EU-FOOD INFORMATION REGULATION 1169/2011 – IMPLEMENTING MEASURES BY MEMBER STATES
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An annotated compilation of implementation measures
taken by Member States of the European Union,
the European Economic Area and Switzerland
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FRAMEWORK OF EU LAW

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A. FIR 1169/2011 – No blanket rule for food information

13 December 2014 was the date when Union law on food information was fully harmonised by virtue of the Food Information Regulation 1169/2011 (FIR).¹ The Regulation applies directly in all Member States²; national law incompatible with the Regulation became inapplicable. By moving from Directives to a Regulation in rulemaking on food labelling³, the law in the statute book reads the same in the EU’s 23 official languages. In principle, the same set of rules apply in 31 European countries⁴ and their influence extends beyond to candidate countries of the EU as well as Switzerland.

Through laborious preparations in the three years between the adoption and publication of the FIR in October/November 2011 and its coming into effect at the end of 2014 (or at least the majority of it, pending compulsory nutritional labelling becoming applicable in 2016), food business operators (FBOs) in Europe adapted to a whole new set of rules governing food labels and commercial communication on food generally. This was done through a focussed effort by FBOs and their associations, aided in no small degree by a discussion process between the European Commission and the Member States which addressed questions of interpretation of the FIR which provided a list of key questions and answers which helps in the reading of Union food information law.

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¹ OJ L 304, 22.11.2011, p. 18
² Article 288 TFEU
³ The FIR was preceded by Directive 79/112/EEC and Directive 2000/13/EC as well as Directive 90/496/EEC
⁴ European Union and European Economic Area (EEA)
Despite the large measure of harmonisation achieved, the FIR does not cover all aspects of food information law. The Union lawmakers deliberately leave some areas of labelling to national legislators to deal with. The principle of subsidiarity, that is, the belief that the national regulator is better positioned to judge what information the consumer needs to receive “depending on local practical conditions and circumstances”, specifically on non-prepacked foodstuffs, has prompted Union legislators to leave this area as exempt from coverage by full harmonisation. This has been recognised by the European Commission in its “Better Regulation Package”. Hence, however insufficiently developed as an integration requirement, EU lawmakers’ regard for the interests of small and medium sized enterprises (SMEs) in retail, crafts and gastronomy within the food sector led to their allowing Member States to define the right degree of

5 Written Question E-011733/2015 by Renate Sommer with answer by Commissioner Andriukaitis of 23.9.2015
6 Article 5 TEU
7 Recital 48 of the preamble to the FIR
8 Commissioner John Dalli in his answer of 16.1.2012 to Written Question E-011319/2011: “In the light of subsidiarity and given that foods sold without packaging or which are packed on the sales premises at the consumer’s request or pre-packed for direct sale are subject to very limited cross-border trade, Regulation (EU) 1169/2011 maintains the existing rules leaving it up to the Member States to decide, with the exception of substances causing allergies or intolerances, whether and which labelling particulars should be provided on such foods.”
9 Staff Working Document (SWD(2015) 110 final of 19.5.2015), pp. 92-94: “The Regulation [the FIR] allows Member States to adopt national measures setting out the means through which information about allergens for foods offered for sale as non-prepacked, or packed on the sales premises at the consumer’s request or prepacked for direct sale is to be made available and, where appropriate, its form of expression. This flexibility allows adaptation of the provision of information on allergens to the needs and specificities of SMEs, in particular restaurants, canteens, hotels etc.” http://ec.europa.eu/smart-regulation/better_regulation/documents/swd_2015_110_en.pdf
10 Compare, for instance, Article 11 to 13 TFEU or Article 168(1) TFEU
11 SME concerns in food law are mostly limited to transition periods (cf. recital 54 of the preamble to the FIR) and simplified application procedures

The most significant of these unregulated areas concern non-prepacked food, regarding which Article 12(5) FIR and Article 44 FIR place responsibility on the national legislators. While allergen labelling is compulsory already under the FIR as it stands, Member States are entitled to establish labelling rules for non-prepacked foods insofar as they can trigger allergies and intolerances (Article 44(1)(a) FIR). Member States may or may not establish rules for other mandatory particulars of Article 9 and 10 FIR (Article 44(1)(b) FIR). They may also adopt measures that regulate the way allergens and other elements of the food label are presented (Article 44(2) FIR).

