

The Food Allergy Risk Management in the EU Labelling Legislation

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Abstract Food allergy represents an increasing public health issue, and a large number of food control authorities have provided regulations aimed to minimize the risk of allergic reaction for sensitized consumers. The Food and Agriculture Organization of the United Nations together with the World Health Organization established the Codex Alimentarius Commission whose main goal is to protect the consumers' health. To pursue this task the Commission listed the foods and ingredients causing the most severe allergic reactions that should be labelled. It has been reported that some cases of specific foods hypersensitivity display a different prevalence among different Countries. Thus, the European Union drew up a list of mandatory allergens (that must be labelled) longer than that provided by Codex Alimentarius. As a consequence of the complexity of the legal phraseology of the European Union (EU) and/or European Community (EC) the Regulations and/or Directives were differently translated in all EC/EU official languages determining possible misinterpretations of the legislation. Moreover, food labelling regulations were also established with the goal to promote the consumers' conscious choice about what they eat. Starting from the case of the fermented beverages, we analysed

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the European legislative scenario concerning the allergen labelling of the last fifteen years, highlighting that mistranslations, misinterpretations and lack of information in the EU Regulations might lead to health and ethical issues.

Keywords Food labelling · European Union legislation · Directive and regulation misinterpretation · Food allergens · Consumers' risk and conscious choice

Background and Justification

As for other health threats, the management of the food allergen risk needs a safety policy that consists of three aspects: assessment, management and communication (Jensen and Sandoe 2002; Sperling 2010). Health control authorities and the involved scientific community aim to evaluate the potential adverse effects on human health of foodborne hazard (risk assessment). In risk management, decision-making is a political/administrative/technological process. It involves both the evaluation of the sociological and political relevance of the phenomenon, and the elaboration of advanced technologies to minimize, or at least, to control the risk in a perspective of implementations. The last level of a safety policy is the spread of information about the risk among the interested parties, i.e., risk assessors, risk managers, and public audience (Jensen and Sandoe 2002; Sperling 2010).

In food safety, ethics intervenes in all the three levels of risk analysis: it makes value judgments in the risk assessment, it helps taking decisions in the risk management, and it contributes to the risk communication through the food labelling (Sperling 2010). This last has not only the goal to protect the consumer's health but also to create conditions that allow consumers to make conscious choices regarding their nutrition and eating habits. For instance, the use of animal proteins as fining agents in fermented beverages could represent a concern for some ethical practices, such as vegetarianism or veganism, or for religious faiths (e.g., Judaism). As a consequence, the consumption of animal products thereof is regulated and sometimes avoided by these ethical practices (Rizzi et al. 2016).

The Food and Agriculture Organization of the United Nations (FAO) together with the World Health Organization (WHO) established in the 1960s the Codex Alimentarius Commission (composed by 187 Member Countries) to develop international food standards, to protect consumers' health and to promote the food trade (<http://www.fao.org/fao-who-codexalimentarius/en/>). FAO estimated that eight allergenic foods are responsible for more than 90% of all food allergies (FAO 1995). For this reason, according to the Codex Alimentarius (1999), the foods that include milk, eggs, fish, crustaceans, peanuts, soybeans, tree nuts, and gluten-containing cereals (most specifically wheat) as ingredients, must be specifically labelled. However, there are examples of allergies to other foods, whose prevalence has a particular distribution in different Countries. This is the case of celery in Switzerland/Austria, and of rice and buckwheat mainly in Japan (Cochrane et al. 2009; Mills et al. 2007; Eriksson et al. 2004; Taylor and Hefle 2001; EFSA 2004).

This implies that the requirements for mandatory food allergen declarations are different across the different Countries, where the allergen labelling lists are focused on the local prevalence patterns of sensitization (Gendel 2012). In Europe, scientific evidences indicate that sesame seeds, mustard, celery and lupine are involved in allergic/adverse reactions occurring in people of some of the Member States. For this reason, the list of mandatory labelling allergens was extended (EFSA 2004, 2005, 2006).

Recently, we investigated the presence of exogenous proteins in fermented beverages (i.e., wine and cider). The aim of the studies was to verify the allergenic risk related to these molecules that might represent “hidden allergens”, since they are present but not declared on the label of the products (Rizzi et al. 2016). In particular, we highlighted the presence of proteins from milk, wheat and egg in wines and cider (Simonato et al. 2011; Tolin et al. 2012a, b; Mainente et al. 2016). On the basis of these and other studies, e.g., the one by Puglisi and Frieri (2007) even on different foods, the possibility for sensitized people to be inadvertently exposed to molecules that elicit anaphylaxis represents cause of great concern.

