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Information to Consumers on the Absence or Reduced Presence of Gluten in Food

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Information to consumers on the absence or reduced presence of gluten in food: Commission Implementing Regulation (EU) No 828/2014

Luis González Vaqué

«Amb nova falç comenceu a segar el blat
madur i, amb ell, les
males herbes»

Salvador Espriu

I. Introduction

On 30 July 2014, the European Commission adopted Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food¹.

This article seeks to analyse what is new in this Community legislation. To do so it would be appropriate to first look briefly at Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten², especially because Implementing Regulation No. 828/2014 will only enter into force on 20 July 2016³, and in the meantime the 2009 Regulation will continue to regulate information about the food in question.

I shall also summarise the *Codex Alimentarius* Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118 – 1979). This Standard is mentioned in recital 12 of Commission Implementing Regulation No 828/2014, which states that “The Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten [...] should be taken appropriately into consideration for the purposes of this Regulation”. Furthermore the Commission had already referred to this Standard in recital 11 of Regulation No 41/2009⁴.

There is no doubt that Commission Implementing Regulation No 828/2014 regulates a very *sensitive* area of concern – that of people with coeliac disease who suffer from a permanent intolerance to gluten. Wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and khorasan wheat), rye and barley have been identified as grains that are scientifically reported to contain gluten, and “the gluten present

¹ OJ L 228, 31.7.2014, p. 5 (on this Regulation see “Commission sets out gluten labelling rules”, *EU Food Law*, No. 636, 2014, 2-3; and NAVALÓN VALDECABRILLAS, M., “Sigue el debate sobre los productos *gluten-free*”, *BoDiAlCo*, No. 9, 2014, 13-22).

² OJ L 16, 21.1.2009, p. 3.

³ See Article 5 of the aforementioned Implementing Regulation No. 828/2014.

⁴ In fact the recital is more explicit: “the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten was adopted by the 31st session of the *Codex Alimentarius* Commission in July 2008 [...], with a view to enabling those persons to find on the market a variety of food suitable to their needs and to their level of sensitivity to gluten”. It goes on to add that “that standard should be taken appropriately into consideration for the purposes of this Regulation”.

in those grains can cause adverse health effects to people intolerant to gluten and therefore its consumption should be avoided by such people"⁵. Clearly this is a health protection issue, but given my limited knowledge of this field I shall not approach the issue from such a perspective, especially given the already wide range of work published which does so⁶. Indeed I shall altogether forego dealing with medical, socio-economic or technical issues in order to focus instead on a legal analysis of relevant provisions.

II. Commission Regulation (EC) No 41/2009

1. Community level harmonisation of the conditions for the use of the terms related to the absence of gluten in foodstuffs.

The Commission adopted this Regulation to provide clarification and avoid confusion among consumers because of the different national rules governing the composition and labelling of foodstuffs appropriate for people intolerant to gluten. In doing so it took into particular consideration the provisions of articles 3.2 and 4a of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses⁷. It also specifically took into account Article 2.3 where said Article provides for the possibility for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability: "therefore, it should be possible for a

⁵ See the first recital of Commission Implementing Regulation No 828/2014.

⁶ See for example CASE, S., "The gluten-free diet: How to provide effective education and resources", *Gastroenterology*, Vol. 128 No. 4 Sup. 1, 2005, S128-S134; CICLITIRA, P. J., "Gluten-free diet—what is toxic?", *Best Practice & Research Clinical Gastroenterology*, Vol. 19 No. 3, 2005, 359-371; DEVILLE-ALMOND, J. and HALLIWELL, K., "Understanding and interpreting nutrition information on food labels", *Nursing Standard*, Vol.28, No., 2014, 50-57; HOLMES et al., "Malignancy in coeliac disease--effect of a gluten free diet", *Gut*, Vol. 30, No. 3, 1989, 333-338; HOYT, A. M., "Gluten free-dom: my journey to becoming an unintentional expert", *Baylor University Medical Center Proceedings*, Vol. 27, No. 3, 2014, 276-282; KONING, F. et al., "The million-dollar question: is 'gluten-free' food safe for patients with celiac disease?", *The American Journal of Clinical Nutrition*, Vol. 97, No. 1, 2013, 3-4; LEE, S. K. et al., "Duodenal histology in patients with celiac disease after treatment with a gluten-free diet", *Gastrointestinal Endoscopy*, Vol. 57, No. 2, 2003, 187-191; MERCER, S. W. and MARTIN, U., "A comparison of general practitioners prescribing of gluten-free foods for the treatment of coeliac disease with national prescribing guidelines", *Journal of Human Nutrition and Dietetics*, Vol. 27, No. 1, 2014, 96-104; McCABE, M.S., "Balancing consumer protection and scientific integrity in the face of uncertainty: the example of gluten-free foods", *Food & Drug Law Journal*, Vol. 65, No. 2, 2010, 367-390; NIEWINSKI, M. M., "Advances in Celiac Disease and Gluten-Free Diet", *Journal of the American Dietetic Association*, Vol. 108, No. 4, 2008, 661-672; SATURNI, L., "The Gluten-Free Diet: Safety and Nutritional Quality", *Nutrients*, Vol. 2, No. 1 (2010) 16-34; STEVENS, L. and RASHID, M., "Gluten-Free and Regular Foods: A Cost Comparison", *Journal Canadian Journal of Dietetic Practice and Research*, Vol. 69, No. 3, 2008, 147-150; THEETHIRA, T. G. et al., "Nutritional consequences of celiac disease and the gluten-free diet", *Expert Review of Gastroenterology & Hepatology*, Vol. 8, No. 2, 2014, 123-129; VAN LANDSCHOOT, A., "Gluten-free barley malt beers", *Cerevisia*, Vol. 36, No. 3, 2011, 93-97; VERRILL, L. et al., "Food label usage and reported difficulty with following a gluten-free diet among individuals in the USA with coeliac disease and those with noncoeliac gluten sensitivity", *Journal of Human Nutrition and Dietetics*, Vol. 26, No. 5, 2013, 479-487; WAHAB, P. J. et al., "Histologic Follow-up of People With Celiac Disease on a Gluten-Free Diet - Slow and Incomplete Recovery", *American Journal of Clinical Pathology*, No. 118, 2002, 459-463; and WILSON, N. L. W. and WOROSZ, M. R., "A Cautionary Tale of Purity, Labelling and Product Literacy in the Gluten-Free Market", *Journal of Consumer Affairs*, Vol. 46, No. 2, 2012, 288-318.