Member States may request additional mandatory particulars (other than those foreseen in the FIR) for specific types or categories of food and justified by a list of grounds provided by the FIR (Article 39). For a selected number of pre-packed foods the national legislature retains a responsibility if it so chooses (Articles 40 to 42 FIR). It is also free by a measure to design a language regime for food labelling (Article 15(2) FIR). Provided that these measures do not run counter to the free movement of goods, the Member States may, therefore, make additional mandatory labelling
rules for loose goods. Moreover, Member States are implicitly given leeway in determining which artisanal foods are exempted from mandatory nutrition labelling (Article 16(3) FIR and Annex V No. 19 FIR).

The purpose of this paper is to describe the laws and statutes instituted by Member States in response to the FIR’s implementing programme that is set out in the following.

B. Compulsory labelling requirements for non-prepacked food

Union law requires that information on allergens and products and substances causing food intolerances must be available and easily accessible for all foodstuffs, pre-packed or not (Article 12(1) FIR and Article 44(1)(a) FIR). Member States are entitled, but no obliged, to make food information on other particulars of Articles 9 and 10 FIR mandatory (Article 44(1)(b) FIR). Member States may also enact rules on the means through which these particulars on non-prepacked food are to be made available (Article 44(2) FIR). Today, more than half of 28 Member States have adopted laws to that end or have notified draft laws to the Commission’s TRIS system.

I. Concept of ‘non-prepacked’

Food in a package is referred to as ‘pre-packed’. Food that is not pre-packed is referred to as ‘loose goods’. Union law defines what is ‘pre-packed’ and in so doing marks the boundary of food labelling which falls within the coordinated field of the FIR on the one hand side and what is for the Member States to determine on the other.

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16 Recital 49 of the preamble to the FIR
1. Definition of ‘pre-packed food’

What had been defined as ‘pre-packed foodstuff’ in its predecessor Directive\textsuperscript{17}, is defined as ‘pre-packed food’ for the purposes of the FIR (Article 2(2)(e) FIR). Food not falling into the ‘pre-packed’ category, is outside the scope of the FIR and falls into the lap of the national regulator. This simple in/out-scheme explains the importance of categorising foods properly.

Union law offers two definitions of “pre-packed”:

<table>
<thead>
<tr>
<th>Article 2(2) of Directive 76/211/EEC</th>
<th>Article 2(2)(e) FIR</th>
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<tbody>
<tr>
<td>A product is pre-packed when it is placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification.”</td>
<td>‘Pre-packed food’ means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; ‘pre-packed food’ does not cover foods packed on the sales premises at the consumer’s request or pre-packed for direct sale</td>
</tr>
</tbody>
</table>

Article 2(2)(e) FIR prevails as \textit{lex specialis} over Article 2(2) of Directive 76/211/EEC while the latter remains relevant in the context of the application of the ‘e’-sign and other elements of ‘packaging law’ (nominal qualities, tolerable negative error, print size).

Given that the FIR is part of the wider context of ‘product labelling and packaging’, it is worth noting that the Commission’s work programme for 2015 foresees a review, in the framework of the REFIT-programme (“Regulatory

\textsuperscript{17} Article 1(2)(b) of Directive 2000/13/EC
Fitness and Performance Programme\textsuperscript{18}, of the (food and non-food) packaging directives, most of which originate from the 1970s. The ‘Packaging Directives’ are Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers, Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products, and Directive 2007/45/EC laying down rules on nominal quantities for pre-packed products. A stakeholder consultation has been conducted\textsuperscript{19} that may blaze the trail for consolidating the Directives into a single Regulation. Most recently, a ‘roadmap’ has been published suggesting that a Commission report on the issue will even be published still in 2015.\textsuperscript{20}

Case law of the European Court of Justice (ECJ) will eventually also provide guidance on the proper reading of the notion of ‘pre-packed food’. A first reference for a preliminary ruling has been referred by a German court asking the ECJ\textsuperscript{21}:

“Are individual portions of honey which are packaged in bulk in a carton containing all the labelling elements, including the indication of the country of origin, and which are not sold as individual portions to final consumers nor supplied individually to mass caterers, ‘pre-packaged foodstuff’ or ‘pre-packed food’ within the meaning of Article 1(3)(b) of Directive 2000/13/EC and Article 2(2)(e) of Regulation (EU) No 1169/2011 respectively, for which there is a corresponding labelling requirement, or are such portions of honey not subject to the labelling requirements for

\textsuperscript{18} http://ec.europa.eu/smart-regulation/refit/index_en.htm

\textsuperscript{19} “Share your experiences on the EU rules on pre-packaging of products” http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=8026


pre-packaged foodstuff/pre-packed foods due to their not being offered for sale as a single item?