The presence of allergens in a food may derive from two potential sources: the allergen is an ingredient that must be labelled (with some exceptions), or it is the result of an unintentional contamination. The latter occurrence may be due to shared equipment in different food preparations, wrong use of processing aids that contain allergenic substances, or lack of expertise and ignorance of the law by the producer (Taylor et al. 2009). The last case could be a consequence of the complexity of the legal phraseology of the European Union (EU) and/or the European Community (EC) Regulations and/or Directives that have to be also carefully translated in all EC/EU official languages to avoid misinterpretations. This suggests that the third level of food safety policy (i.e., risk communication) has not safeguarded the consumers’ interest, not only for the individual’s health, but also from the ethical point of view.

EU/EC Regulations and Directives on Food Labelling

The Directive 2000/13 (Commission of the European Communities, 2000) was the first attempt to regulate the labelling of foodstuffs produced in the Member States. In particular, article 6(8) stated that “an ingredient compound may be included in the list of ingredients [*omissis*]. Such a list, however, shall not be compulsory: (a) where the compound ingredient constitutes less than 25% of the finished product [*omissis*]”. Taking into consideration that the intake of few milligrams and even micrograms of allergen can trigger a food adverse reaction (EFSA 2014) and that it is not possible to predict neither the dose–response level of an allergic consumer to a food allergen, nor the level of severity of the allergic reaction (Hourihane and Knulst 2005; Taylor et al. 2009), it is evident that Directive 2000/13 did not fully protect the health of the allergic individuals.

To guarantee a higher level of health care for sensitized consumers, the Directive 2000/13 was amended by the Directive 2003/89 (Commission of the European Communities, 2003) that, by adding the paragraph 3(a) to Art. 6, established that “any ingredient, as defined in paragraph 4(a) and listed in the also newly introduced

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
 Crustaceans and products thereof
 Eggs and products thereof
 Fish and products thereof
 Peanuts and products thereof
 Soybeans and products thereof
 Milk and 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*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof
 Celery and products thereof
 Mustard and products thereof
 Sesame seeds and products thereof
 Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.'

Fig. 1 Ingredients that must be labelled listed in the Annex IIIa of Directive 2003/89 (©European Union, <http://eur-lex.europa.eu/>, 1998–2016)

Annex IIIa (Fig. 1), shall be indicated on the labelling where it is present in beverages referred to in paragraph 3 [*omissis*]. An indication is not necessary when the ingredient is already included under its specific name in the list of ingredients or in the name under which the beverage is sold". In particular, the Annex IIIa listed twelve ingredients that, regardless of their concentration, had to be labelled according to the new provision.

In addition, the new article 6(11), also introduced by the Directive 2003/89, stated that "The list in Annex IIIa shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge [*omissis*]. Updating could also be effected by the deletion from Annex IIIa of ingredients for which it has been scientifically established that it is not possible for them to cause adverse reactions [*omissis*]. To this end, the Commission shall after consultation with the European Food Safety Authority (EFSA), adopt a list of those ingredients or substances, which shall consequently be excluded from Annex IIIa, pending the final results of the notified studies, or at the latest until 25 November 2007". In this legal framework, therefore, the Commission adopted the Directive 2005/26 (Commission of the European Communities, 2005) establishing a list of food ingredients or substances thereof provisionally excluded from Annex IIIa (Fig. 2).

The reason why some food ingredients and substances were excluded from labelling is based on the EFSA scientific opinions that judged "...not likely, or not very likely, to cause adverse reactions in susceptible individuals" (Directive 2005/26). In some cases, EFSA concluded that "the incomplete scientific data submitted do not allow the Panel to evaluate the likelihood that" specific ingredients/substances may trigger the allergic reaction in susceptible individuals (EFSA 2007).

However, the list contained in the Annex of the 2005 Directive (Fig. 2) counted potentially allergens, such as egg lysozyme (only if used as additive in winemaking), and egg albumin, fish gelatine or isinglass, milk (casein) products used as fining agents in wine, beer or cider-making.