⁷ OJ L 186, 30.6.1989, p. 27. This regulation was repealed by Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21) which itself is no longer applicable from 16 December 2014 under Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

normal food which is suitable as part of a gluten-free diet because it does not contain ingredients derived from gluten containing grains or oats *to bear terms indicating the absence of gluten*⁸⁹. But Directive 89/398/CEE also stipulated that statements which appear on labelling should not deceive the consumer by suggesting that a food product has particular characteristics when in fact all similar products possess said characteristics. It was therefore *necessary to provide for exceptions*. Furthermore, *to explain the reasoning behind some of the provisions being included*, the Commission referred in Regulation No 41/2009 to a piece of Community legislation which is still in force and *applicable* at the time of writing¹⁰. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs¹¹.

Likewise the Commission also noted that the food industry had developed a range of products presented as 'gluten-free' or similar equivalent terms. Nevertheless, differences between national provisions concerning the conditions for the use of such product descriptions could still impede the free movement of the concerned products and fail to ensure the same high level of protection for consumers.

As elsewhere then, harmonisation aimed at ensuring the free movement of goods, applicable in this case "...to [all] foodstuffs other than the infant formulae and follow-on formulae covered by Directive 2006/141/EC¹²¹³, was made compatible with the fundamental general interest of health protection.

2. Identification and characteristics of a specific population group that may need foodstuffs intended for particular nutritional uses

The first recital of Regulation No 41/2009 notes that Directive 89/398/EEC referred to foodstuffs intended for particular nutritional uses (which owing to their special composition or manufacturing process are intended to satisfy the particular nutritional requirements of specific categories of the population). It then goes on to emphasise that "people with coeliac disease are such a specific group of the population suffering from a permanent intolerance to gluten".

By way of further detail, the Commission included the following information in the recitals of Regulation No 41/2009:

⁸ Emphasis added by the author.

⁹ See the eighth recital of Regulation No 41/2009.

¹⁰ August 2014.

¹¹ OJ L 109, 6.5.2000, p. 29. On this Community regulation see BUREAU, J. C. and VALCESCHINI, E., "European food-labeling policy: successes and limitations", *Journal of Food Distribution Research*, Vol. 34, No. 3, 2013, 70-74; CHEFTEL, J. C., "Food and nutrition labelling in the European Union", *Food Chemistry*, Vol. 93 No. 3, 2005, 531-550; LUCAS-PUGET, A. S., "Les allégations sur les produits alimentaires de consommation courante: Quelques questions d'actualité", *Les Petites affiches*, Vol. 395, No. 103, 2006, 4-16; PRZYREMBEL, H., "Food labelling legislation in the EU and consumers information", *Trends in Food Science & Technology*, Vol. 15, No. 7-8, 2004, 360-365; and PUOTI, P., "Etichettatura dei prodotti agroalimentari: aspetti problematici", *Diritto comunitario e degli scambi internazionali*, No. 3, 2004, 613-648.

¹² Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).

¹³ See Article 1 ("Scope") of Regulation No. 41/2009.

- wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and kamut), rye and barley, have been identified as grains that are scientifically reported to contain gluten¹⁴;
- the gluten present in those grains can cause adverse health effects to persons intolerant to gluten and therefore should be avoided by them¹⁵; and
- The removal of gluten from gluten-containing grains presents considerable technical difficulties and economic constraints and therefore the manufacture of totally gluten-free food is difficult, and consequently many foodstuffs for this particular nutritional use on the market may contain low residual amounts of gluten¹⁶.

It is also worth recalling that upon adopting a Community regulation on *foodstuffs for people intolerant to gluten* (in other words “foodstuffs for particular nutritional uses which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten”¹⁷), the Commission not only had take into consideration the fact that some of the products in question might contain small residual amounts of gluten, but also that

- despite stating that most but not all people with intolerance to gluten can include oats in their diet without adverse effect on their health, the possible contamination of oats with wheat, rye or barley during grain harvesting, transport, storage and processing could not be excluded; and
- different people with intolerance to gluten may tolerate variable small amounts of gluten within a restricted range.

In order to enable individuals to find on the market a variety of foodstuffs appropriate for their needs and for their level of sensitivity, a choice of products should be possible with different low levels of gluten within such a restricted range.

3. Scope and definitions

As seen above, Regulation No 41/2009 applies to foodstuffs other than the infant formulae and follow-on formulae covered by Directive 2006/141/EC¹⁸.

¹⁴ See the third recital of Regulation No 41/2009.

¹⁵ *Ibidem*.

¹⁶ See the fourth recital of Regulation No 41/2009.

¹⁷ See the definition in Article 2(a) of Regulation No 41/2009.

¹⁸ See Article 1 of Regulation No 41/2009. In the ninth recital of this Regulation the Commission notes that Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1) prohibits the use of ingredients containing gluten in the manufacture of such foodstuffs, and concludes that “therefore, the use of the terms ‘very low gluten’ or ‘gluten-free’ on the labelling of such products should be prohibited given that pursuant to the present Regulation, this labelling is used for indicating respectively a content of gluten not exceeding 100 mg/kg and 20 mg/kg.”

This succinct description of the Regulation's scope of application¹⁹ is accompanied by three definitions: *foodstuffs for people intolerant to gluten* (as explained earlier this means "... *foodstuffs for particular nutritional uses*"²⁰ which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten"²¹), *gluten* ("... a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0,5 M sodium chloride solution"²²) and wheat ("... means any *Triticum* species"²³).

4. Foodstuffs for people intolerant to gluten²⁴

4.1 Rules on composition

In summary, it is a basic rule that foodstuffs for people intolerant to gluten, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten, shall not contain a level of gluten exceeding 100 mg/kg in the food as sold to the final consumer.