Is the answer different if those individual portions are supplied in mass catering establishments not only in meals that are paid for as a whole but are also sold individually?”

2. **Concept of ‘food packed on the sales premises at the consumer’s request’**

Article 2(2)(e) FIR states that the concept of ‘pre-packed food’ does not cover food items that are packed at the point of sale on the request of the purchaser (which is an exception to the rule established by Article 12(2) FIR of food information appearing directly on the package).

3. **Concept of ‘food pre-packed for direct sale’**

Article 2(2)(e) FIR also states that the definition of ‘pre-packed food’ does not include food packed for direct sale (providing a further exception to Article 12(2)FIR). The exact meaning of ‘direct sale’ is not further clarified. However, the exception is designed to alleviate the regulatory burden for self-service retail businesses where foods are packed at the same premises from which they are sold. Customs vary between Member States, however, in the application of the clause, and while in some jurisdictions direct sale is understood to only cover sales made on the same day as the packaging occurs, others allow for the following day to be included, or a time period of 48 hours. Attempts to find a common approach have also failed because of the near-impossibility of finding a rule that suits the huge variety of foods offered. The wording of the draft Q&A below was also unsuccessful (never endorsed and eventually rejected by the joint Commission/Member States-Working Group):

“What is the meaning of direct sale in the provision for foods prepacked for direct sale? (Article 44 FIR)
The Regulation does not provide a definition of ‘foods pre-packed for direct sale’. Article 44 FIR allows Member States to adopt national rules concerning the provision of information on such foods. Based on the general principle that consumers should have the possibility to be adequately informed about the food they purchase, ‘foods pre-packed for direct sale’ are foods that have been pre-packed in the absence of the consumer and then put on display for sale and competent sales staff is directly available to provide information to consumers.

Any food sold through ‘self-service’ without direct intervention of competent sales staff should bear all the necessary information for consumers, in which case rules for pre-packed foods shall apply.”

The information that must be provided for food which is pre-packed for direct sales and offered on a self-service basis is subject to Article 44 FIR.

II. Allergen labelling

The mandatory requirement to provide allergen information for non-prepacked food, including for food provided in restaurants and cafés, is a novelty in EU law. The predecessor Directive of the FIR continued to leave this area to the Member States. The Commission’s proposal of 2008 suggested making the FIR’s requirements for providing food information to consumers mandatory for non-prepacked food while leaving it to the Member States to regulate the presentation of this information and to establish exceptions where relevant (though not with regard to allergen labelling). Such a blanket application of food information law was considered too burdensome for small and medium sized FBOs which often offer non-prepacked food to consumers. Handcrafted food is inevitably subject to variations that would require constant changes to the way it is labelled. The non-standardised conditions often prevailing in SME food production and retail would

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22 Article 14 of Directive 2000/13/EC
23 Article 41 of the Commission’s proposal (COM(2008) 40)
have made it exceedingly difficult to comply with the intricacies of food information law. The compromise which was eventually found continued to make it mandatory to provide information on allergens, while returning responsibility for other elements of food information to the national regulator.

Proper and exhaustive allergen labelling is of primary concern for sensitive consumers (recitals 28 and 48). People suffering from food allergies and intolerances have an interest in this kind of food information no matter whether the food in question is pre-packed or not. FBOs will have an interest in avoiding product liability issues arising from the strict liability regime established by Directive 85/374, as amended by Directive 1999/34.

III. National measures on mandatory particulars
(Article 44(1)(b) FIR)

While allergen labelling for un-prepacked food is a ‘must’ for Member States to comply with, imposing further labelling requirements for lose goods is a ‘can’ possibility only. It is left to the discretion of the national regulator to pick and chose from the list of mandatory particulars of Article 9 and 10 FIR (for additional mandatory particulars cf. Article 39 FIR). The national chapters of this compilation show to what extent use has been made of this possibility.