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	— Wheat based glucose syrups including dextrose⁽¹⁾ — Wheat based maltodextrins⁽¹⁾ — Glucose syrups based on barley — Cereals used in distillates for spirits
Eggs	— Lysozym (produced from egg) used in wine — Albumin (produced from egg) used as fining agent in wine and cider
Fish	— <u>Fish gelatine used as carrier for vitamins and flavours</u> — <u>Fish gelatine or Isinglass used as fining agent in beer, cider and wine</u>
Soybean	— Fully refined soybean oil and fat⁽¹⁾ — Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, 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
Milk	— Whey used in distillates for spirits — Lactitol — <u>Milk (casein) products used as fining agents in cider and wines</u>
Nuts	— Nuts used in distillates for spirits — Nuts (almonds, walnuts) used (as flavour) in spirits
Celery	— Celery leaf and seed oil — Celery seed oleoresin
Mustard	— Mustard oil — Mustard seed oil — Mustard seed oleoresin

⁽¹⁾ And products thereof, in so far 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.

Fig. 2 Ingredients temporarily excluded from labelling according to Directive 2005/26. The underlined substances are food ingredients that underwent to the Directive 2007/68 (©European Union, <http://eur-lex.europa.eu/>, 1998–2016)

As a consequence, in 2007 on the basis of the new EFSA scientific opinions, the European Commission modified the Annex IIIa of the 2000 Directive and drafted an updated list of fourteen ingredients that must be labelled in foodstuffs. The list indicated some exceptions represented by products thereof that are likely not to contain allergens (Fig. 3).

It is important to underline that the Commission Directive 2007/68, repealing the Directive 2005/26, added two new ingredients to the mandatory list (i.e., lupin, molluscs and products thereof), and became more restrictive for other products thereof that, starting from the 26th November 2007, must be labelled. The food ingredients that underwent to the new normative are highlighted in Fig. 2.

On the 25th October 2011, the European Parliament and the Council of the European Union adopted the Regulation 1169/2011 (Commission of the European Communities, 2011) that repealed the Directive 2000/13 and indicated in its Annex II the substances or products that cause food allergies or intolerances that must be

1. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except:
 - (a) wheat-based glucose syrups including dextrose ⁽¹⁾;
 - (b) wheat-based maltodextrins ⁽¹⁾;
 - (c) glucose syrups based on barley;
 - (d) 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:
 - (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
 - (b) fish gelatine or Isinglass used as fining agent in beer and wine.
5. Peanuts and products thereof.
6. Soybeans and products thereof, except:
 - (a) fully refined soybean oil and fat ⁽¹⁾;
 - (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;
 - (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - (d) plant stanol ester produced from vegetable oil sterols from soybean sources.
7. Milk and products thereof (including lactose), except:
 - (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;
 - (b) lactitol.
8. Nuts, i.e. almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:
 - (a) 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. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.
13. Lupin and products thereof.
14. Molluscs and products thereof.^{*}

⁽¹⁾ 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.

Fig. 3 Ingredients listed in the Annex IIIa of Directive 2007/68 (Commission of the European Communities, 2007) and that must be labelled (©European Union, <http://eur-lex.europa.eu/>, 1998–2016)

labelled (Fig. 3). This Annex reconfirms the list of substances, reported in the former Annex IIIa of the 2000 Directive resulting from the Commission Directive 2007/68.

It is noteworthy that the Regulation 1169/2011 has been wrongly translated in some languages of the Member States, e.g., Italian, Spanish and French. As a matter of fact, the term “products thereof” was translated in “products based on”. This means that a single constituent of a food is not considered an ingredient and then can be omitted from the label. For example, the omelette is a “product based on egg”, because the whole egg is an ingredient of this food. On the contrary, egg lysozyme (a well-known allergen) is an “egg product thereof” because it is purified from the egg white, but it cannot be considered a “product based on egg”, since the whole egg is not an ingredient of lysozyme. As a consequence of this mistranslation in some European food products it could be possible to detect allergens that are not labelled (e.g., hen egg lysozyme detected in Italian ciders by Mainente et al. 2017), because they are not reported in the Annex II of the Regulation 1169/2011, and thanks to the free movement of goods, these products could be distributed in the market of the different Member States.

Notably, the cited EU Regulations were drafted with the goal to protect allergic individuals, but they do not take into consideration the food ethics, because some religious faiths and philosophic practices choose the (total or partial) abstaining from the consumption of animal products thereof (Rizzi et al. 2016).