Oats contained in foodstuffs for people intolerant to gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats must not exceed 20 mg/kg.

On the other hand, foodstuffs for people intolerant to gluten, consisting of or containing one or more ingredients which substitute wheat, rye, barley, oats or their crossbred varieties shall not contain a level of gluten exceeding 20 mg/kg in the food as sold to the final consumer.

4.2 Rules on labelling, presentation and advertising: the terms 'very low gluten' and 'gluten-free'

Let us recall that in principle the term «very low gluten» is to be used in the labelling, presentation and advertising of foodstuffs for people intolerant to gluten and which consist of or contain one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties specially processed to reduce the gluten. The term «gluten-free» may be used if the gluten content does not exceed 20 mg/kg in total in the food as sold to the final consumer.

¹⁹ Resulting, ironically, in a scope which is limitless (See NAVALÓN VALDECABRILLAS, M., *op. cit.*, p. 14).

²⁰ Emphasis added by the author.

²¹ See footnote 17.

²² See the definition given in Article 2(b) of Regulation No 41/2009.

²³ *Ibidem*, Article 2(c).

²⁴ For more detail see Article 3 of Regulation No 41/2009.

Regulation No 41/2009 provides that the term «gluten-free» should be used in the labelling, presentation and advertising of foodstuffs for people intolerant to gluten and which consist of or contain one or more ingredients replacing wheat, rye, barley, oats or their crossbred varieties specially processed to reduce the gluten.

Likewise, it also provides that where applicable, the terms «very low gluten» or «gluten-free» should appear *very close to the name under which the product is sold*.

5. *Other* foodstuffs suitable for people intolerant to gluten (Article 4 of Regulation No. 41/2009)

Without prejudice to Article 2(1)(a)(iii) of Directive 2000/13/EC, the labelling, advertising and presentation of the following foodstuffs may bear the term 'gluten-free' provided that the gluten content does not exceed 20 mg/kg in the food as sold to the final consumer:

- a) foodstuffs for normal consumption; and
- b) foodstuffs for particular nutritional uses which are specially formulated processed or prepared to meet special dietary needs other than those of people intolerant to gluten but which are nevertheless suitable, by virtue of their composition, to meet the *special dietary needs* of people intolerant to gluten.

III. The Commission Implementing Regulation (EU) No 828/2014

1. Consumer information on the absence or reduced presence of gluten in food, after Regulations (UE) No 1169/2011 and No 609/2013 enter into force.

In the context of the revision of the legislation on foodstuffs intended for particular nutritional uses Regulation (EU) No 609/2013 of the European Parliament and of the Council²⁵ repeals Regulation (EC) No 41/2009 *with effect from 20 July 2016*. In order to guarantee that after that date, the provision of information on the absence or reduced presence of gluten in food continues to be based on the relevant scientific data and is not provided on a divergent basis which could mislead or confuse the consumers, in accordance with the requirements laid down in Article 36(2) of Regulation (EU) No 1169/2011²⁶, the Commission adopted Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in

²⁵ See footnote 7.

²⁶ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18). On this see Regulation: BREMMERS, H., "An Integrated Analysis of Food Information to Consumers: Problems, Pitfalls, Policies and Progress", *Proceedings in Food System Dynamics*, 2012, 614–627 (available at <http://131.220.45.179/ojs/index.php/proceedings/article/view/262/243> , last accessed on 14 August 2013); FERRO, M. and IZZO, U., "Diritto alimentare comparato", *Il Mulino*, 2012, 126–131; and NIHOUL, P. and VAN NIEUWENHUYZE, E., "L'étiquetage des denrées alimentaires: une pondération réussie entre intérêts contradictoires?", *Journal de droit européen*, Vol. 20, No. 192, 2012, 237–243.

food²⁷. This Regulation seeks to ensure that “uniform conditions for the application of these requirements to food information provided by food business operators on the absence or reduced presence of gluten in food are maintained in the Union and *these conditions should be based on Regulation (EC) No 41/2009*^{28”29}.

The Commission naturally adheres to the same rationale behind Regulation (EC) No 41/2009, which sets out harmonised rules on the information provided to consumers on the absence (‘gluten-free’) or reduced presence of gluten (‘very low gluten’) in food. It justifies this *continuity* by stressing that on the grounds that “the rules of that Regulation are *based on scientific data*³⁰ and guarantee that consumers are not misled or confused by information provided on a divergent basis on the absence or reduced presence of gluten in food”³¹. Such continuity is also clearly confirmed by other recitals of Implementing Regulation No 828/2014:

- in stating that “information on the absence or reduced presence of gluten in food should help people intolerant to gluten to identify and choose a varied diet when eating inside or *outside*³² the home”³³;
- in acknowledging that “certain foods have been specially produced, prepared and/or processed to reduce the gluten content of one or more gluten-containing ingredients or to substitute the gluten-containing ingredients with other ingredients naturally free of gluten”³⁴ (moreover other foods are made exclusively from ingredients that are naturally free of gluten³⁵);
- in reiterating that “the removal of gluten from gluten-containing grains presents considerable technical difficulties and economic constraints and therefore the manufacture of *totally gluten-free food*³⁶ when using such grains is difficult”³⁷; and

²⁷ See footnote 1.

²⁸ Emphasis added by the author.

²⁹ See the fourth recital of Commission Implementing Regulation No 828/2014.

³⁰ Emphasis added by the author.

³¹ See the third recital of Commission Implementing Regulation No 828/2014.

³² Emphasis added by the author.

³³ See the recital of Commission Implementing Regulation No 828/2014.

³⁴ *Ibidem*, fifth recital.

³⁵ *Ibidem*.

³⁶ Emphasis added by the author.

³⁷ See the sixth recital of Commission Implementing Regulation No 828/2014 (which repeats what is stated in the fourth recital of Regulation No 41/2009).

- and in concluding that “many foods especially processed to reduce the gluten content of one or more gluten-containing ingredients on the market may contain low residual amounts of gluten”³⁸.