IV. Means of expression and presentation
(Article 44(2) FIR)

Member States may enact rules on the way of presenting the particulars required by Article 44(1) FIR. In the context of this provision belongs the discussion whether, for instance, displays of information at the point of sale or information given by word of mouth could suffice to inform the consumer appropriately.
C. Labelling requirements for pre-packed food

I. National measures additional to mandatory particulars (Article 39 FIR)

Within the margins set by Article 39 FIR, Member States are authorised to add to the mandatory particulars of the FIR, but only for specific types of food and in order to pursue a limited number of recognised objectives. Such national measures must not, however, “prohibit, impede or restrict the free movement of goods that are in conformity” with the FIR.24

The example of Italy shows how this clause may be applied. Italy is keen to re-introduce an obligation to inform the consumer of food production sites. It may also be required to replace a ban on the use of powdered, condensed and reconstituted milk in dairy products currently existing (Law No 138 of 11 April 1974) with a labelling requirement. Such measures would fall within the ambit of Article 39 FIR.

Regarding the indication of food production sites the responsible Commissioner spelt out the conditions under which such national measures might be established in an answer to a parliamentary question25:

“Article 39(1) FIR provides an exhaustive list of possible justifications for Member States to adopt measures requiring additional mandatory particulars for specific types or categories of foods. Paragraph 2 of that Article specifies that Member States may introduce measures concerning the mandatory indication of the country of origin or place of provenance of foods only where there is a proven link between certain qualities of the food and its origin or provenance and when evidence is provided that the majority of consumers attach significant value to the provision of this information. The Commission would like however to clarify that it does not consider

24 Recital 49
25 Written Question P-001644-15 “Information regarding food production sites” by MEP Elisabetta Gardini with answer by Andriukaitis of 27.2.2015
information on origin or provenance neither as a tool for the prevention of fraud, nor as a tool for the protection of public health. There are other mechanisms in place to ensure the safety and the traceability of food.

Article 26(2)(a) FIR already requests the indication of the country of origin or place of provenance when its omission might mislead the consumer as to the true origin of the food, in particular if the information accompanying the food or the label, such as the trademark mentioned by the Honourable Member, would otherwise imply a different origin.”

Regarding the possible introduction of a labelling requirement on the use of powdered, condensed or reconstituted milk in cheesemaking and other dairy products required by Italian law de lege ferenda (as an alternative of an outright ban of use) the Commission further clarified in another answer to a parliamentary question:

“Article 39(1) FIR allows Member States to adopt measures requiring additional mandatory particulars (i.e. food information) for specific types or categories of food, provided that such additional mandatory food information are justified on the grounds of the protection of public health, the protection of consumers, the prevention of fraud, the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition. An appropriate labelling of milk products could be a proportionate alternative to banning the use of milk powder in the manufacturing of milk products. If the Italian authorities were to envisage imposing for dairy products the indication of the raw material used and the type of storage, dehydration and rehydration to which it was subjected, these labelling rules would have to be notified in advance to the Commission and the other Member States, in accordance with the procedure laid down in Article 45 FIR. According to this procedure, the Commission would then have three months to examine the measures envisaged and the reasons justifying them.”

26 Written Question E-010809-15 “Formal notice from the Commission asking Italy to repeal Law No 138 of 11 April 1974 concerning the ban on the use of powdered, condensed and reconstituted milk in dairy products” with answer by Commissioner Adriukaitis of 25.8.2015
The Commissioner specified in his answer to another parliamentary question 27:

“Regulation (EU) No 1169/2011 [FIR] allows Member States to introduce national rules in the area of food information to consumers subject to certain conditions. As regards the matters specifically harmonised by the Regulation, MS may not adopt nor maintain national measures unless authorised by Union law [Article 38(1) FIR]. Such measures must not give rise to obstacles to free movement of goods. In addition, without prejudice to Article 39, Member States may adopt national measures concerning matters not specifically harmonised by this Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation [Article 38(2) FIR].

In the specific case of national measures exclusively falling within the scope of Article 39 of Regulation (EU) No 1169/2011 [i.e. national measures requiring additional mandatory particulars for specific types or categories of foods as well as national measures concerning the mandatory indication of the country of origin or place of provenance of foods where there is a proven link between certain qualities of the food and its origin of provenance], the special notification procedure set out in Article 45 thereof must be followed before such measures may be introduced. In addition, national measures that fall within the scope of Directive 98/34/EC [now Directive 2015/1535] because they constitute draft technical regulations (e.g. as it may be the case for some national measures falling under Article 44 of the Regulation [i.e. national measures for non-prepacked foods]) must follow the general procedure laid down in the latter Directive before are introduced. Finally, national measures falling within Articles 40 and 43 of Regulation (EU) No 1169/2011 [i.e. national measures concerning certain derogations for milk and milk products presented in glass bottles intended for reuse and the voluntary indication of reference intakes for specific population groups] are only required to be communicated to the

27 Written Question E-011733-15 “National rules introduced in the context of Regulation (EU) No 1169/2011 (Food Information Regulation)” by Renate Sommer with answer by Commissioner Anndriukaitis of 23.9.2015
Commission without delay, once adopted. In the latter case, there is no prior evaluation of the measures.