As for the labelling and presentation of certain wine sector products (i.e., beverages containing more than 1.2% by volume of alcohol), it is interesting to note that the European Commission adopted the Regulation 579/2012 (Commission of the European Communities, 2012) that indicates that sulphites, milk and eggs (and their based products) must be labelled together with specific pictograms to “improve the readability of the information provided to consumers and offer better guarantees for consumers” (recital 4 of Regulation 579/2012) (Figs. 4, 5).

This regulation overcame the problems of misinterpretation of the sentence “product thereof” present in the EC Directives and EU Regulations starting from the year 2000. However, it is noteworthy that Regulation 579/2012 is referred only to certain wine sector products.

Concluding Remarks

Along the last years the European Community and the European Union issued laws to provide information to consumers, to prevent omissions or misleading actions, and to protect the health of citizens of the Member States. Under this view, a particular attention has been given to the labelling of food products. The recent Regulation 1169/2011 acknowledges that “certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people, and some of those allergies or intolerances constitute a danger to the health of those concerned” (Regulation 1169/2011). For this reason, according to EFSA scientific opinion it has been drafted a list of allergenic substances that must be labelled on foodstuffs.

Language	Terms concerning sulphites/sulfites	Terms concerning eggs and egg-based products	Terms concerning milk and milk-based products
in Bulgarian	„сулфити“ or „сърпи диоксид“	„айде“, „айден протеин“, „айден продукт“, „айден лизозим“ or „айден албумин“	„мляко“, „млякени продукти“, „млякени казеин“ or „млякени протеин“
in Spanish	«sulfitos» or «dióxido de azufre»	«huevo», «proteína de huevo», «ovo-producto», «lisozima de huevo» or «ovalbúmina»	«leche», «productos lácteos», «caseína de leche» or «proteína de leche»
in Czech	„siričitany“ or „oxid siričitý“	„vejce“, „vaječná bílkovina“, „výrobky z vajec“, „vaječný lysozym“ or „vaječný albumin“	„mléko“, „výrobky z mléka“, „mléčný kasein“ or „mléčná bílkovina“
in Danish	«sulfitter» or «svovldioxid»	«æg», «eggprotein», «ægprodukt», «æglysozym», or «egalbumin»	«mælk», «mælkeprodukt», «mælkecasein» or «mælkeprotein»
in German	„Sulfit“ or „Schwefeldioxid“	„Ei“, „Eiprotein“, „Eiprodukt“, „Lysozym aus Ei“ or „Albumin aus Ei“	„Milch“, „Milcherzeugnis“, „Kasein aus Milch“ or „Milchprotein“
in Estonian	„sulfitid“ or „vääveldioksiid“	„mun“, „munaprotein“, „munatooted“, „munaliisosiim“ or „munaliibuntin“...	„piim“, „piimatooted“, „piimakasein“ or „piimaprotein“
in Greek	«θειώδη», «διοξείδιο του θείου» or «ανθρακίτης του θειώδους οξέος»	«αυγό», «προτεΐνη αυγού», «πρωϊόν αυγού», «λυσοζύμη αυγού» or «αλβουμίνη αυγού»	«γάλα», «πρωϊόντα γάλακτος», «καζεΐνη γάλακτος» or «προτεΐνη γάλακτος»
in English	‘sulphites’, ‘sulfités’, ‘sulphur dioxide’ or ‘sulfur dioxide’	‘egg’, ‘egg protein’, ‘egg product’, ‘egg lysozyme’ or ‘egg albumin’	‘milk’, ‘milk products’, ‘milk casein’ or ‘milk protein’
in French	«sulfités» or «anhydride sulfureux»	«œuf», «protéine de l'œuf», «produit de l'œuf», «lysozyme de l'œuf» or «albumine de l'œuf»	«lait», «produits du lait», «caseïne du lait» or «protéine du lait»
in Italian	«solfiti», or «anidride solforosa»	«uovo», «proteina dell'uovo», «derivati dell'uovo», «lisozima da uovo» or «ovalbumina»	«latte», «derivati del latte», «caseina del latte» or «proteina del latte»
in Latvian	“sulfiti” or “sēra dioksīds”	“olas”, “olu olbaltumviela”, “olu produkti”, “olu lizocīms” or “olu albumīns”	“piens”, “piena produkti”, “piena kazeīns” or “piena olbaltumviela”