2. Scope and subject matter

Article 1 of Commission Implementing Regulation No 828/2014 provides that “this Regulation applies to the provision of information to consumers on the absence or reduced presence of gluten in food”.

3. Definitions

Article 2 only includes two definitions:

- *gluten*: “a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0,5 M sodium chloride solution”; and
- *wheat*: “...any *Triticum* species”.

Both of these definitions are practically identical to those which appear in Regulation No 41/2009³⁹, although it is worth adding that the rather obvious definition of *foodstuffs for people intolerant to gluten* which appears in the 2009 Regulation has been removed.

4. Basic rules (Article 3 and Annex)

Article 3 (“Information to consumers”) of the Regulation under study here provides that

“1. Where statements are used to provide information to consumers on the absence or reduced presence of gluten in food, such information shall be given only through the statements and in accordance with the conditions set out in the Annex.

2. The food information referred to in paragraph 1 may be accompanied by the statements ‘suitable for people intolerant to gluten’ or ‘suitable for coeliacs’.

3. The food information referred to in paragraph 1 may be accompanied by the statements ‘specifically formulated for people intolerant to gluten’ or ‘specifically formulated for coeliacs’ if the food is specially produced, prepared and/or processed to:

- (a) reduce the gluten content of one or more gluten-containing ingredients;
- or

³⁸ Likewise see the sixth recital of Commission Implementing Regulation No 828/2014, as well as the fourth recital of Regulation No 41/2009 *in fine*.

³⁹ The only difference is a very minor change in the definition of *gluten*.

(b) substitute the gluten-containing ingredients with other ingredients naturally free of gluten.”

For its part the Annex (“Statements on the absence or reduced presence of gluten in food that are allowed to be made and conditions thereof”), provides:

“A. General requirements

GLUTEN-FREE

The statement ‘gluten-free’ may only be made where the food as sold to the final consumer contains no more than 20 mg/kg of gluten.

VERY LOW GLUTEN

The statement ‘very low gluten’ may only be made where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, contains no more than 100 mg/kg of gluten in the food as sold to the final consumer.

B. Additional requirements for food containing oats

Oats contained in a food presented as gluten-free or very low gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg/kg.”

The Commission has chosen to create a *positive* list,⁴⁰ which has the advantage of being easy to read and interpret.

It has also agreed to allow the sale of ‘gluten-free’ or ‘very low gluten’ products because it considers that different people with intolerance to gluten may tolerate variable small amounts of gluten within a restricted range and “in order to enable individuals to find on the market a variety of foodstuffs appropriate for their needs and for their level of sensitivity, a choice of products should be possible with different low levels of gluten within such a restricted range⁴¹(...) it is important, however, that the different products are properly labelled in order to ensure their correct use by people intolerant to gluten with the support of information campaigns fostered in the Member States⁴²”.

The ninth recital of Commission Implementing Regulation No 828/2014 goes on to state clearly that

⁴⁰ And a “closed” one according to NAVALÓN VALDECABRILLAS, M., *op. cit.*, p. 17.

⁴¹ See the eighth recital of Commission Implementing Regulation No 828/2014.

⁴² The imposition of certain obligations on Member States in a Regulation which, in principle, should not be *transposed* is nothing new (see NAVALÓN VALDECABRILLAS, M., *op. cit.*, p. 18). In fact Regulation No 41/2009 already referred to “the support of information campaigns fostered in the Member States”.

"It should be possible for a food which is specially produced, prepared and/or processed to reduce the gluten content of one or more gluten-containing ingredients or to substitute the gluten-containing ingredients with other ingredients naturally free of gluten to bear terms indicating either the absence ('gluten-free') or reduced presence ('very low gluten') of gluten in accordance with the provisions laid down in this Regulation. It should also be possible for this food to bear a statement informing consumers that it is specifically formulated for people intolerant to gluten."

What about foods containing ingredients *naturally free of gluten*? For the Commission it should be possible for such foods to "... bear terms indicating the absence of gluten, in accordance with the provisions laid down in this Regulation and provided that the general conditions on fair information practices set out in Regulation (EU) No 1169/2011 are complied with"⁴³. It is worth bearing in mind here that Article 36.2 of Regulation No 1169/2011 provides that "food information provided on a voluntary basis shall meet the following requirements: (a) it shall not mislead the consumer [...]; (b) it shall not be ambiguous or confusing for the consumer, and (c) it shall, where appropriate, be based on the relevant scientific data" (and it so happens that Article 36.3 of the Regulation gives the Commission the power to "adopt implementing acts on the application of the requirements [which refer] to the following voluntary food information: (a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances; [and] (d) *information on the absence or reduced presence of gluten in food*"⁴⁴).

In regard to paragraph B of the Annex, it is worth noting that in the seventh recital of Commission Implementing Regulation No 828/2014, the Commission states that most people with intolerance to gluten can include oats in their diet without adverse effect on their health. It adds that "this is an issue of ongoing study and investigation by the scientific community [although] a major concern is the contamination of oats with wheat, rye or barley that can occur during grain harvesting, transport, storage and processing". Thus it can be seen why the risk of gluten contamination in products containing oats was taken into account in drawing up the legislation regulating the information presented by producers in these food products.

5. Infant formulae and follow-on formulae

⁴³ See the tenth recital of Commission Implementing Regulation No 828/2014, which also notes that "in particular, food information should not be misleading by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics".

⁴⁴ Emphasis added by the author [point (d) was introduced by the Commission Delegated Regulation (EU) No 1155/2013 of 21 August 2013 amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards information on the absence or reduced presence of gluten in food (OJ L 306, 16.11.2013, p. 7)]. In any case Annex II ("Substances or Products Causing Allergies or Intolerances") of Regulation (EU) No 1169/2011 already mentioned "Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except: (a) wheat based glucose syrups including dextrose [and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated]; (b) wheat based maltodextrins [and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated]; (c) glucose syrups based on barley; [and] (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin" (See NAVALÓN VALDECABRILLAS, M., *op. cit.*, p. 20).