The Commission is currently working on developing an EU database to facilitate the identification of all EU and national mandatory labelling rules in a simple way. This will offer a user-friendly tool for all food business operators and especially small- and medium-sized enterprises to consult.”

II. Milk and milk products (Article 40 FIR)

Reusable glass bottles with indelible (non-removable) marks (not labels) already benefit from certain derogations under Article 16(1) FIR. National law may further advantage producers by exempting them from displaying particulars – which are otherwise mandatory for milk and milk products – when offering them in reusable glass bottles.

III. Alcoholic beverages (Article 41 FIR)

Beverages containing more than 1.2% alcohol are exempted from the requirement to list ingredients and from providing a nutrition declaration. In order to determine whether such labelling would be appropriate, the Commission was required to issue a report by December 2014. If appropriate, this report was to be accompanied by a legislative proposal, that is, an initiative for the adoption of secondary law by the co-legislators (and not a delegated act adopted by the Commission). The report has not yet been

28 Article 3 No. 5 of Directive 94/62/EC on packaging and packaging waste
29 Article 2(2)(i) FIR
30 Article 9(1)(a), (c), (e), (f) and (l) FIR
31 Article 9(1) and Article 10(1) FIR
33 Article 16(4) FIR
34 Recital 40
presented and a draft regulation is not in sight despite political pressure from
the European Parliament which is calling for the presentation of a new EU
Alcohol Strategy, together with a bundle of related measures.35 The Com-
misson explains its approach in its answer to a parliamentary question36:

“Article 16 FIR requires the Commission to adopt a report concerning the
application of the requirements to provide information on ingredients and
nutrition information on alcoholic beverages.

The Commission has initiated exploratory actions and led preliminary
discussions with Member States, but further work remains to be done
before the Commission is able to provide a date for the adoption of the
planned report.

The Commission notes that the FIR allows, on a voluntary basis, the
declaration of the energy value alone for alcoholic beverages, while, for
other foodstuffs the energy declaration is only one of the elements of
the mandatory nutrition declaration. This facilitated declaration has the
objective to encourage alcoholic beverages manufacturers to provide this
information. In that context, the Commission welcomes the commitment
of the association The Brewers of Europe to voluntarily provide consumers
with information about the energy value of its members’ products.”

This shows that industry-based initiatives are favoured rather than further
regulation. As part of a voluntary agreement by the Brewers of Europe,
their members will gradually undertake to list ingredients and nutritional
information of beer.37

In the absence of relevant EU legislation, Member States are permitted,
under Article 41 FIR, to maintain already extant provisions of national

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35 European Parliament resolution on Alcohol Strategy of 28.4.2015; European Parliament press
release “Alcoholic drinks should state calorie content, say MEPs” of 29.4.2015
36 Written Question P-006167-15 “Nutritional declaration for alcoholic beverages” with answer
by Commissioner Andriukaitis of 18.5.2015
37 Brewers of Europe: “What’s in a beer? Europe’s brewers commit to ingredients listing and
nutrition information for consumers” (26.3.2015)
law on ingredient labelling. They are prevented, however, from introducing new regulations. Concerning beer, for example, the law of eleven States (Austria, Bulgaria, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania, Sweden and Switzerland) already obliges producers to provide a list of ingredients.

IV. Expression of net quantity (Article 42 FIR)

Net quantity\textsuperscript{38} must be expressed in metric units\textsuperscript{39}. As long as no legal provisions have been made by the Commission through delegated acts for specific foods\textsuperscript{40}, Member States may retain national rules on net quantity extant at the time the FIR came into effect. The Commission must be informed of these provisions.

