is made exclusively from ingredients naturally free of gluten.

Approximately 6 weeks later, on August 21, 2013, the Commission issued a Commission-delegated regulation [(EC) 1155/2013; 20] amending Regulation No. 1169/2011 “on the provision of food information to consumers as regards information on the absence or reduced presence of gluten in food.” This states that in the first subparagraph of Article 36(3) of Regulation (EU) 1169/2011, the following point (d) is added: “(d) information on the absence or reduced presence of gluten in food.”

Although the original gluten-free labeling regulation would no longer be in force after 2016, and the requirement for labeling had been integrated into (EC) 1169/2011, there would be no criteria for what is considered gluten-free or low gluten after 2016 because this is not stated in (EC) 609/2013 or (EC) 1169/2011 [amended through (EC) 1155/2013]. Therefore, it took another regulation to define this, (EC) 828/2014 (21), stating the “requirements for the provision of information to consumers on the absence or reduced presence of gluten in food.” The levels of 20 mg/kg gluten for “gluten-free” labeling and 100 mg/kg for “very low gluten” labeling from (EC) 41/2009/EC are maintained in general, but are now dealt with in the annex of the regulation (22).

Conclusions

By now, Consumer Information Regulation (EC) 1169/2011 contains both the food allergen and intolerance labeling requirements, as well as the gluten-free labeling requirements, whereas their definition is regulated under (EC) 828/2014.

Because of its short time in existence, this Consumer Information Regulation has experienced no less than 12 corrections and 7 amendments, and it is not unreasonable to anticipate that there will be more.

Because of (EC) 1169/2011, including all its amendments, the Regulation does not contain instructions on how to label accidental contamination of food allergens, and, given the proliferation of “may contain” labeling and the pressure by food industry and patient advocacy groups, it can be reasonably assumed that at some stage another legal act will be established to address the issue of adventitious contamination with food allergens and provide either guidance or even threshold levels for labeling. However, because EFSA has just issued a call for a project to “develop reference (harmonised) methodologies for the detection and quantification of allergens in foods” and to “generate good quality data on minimum eliciting doses ... and minimum observed eliciting doses” (with a run time of 4 years and a decision of the project awards to be made in late 2017), it is not likely to see any levels before 2024. In the meantime, the food industry in Europe will not let the situation linger and is likely to create a fait accompli well before that time by setting self-set levels and working through certification schemes.

It is not entirely unlikely that EFSA will recommend that some fruits enter the list food allergens, requiring mandatory labeling.

In summary, the complexity of the regulatory environment and processes in Europe makes it difficult for the industry to follow up and stay up-to-date. Modifications take place so often that it has reached the point to almost require a system that facilitates tracing the development of amendments back to the proper regulation. In the meantime, important aspects, such as the adventitious presence of allergens due cross-contamination and threshold values, are still not addressed.

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