Commission Directive 2006/141/EC⁴⁵ prohibits the use of ingredients which contain gluten in the manufacture of infant formulae and follow-on formulae. So for the sake of consistency there was a need for the terms 'gluten-free' or 'very low gluten' to be prohibited from appearing in information about these products, because under the 2014 Regulation, such terms are used to indicate a gluten content that does not exceed 100 mg/kg and 20 mg/kg respectively. This has been achieved by Article 4 of Commission Implementing Regulation No 828/2014:

"The provision of food information on the absence or reduced presence of gluten in infant formulae and follow-on formulae as defined in Directive 2006/141/EC shall be prohibited".

Here we might recall that infant formulae and follow-on formulae simply fell outside the scope of application Regulation No 41/2009, although for all intents and purposes the effect is the same as that of prohibiting "the use of the terms 'very low gluten' or 'gluten-free' on the labelling of such products..."⁴⁶.

6. Entry into force and application

Article 5 of Commission Implementing Regulation No 828/2014 provides that

"This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

*It shall apply from 20 July 2016*⁴⁷.

This Regulation shall be binding in its entirety and directly applicable in all Member States".

IV. The *Codex Alimentarius* Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten

As mentioned in the Introduction, recital 12 of Commission Implementing Regulation No 828/2014 states that "the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten should be taken appropriately into consideration for the purposes of this Regulation".

The Commission again refers to Standard CODEX STAN 118 – 1979⁴⁸, the scope of which is as follows:

"[Section] 1.1 This standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

⁴⁵ See footnote 18.

⁴⁶ See the ninth recital of Regulation No 41/2009.

⁴⁷ Emphasis added by the author.

⁴⁸ I say again because it had already been referred to in Regulation No 41/2009 (See NAVALÓN VALDECABRILLAS, M., *op. cit.*, 19-20).

[Section] 1.2 Foods for general consumption which by their nature are suitable for use by people with gluten intolerance may indicate such suitability in accordance with the provisions of Section 4.3.”.

Elsewhere, Section 4.3 stipulates that a food which, by its nature, is suitable for use as part of a gluten-free diet shall not be designated “special dietary”, “special dietetic” or any other equivalent term. However, such a food may bear a statement on the label that “this food is by its nature gluten-free” provided that it complies with the essential composition provisions for gluten-free as set out in section 3.1 and provided that such a statement does not mislead the consumer. Furthermore “more detailed rules in order to ensure that the consumer is not misled may be determined at the national level”⁴⁹.

It is interesting to *compare* the definitions contained in Commission Implementing Regulation No 828/2014 with those in Section 2.1 of the Standard in question, which read as follows:

- *Gluten-free foods* “...are dietary foods

- a) consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats⁵⁰ or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

- b) consisting of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats⁵¹ or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer”.

- *Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg*⁵²: “these foods consist of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats⁵³ or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer”.

Section 2.2 contains the following “*Subsidiary*”⁵⁴ Definitions”:

⁴⁹ See also Section 4.3 of Standard CODEX STAN 118 – 1979.

⁵⁰ Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level

⁵¹ See previous footnote.

⁵² Decisions on the marketing of foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg may be determined at the national level.

⁵³ See footnote 50.

⁵⁴ Emphasis added by the author.

- *Gluten*: "...a protein fraction from wheat, rye, barley, oats⁵⁵ or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl".
- *Prolamins*: "...the fraction from gluten that can be extracted by 40 - 70% of ethanol" (the prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats⁵⁶avenin⁵⁷).

With regard to the "essential composition and quality factors" it would be useful to cite the relevant Sections here:

"3.1 For products referred to in 2.1.1 a) and b) [i.e. *gluten-free foods*], the gluten content shall not exceed 20 mg/kg in the food as sold or distributed to the consumer.

3.2 For products referred to in 2.1.2 [in other words *foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg*] the gluten content shall not exceed 100 mg/kg in the food as sold or distributed to the consumer.

3.3. *Products covered by this standard substituting important basic foods, should supply approximately the same amount of vitamins and minerals as the original foods they replace*⁵⁸.

3.4 The products covered by this standard shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten."

Given that the main purpose of Commission Implementing Regulation No 828/2014 is to lay down harmonising rules on the information to consumers about the absence or reduced presence of gluten in foodstuffs, special attention should be paid to the principles of labelling contained in Standard CODEX STAN 118 – 1979 (sections 4.1, 4.2 and 4.3⁵⁹). The relevant provisions of this Standard first refer to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)⁶⁰ and the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)⁶¹. They then appear to differentiate between:

⁵⁵ See footnote 50.

⁵⁶ *Idem*.

⁵⁷ See Section 2.2.2 of Standard CODEX STAN 118 – 1979, which confirms that it is common to refer to gluten sensitivity: "The prolamin content of gluten is generally taken as 50%".

⁵⁸ Emphasis added by the author.

⁵⁹ I have referred to this in Section 4.3 above, and have therefore not repeated it here.

⁶⁰ Available at http://www.codexalimentarius.org/download/standards/32/CXS_001e.pdf.

⁶¹ http://www.codexalimentarius.org/download/standards/292/CXS_146e.pdf.

- *gluten-free foods*, in which the term "gluten-free" shall be printed in the immediate proximity of the name of the product; and
- *Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg*, whose labelling should be determined at the national level (however these products must not be called gluten-free because "the labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product"⁶²).

Brevitatis causae, I shall summarise the provisions of Standard CODEX STAN 118 – 1979 on *Methods of Analysis and Sampling* by simply noting that the quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity; the antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients; methods used for determination should be validated and calibrated against a certified reference material, if available⁶³, etc.

V. Conclusions

1. Protecting a vulnerable section of the population

For the EU offering a high level of protection to people with coeliac disease that suffer from a permanent intolerance to gluten has been an ongoing concern in recent years. As highlighted in the Introduction, wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and khorasan wheat), rye and barley have been identified as grains that are scientifically reported to contain gluten⁶⁴; and the gluten present in those grains can cause adverse health effects to people intolerant to gluten and therefore its consumption should be avoided by such people ... Moreover there is no need to keep reiterating that suitable labelling of products is a fundamental aspect of this protection.