in Lithuanian	„sulfitai“ or „sėros dioksidas“	„kiaušiniai“, „kiaušinių baltymai“, „kiaušinių produktai“, „kiaušinių lizocinas“ or „kiaušinių albuminas“	„pienas“, „pieno produktai“, „pieno kazeinas“ or „pieno baltymai“
in Hungarian	„szulfitok“ or „kén-dioxid“	„tojás“, „tojásból származó fehérje“, „tojástermék“, „tojásból származó lizozim“ or „tojásból származó albumin“	„tej“, „tejtérmékek“, „tejkazein“ or „tejfőhénye“
in Maltese	“sulfiti”, or “diossidu tal-kabrit”	“bajd”, “proteina tal-bajd”, “prodott tal-bajd”, “lizozima tal-bajd” or “albumina tal-bajd”	“halib”, “prodotti tal-halib”, “kaseina tal-halib” or “proteina tal-halib”
in Dutch	«sulfiten» or «zwaveldioxide»	«ei», «eiproteïne», «eiderivaat», «eilysozym» or «eialbumine»	«melk», «melkderivaat», «melkcaseïne» or «melkproteïne»
in Polish	„siarczyny“, „dwutlenek siarki“ or „tlenek siarki“	„jajo“, „białko jaja“, „produkty z jaj“, „lizozym z jaja“ or „albumin z jaja“	„mleko“, „produkty mleczne“, „kazein z mleka“ or „białko mleka“
in Portuguese	«sulfitos» or «dióxido de enxofre»	«ovo», «proteína de ovo», «produto de ovo», «lisozima de ovo» or «albumina de ovo»	«leite», «produtos de leite», «caseína de leite» or «proteína de leite»
in Romanian	„sulfiti“ or „Dioxid de sulf“	„ouă“, „proteine din ouă“, „produse din ouă“, „lizozimă din ouă“ or „albumină din ouă“	„lapte“, „produse din lapte“, «azeină din lapte» or «proteine din lapte»
in Slovak	„siričitany“ or „oxid siričitý“	„vajce“, „vaječná bielkovina“, „výrobok z vajec“, „vaječný lysozym“ or „vaječný albumin“	„mlieko“, „výrobky z mlieka“, „mliečne výrobky“, „mliečny kazein“ or „mliečna bielkovina“
in Slovene	„sulfiti“ or „žveplov dioksid“	„jajce“, „jajčne beljakovine“, „proizvod iz jajc“, „jajčni lizocim“ or „jajčni albumin“	„mleko“, „proizvod iz mleka“, „mlečni kazein“ or „mlečne beljakovine“
in Finnish	“sulfitit”, “sulfititeja” or “rikkidioksidi”	“kananmunua”, “kananmunaproteiini”, “kananmunatuotetta”, “lysoosymia (kananmunasta)” or “kananmuna-albumiinia”	“maidon”, “maidotuotteita”, “kasiinia (maidosta)” or “maitoproteiinia”
in Swedish	“sulfit” or “svaveldioxid”	“ägg”, “äggprotein”, “äggprodukt”, “ägglysozym” or “äggalbumin”	“mjölk”, “mjölkprodukter”, “mjölk-kasein” or “mjölkprotein”

Fig. 4 Constituent ingredients of wine products sector concerning sulphites, milk and eggs (and their based products) that must be labelled together with specific pictogram, according to Regulation 579/2012 (©European Union, <http://eur-lex.europa.eu/>, 1998–2016)



Fig. 5 Pictograms concerning sulphites, milk and eggs (and their based products) that must be labelled together with the constituent ingredients of wine products sector, according to Regulation 579/2012 (©European Union, <http://eur-lex.europa.eu/>, 1998–2016)

The complexity of the topic makes the interpretation of the regulations difficult, and this sometimes could lead to their mistranslation. This problem was partially overcome by Regulation EU 579/2012, but it refers only to specific products of the wine market. However, in our opinion also this regulation is incomplete because it takes into account only sulphur dioxide and proteins/allergens from milk and egg that must be labelled. Other proteins, such as those from animal origin (e.g., isinglass) could be used in winemaking, but their potential presence could be omitted on the label. This represents not only a health concern but also an omission in terms of ethics.

Compliance with Ethical Standards

Conflict of interest The authors declared that they have no conflict of interest.

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