That food suitable for coeliacs is an issue which causes concern and alarm is shown by the number of questions for written answer to the Commission (Rule 117) submitted by members of the European Parliament on the issue. To avoid this article going beyond the reasonable limits permitted, I will now list just some of these questions. In choosing them I have prioritised those of more recent relevance, as well as the need for this small but representative list to include the widest possible range of perspectives on the issues surrounding allergies and intolerances⁶⁵:

♦ E-010586-12, 20 November 2012 - Question for written answer to the Commission from Esther Herranz García:

Question for written answer to the Commission

⁶² See Section 4.2 of Standard CODEX STAN 118 – 1979.

⁶³ *Ibidem*, Section 5.1.

⁶⁴ See the first recital of Commission Implementing Regulation No 828/2014.

⁶⁵ For a more complete if not exhaustive list, see NAVALÓN VALDECABRILLAS, M., *op. cit.*, p. 13.

"Gluten intolerance is a medical condition which, on average, affects one European in eighty. Those who suffer from it must directly pay the higher cost of gluten-free food products, which are more expensive on account of the fact that they are classed as dietary products. Furthermore, the amount of value-added tax (VAT) charged on gluten-free products is not uniform within the European Union — it varies from one Member State to another.

Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten came into force on 1 January 2012. However, no European body monitors compliance with that regulation and certain Member States are failing to comply with it. This puts coeliacs at risk of poisoning.

1. How can the Commission ensure that labelling standards are being met and are uniform in all the Member States, thus enabling coeliacs to move freely within the EU?
2. Is the Commission planning to regard food products for coeliacs as pharmaceutical products and not as dietary products, as they are currently classed?
3. Does the Commission not consider that the value-added tax charged on such products should be made uniform within the European Union?
4. Given that a coeliac spends on average EUR 408.20 more per year on basic products such as bread, biscuits and pasta than does a non-coeliac, what measures does the Commission think could be taken in order to alleviate this state of affairs?" (Original language of question: ES).

Answer given by Mr Borg on behalf of the Commission (15 January 2013):

"In addition to Regulation (EC) No 41/2009 which sets harmonised rules on the composition and labelling of foodstuffs for people intolerant to gluten, Regulation (EU) No 1169/2011 on food information to consumers *requires for all food the mandatory labelling of ingredients causing the most common allergies or intolerances, including gluten-containing ingredients*⁶⁶.

The Commission is not aware of the cases of non-compliance with Regulation (EC) No 41/2009 reported by the Honourable Member. EU Regulations are directly applicable in Member States and national authorities are responsible to ensure that EC law is complied with. If the Commission becomes aware of a Member State's failure to comply with EC law, it can take action to try to bring the infringement to an end and, where necessary, may refer the case to the Court of Justice of the European Union.

The Commission does not intend to regard foods for coeliacs as pharmaceutical products. The Commission's proposal for a regulation on food for infants and young children and food for special medical

⁶⁶ Emphasis added by the author.

purposes⁶⁷ abolishes the concept of dietetic foods and proposes to transfer the existing rules of Regulation (EC) No 41/2009 under other more appropriate measures of EU food law.

For the VAT rules applied to foodstuffs, the Commission would refer the Honourable Member to its answer to Written Question E-003100/2012⁶⁸. The latest step in the process aiming at harmonising VAT arrangements was the adoption of a communication on the future of VAT⁶⁹, which announces notably a review of the VAT reduced rates⁷⁰. Making the VAT rates uniform across the EU for certain products is however not envisaged within this review."

♦ E-008774/2011, 4 October 2011 - Question for written answer to the Commission de Mara Bizzotto:

Subject: *Rights of people with coeliac disease*

"On 20 June 2011, in its document COM(2011)0353, the Commission announced its intention to repeal the framework Directive on dietetic foods, namely Directive 2009/39/EC⁷¹ and Regulation (EC) No 41/2009. If the Commission's proposal is accepted, the words 'gluten-free' would fall under the general rules on food labelling and would be reduced to the status of general label, i.e. a nutritional indication directed at the general population.

However, coeliac disease is a disease that has been recognised by Italian law No 123/2005 as a 'social disease' that requires, as the only possible treatment, a gluten-free diet. Accordingly, the Commission's intervention, even if its aim is to simplify the lives of all consumers, is likely to endanger the health of citizens suffering from this disease by limiting the safety guarantees offered by gluten-free dietary products that are currently subject to an EU-wide notification system.

Does the Commission believe its proposal complies with the principles of proportionality and subsidiarity?

What will the Commission do to protect vulnerable categories of citizens such as coeliac sufferers, who risk being seriously harmed by its proposal to repeal Regulation (EC) No 41/2009?" (Original language of question: IT).

⁶⁷ COM(2011) 353 final [see: "Nuevas reglas para la publicidad de los alimentos destinados a los lactantes y niños de corta edad, para usos médicos especiales y los destinados al control del peso [Reglamento (UE) n° 609/2013]", *ReDeco - Revista electrónica del Derecho del consumo y la alimentación*, No. 35, 3-12 (disponible en la siguiente página de Internet, consultada el 21 de agosto de 2014: http://ceeudeco3.blogspot.com.es/2013/11/redeco-revista-electronica-del-derecho_8.html)].

⁶⁸ <http://www.europarl.europa.eu/plenary/en/parliamentary-questions.html>.

⁶⁹ COM(2011) 851 final — Communication on the future of VAT — Towards a simpler, more robust and efficient VAT system tailored to the single market.

⁷⁰ http://ec.europa.eu/taxation_customs/common/consultations/tax/2012_vat_rates_en.htm.

⁷¹ See footnote 7.

Answer given by Mr Dalli on behalf of the Commission (25 October 2011):

"The Commission fully recognises that people with coeliac disease need clear information about the gluten content in foods. For this reason, the Commission adopted specific rules harmonising the indication of the absence of gluten in January 2009 through Commission Regulation (EC) No 41/2009. It is important to note that, according to this regulation, the statement 'gluten-free' may already be used both for foods intended for particular nutritional uses and for foods for normal consumption.

In the Commission proposal on food intended for infants and young children, and on food for special medical purposes⁷², it is foreseen to continue regulating at EU level the indication of the absence of gluten in foods. As those statements can be construed as nutrition claims as defined by Regulation (EC) No 1924/2006 of the Parliament and the Council on nutrition and health claims made on foods⁷³, the indication on gluten could be done in the framework of this regulation. In particular, Recital 26 of the proposal states that the Commission shall incorporate the statements 'gluten-free' and 'very low gluten' and their associated conditions of use under Regulation (EC) No 1924/2006 prior to the entry into force of the new proposed regulation.

Moreover, the same high level of protection for human health will be maintained at EU level as the same conditions of use as regulated under Regulation (EC) No 41/2009 will continue to apply without discontinuity, but under a different legislative framework.

In the light of the above, the proposal is fully in line with the principles of subsidiarity and proportionality."

♦ E-007180/2011, 21 July 2011 - Question for written answer to the Commission de Matteo Salvini:

Subject: *Regulation of gluten-free food*

"On 20 June 2011, the Commission published a proposal to repeal Regulation (EC) No 41/2009 and Directive 2009/39/EC, thus abolishing the definition of 'dietary' products and making the term 'gluten-free' merely one of many indications regulated by the rules on labelling.

The AOECS (Association of European Coeliac Societies), of which the Italian coeliac association representing some 110 000 people in Italy is a member, has expressed serious concerns about, and opposition to, this proposal.

The Commission's proposal, whose aim would appear to be a simplification of the rules, seems to overlook the needs of a particularly vulnerable category of consumers, persons with coeliac disease. At the moment, the only known therapy for that disease is to completely exclude gluten from the diet.

⁷² See footnote 67.

⁷³ OJ L 404, 30.12.2006.

Is the Commission aware of this? Does it share the concerns of persons with coeliac disease?

Would it agree that, in order to avoid further risks to the health of persons with coeliac disease, it should modify the proposal and add gluten-free dietary products to the category of foods for special medical purposes? This would provide greater security to those who need to follow this specific medical diet." (Original language of question: IT).

Answer given by Mr Dalli on behalf of the Commission (25 August 2011):

"The Commission fully recognises that people with celiac disease need clear information about the gluten content of foods. For this reason, it adopted specific rules harmonising the indication of the absence of gluten in January 2009 through Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

The regulation establishes specific requirements according to which foods may be voluntarily labelled as 'gluten-free' (when the gluten content is not higher than 20 mg/kg) or 'very low gluten' (when the gluten content is not higher than 100 mg/kg).

These statements can be construed as nutrition claims as defined by Regulation (EC) No 1924/2006⁷⁴ on nutrition and health claims. Consequently, the proposal for a regulation⁷⁵ revising Directive 2009/39/EC incorporates the statements 'gluten-free' and 'very low gluten' and their associated conditions of use under Regulation (EC) No 1924/2006.

It is important to note that the statement 'gluten-free' may already be used for foods intended for particular nutritional uses and for foods for normal consumption. Therefore, the proposal to abolish the concept of dietetic food will simplify the application of these rules and maintain the same level of protection of people intolerant to gluten."

♦ E-002064/2011, 4 March 2011 - Question for written answer to the Commission de Cristiana Muscardini:

Subject: *Coeliac disease on the rise*

"In connection with the approximation of the laws of the Member States concerning foodstuffs for people with special dietary needs, the EU has adopted Regulation (EC) No 41/2009, which will apply from 1 January 2012 and which refers to the composition and labelling of foodstuffs suitable for people intolerant to gluten. This is an appropriate measure to take in a continually evolving situation. In Italy, in fact, since 2007 there has been a significant increase in this disease, with the number of

⁷⁴ See footnote 73.

⁷⁵ http://ec.europa.eu/food/food/labellingnutrition/nutritional/docs/sanco_11224_2011_rev5_it.pdf.

cases rising from 64 000 to 110 480. Of these, 33 323 cases concerned men and 74 647 women. Until recently, it was believed that gluten intolerance was hereditary, but now, the Center for Celiac Research of the University of Baltimore is saying that people can develop coeliac disease and that the likelihood of this grows after the age of 60.

According to the study conducted by the Baltimore centre, intolerance could be linked to the different varieties of wheat used, and especially to high-yield wheat that is particularly rich in gluten and therefore 'toxic' to the body. The study concerned 3 500 US citizens, from whom blood samples had been collected in 1974, when they were already adults. After 15 years, the same people were re-tested and it was found that the number of people with coeliac disease had doubled, rising from one case out of 501 in 1974 to one out of 219 in 1989. This shows that coeliac disease can occur not only in childhood, but at any age. In view of the increase in the incidence of this disease in both the United States and Italy, can the Commission answer the following questions:

1. Can it confirm the above data?
2. Does it share the Baltimore centre's view that the genetic origin of coeliac disease is not the only cause of the disease?
3. If so, is it true that gluten intolerance in adulthood may be due to the variety of wheat enriched with this substance?" (Original language of question: IT).

Answer given by Mr Dalli on behalf of the Commission (27 April 2011):

"The Commission is not familiar with the study conducted by the Centre for Coeliac Research of the University of Baltimore and therefore is not in a position to comment on the data presented by the Centre. According to the information the Commission has at its disposal, population-based studies in the United States and in the EU using various combinations of serological testing and small intestinal biopsy suggest that the prevalence of coeliac disease is in the range of 0.5 to 1.0 % but is greatly under-diagnosed. These prevalence figures include both symptomatic and asymptomatic individuals. Advances in the understanding of the multisystem nature of coeliac disease and the identification of sensitive serologic tests have led to the recognition that coeliac disease is more common than previously thought.

The cause of coeliac is thought to be primarily immune-mediated. Coeliac disease is associated with certain genes and it is often inherited. However, 20 % of the healthy population carry these genes. No genetic test which could identify coeliac disease-causing genes is currently available. Coeliac disease affects people differently. Some people develop symptoms as children, others as adults. Sometimes the disease is triggered or becomes active for the first time after surgery, pregnancy, childbirth, viral infection or severe emotional stress."

♦ E-6283/2010, 2 August 2010 - Question for written answer to the Commission de Marina Yannakoudakis and Charles Tannock:

Subject: *Coeliac disease and food labelling*

"Around one per cent of Europeans suffer from coeliac disease, a serious disease in which the body's immune system reacts to gluten in food.

What legislation is currently in place across the EU regarding the compulsory labelling of products as either gluten-free or containing gluten?

To what extent is the Commission satisfied that the food labelling measures currently in place relating to gluten offer adequate protection to sufferers of coeliac disease?

What concerns does the Commission have about the potential for food being accidentally contaminated with gluten during production?

What further measures is the Commission proposing in this regard?"
(Original language of question: EN).

Answer given by Mr Dalli on behalf of the Commission (27 August 2010):

"In order to facilitate and improve the life of people intolerant to gluten, specific rules harmonising the indication of the absence of gluten were adopted in January 2009 through Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. The regulation harmonises conditions for labelling the absence of gluten in food. In particular, the regulation establishes specific requirements according to which foods may be voluntarily labelled as 'gluten-free' (when the gluten content is not higher than 20 mg/kg) or 'very low gluten' (when the gluten content is not higher than 100 mg/kg) in order to enable coeliacs to find on the market a wide variety of foods appropriate to their needs and to their level of sensitivity. The regulation entered into force in February 2009 and will apply as from the 1 January 2012.

As regards the indication of the presence of gluten in foods, Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs⁷⁶ establishes a list of ingredients that cause intolerance and allergies and which must always be labelled. Cereals containing gluten are included in that list. If wheat, for example, is used in the production of a food and is still present in the finished product, then it must be labelled in the list of ingredients even if the level of gluten is less than 20 mg/kg.

Directive 2000/13/EC covers the labelling of ingredients added intentionally to foods during the production process and does not cover the issue of cross-contamination of foods along the food supply chain.

Whilst some food producers and retailers are already using various forms of advisory labelling to warn consumers about such risks, consumers and enforcement bodies are concerned about the possible overuse of such labelling and find the variety of phrases used confusing. (e.g. 'may contain traces of gluten' or 'has been produced in a factory producing cereals', etc.). There are concerns that excessive use of

⁷⁶ See footnote 11.

advisory warning labels about possible presence of gluten not only unnecessarily restricts consumer choice, but also devalues the impact of the warning label.

The new Commission proposal on the provision of food information to consumers provides the possibility for the Commission to set up rules concerning the use of voluntary information through comitology, including rules on allergen cross-contamination warning labels. This would enable the Commission to frame such voluntary warning labels on the basis of harmonised criteria and wordings.

The Commission believes that Commission Regulation (EC) No 41/2009 on gluten combined with the rules foreseen in Directive 2000/13/EC on labelling and the Commission proposal on the provision of food information to consumers should ensure a high level of protection and a wide range of choice for consumers with allergies and intolerances.”

2. On the other side of the Atlantic...

Although it is not my intention to turn this article into a study of comparative law, it would be relevant to refer briefly to current U.S. legislation in this field. In 2013 the *Food and Drug Administration* (FDA) published a *final rule* [adopted within the framework of the *Food Allergen Labelling and Consumer Protection Act of 2004* (FALCPA)] to define the term “gluten-free” for voluntary use in the labelling of foods⁷⁷ (the compliance date of this final rule is August 5, 2014).

The *final rule* defines the term “gluten-free” to mean that the food bearing the claim does not contain an ingredient that is a gluten-containing grain (e.g., spelt wheat); an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or inherently does not contain gluten; and that any unavoidable presence of gluten in the food is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food).

It is worth highlighting here that a food that bears the claim “no gluten,” “free of gluten,” or “without gluten” in its labelling and fails to meet the requirements for a “gluten-free” claim will be deemed to be misbranded. In addition, a food whose labelling includes the term “wheat” in the ingredient list or in a separate “Contains wheat” statement as required by a section of the Federal Food, Drug, and Cosmetic Act and also bears the claim “gluten-free” will be deemed to be misbranded unless its labelling also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for a “gluten-free” claim.

According to the FDA, establishing a definition of the term “gluten-free” and uniform conditions for its use in food labelling will help ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labelled.

⁷⁷ See the *Federal Register*, Vol. 78 No. 150 of 5.8.2013 (*Rules and Regulations*) p. 47154 (available at <http://www.gpo.gov/fdsys/pkg/FR-2013-08-05/pdf/2013-18813.pdf>).

3. From Regulation (EC) No 41/2009 to Commission Implementing Regulation (EU) No 828/2014

There is little left to add to what has been said so far. Commission Implementing Regulation (EU) No 828/2014 represents an improvement on the legislation it repeals, especially in the way it is presented and thanks to the inclusion of a relatively clear positive list of labels whose use is authorised providing certain conditions are satisfied. The Commission also appears to have taken into consideration the majority of observations and objections raised by members of the European Parliament in the questions listed in this article, at least with regard to labelling.

The Regulation is also generally compatible with the provisions of the *Codex Alimentarius* Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118 – 1979), to which it makes reference in recital 12. Finally, the differences with current U.S. legislation appear to be of little importance and should not therefore represent a problem for TTIP negotiations ⁷⁸.

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⁷⁸ The "Transatlantic Trade and Investment Partnership" currently being negotiated [on this topic see BARBEE, I. and LESTER, S., "The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership", *Journal of International Economic Law*, Vol. 16, No. 4, 2013, 847-867; FELBERMAYR, G. and LARCH, M., "The transatlantic trade and investment partnership (TTIP): Potentials, problems and perspectives", University of Munich - Department of Economics, 2013, 11 pp.; and SESHADRI, V. S., "Transatlantic Trade and Investment Partnership", RIS, 2013, 38 pp. (available at http://ris.org.in/images/RIS_images/pdf/DP%20185%20Amb%20V%20S%20Sheshadri.pdf)].