V. Voluntary indication of reference intakes for specific population groups (Article 43 FIR)

Mandatory particulars concerning reference intakes for adults (in relation to vitamins and minerals as well as energy and selected nutrients) are to be labelled in accordance with Annex XIII.\textsuperscript{41}

Regarding additional voluntary information on reference intakes for specific population groups, the Commission is instructed to adopt an implementing act (Art. 36(3)(c) FIR). Specific population groups may be infants and young children and adults with special dietary needs such as pregnant and lactating women, as well as seniors and athletes. Specific nutritional

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\textsuperscript{38} Annex I, point 2.1 of Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products

\textsuperscript{39} Article 23(1) and Annex IX FIR

\textsuperscript{40} Article 23(2) FIR

\textsuperscript{41} Although food supplements are generally exempted from nutrition declaration under the FIR (Article 29(1)(a) FIR), by reference from the Food Supplement Directive Annex XIII is still applicable (Article 8(3) of Directive 2002/46/EC and Article 53(2) FIR)
needs can arise from local circumstances for instance in Member States with iodine deficiency or vitamin D deficits. In the absence of an implementing act adopted by the Commission, Member States remain entitled to regulate the voluntary indication of reference intakes. As a measure of the substitute performance, when acting in place of the EU-Executive, the national legislature has to keep namely to EFSA recommendations concerning the nutritional needs of children and adolescents.

D. Labelling requirements for pre-packed and non-prepacked food: use of language (Article 15(2) FIR)

For pre-packed food and non-prepacked food alike, Member States may specify that food information must be given in one of the official languages of the EU (Article 15(2) FIR). This clause, which was introduced in Community food labelling legislation in 1997, permits the national regulator to impose the use of a specific language for their territory; a provision that could if used significantly disrupt the flow of goods.

E. Notification procedures under the FIR (Directive 2015/1535 and Article 45 FIR)

As shown, Member States may act in areas assigned to their competence by the FIR. As they do so, however, they are obliged to keep the Commission informed of the measures they are taking, which enables the EU-Executive to act in case national measures overstep the boundaries of the FIR and enter the coordinated field (food information law), or interfere with the principle of free movement of goods (Article 34 TFEU).

43 “That need [to inform and protect the consumer] means that Member States may, in compliance with the rules of the Treaty, impose language requirements” (recital 7 of Directive 2000/13/EC)
As recital 48 emphasises, all national “doing it alone” measures have to comply with the principles of the internal market and above all the free movement provisions of the Treaty.

The FIR provides for no less than three mechanisms for a formalised dialogue between Member States and the Commission:

The standard procedure that applies across the field of technical standards and regulations is the information procedure instituted by Directive 98/34/EC\textsuperscript{44}, now codified as Directive 2015/1535\textsuperscript{45} (http://ec.europa.eu/enterprise/tris). The information procedure obliges Member States to notify to the Commission draft national technical regulations relating to all products including those related to food and information on food.\textsuperscript{46} Most FIR implementing measures discussed in this compilation have been notified in this manner (see Annex), allowing the Commission to comment (which it did in several instances), as well also allowing the general public to comment. The underlying idea is to provide a mechanism for review at European level before the relevant texts are adopted nationally.

Article 45 FIR establishes a partial exception from this general rule. The notification procedure involves the Standing Committee (PAFF) and is meant to create a mechanism of scrutiny for additional mandatory particulars adopted under Article 39 FIR if this is deemed necessary. By involving the forum of the PAFF, national measures are put to a peer group test. For instance, Italian complaints against the British ‘traffic light’ nutrition labelling scheme were discussed between Member States within the PAFF, which evaluated their potential impact on the internal market and the free flow of goods across national jurisdictions.\textsuperscript{47}


\textsuperscript{45} OJ L 241 of 17.9.2015, p. 1

\textsuperscript{46} Article 1(1) of Directive 98/34/EC defined the term “product” as including “any agricultural product, including fish products”

\textsuperscript{47} A ‘letter of formal notice’ was sent end September 2014 (the first, if preliminary, stage in EU infringement proceedings), but not followed up by a (second stage) ‘reasoned opinion’ that
Articles 40, 42, 43 and 44(3) FIR, finally, request a simple form of communication whereby Member States need to inform the Commission of the relevant texts of national law.

The Commission summarises this system of checks and balances as follows:

“In the specific case of national measures exclusively falling within the scope of Article 39 FIR [i.e. national measures requiring additional mandatory particulars for specific types or categories of foods as well as national measures concerning the mandatory indication of the country of origin or place of provenance of foods where there is a proven link between certain qualities of the food and its origin of provenance], the special notification procedure set out in Article 45 thereof must be followed before such measures may be introduced. In addition, national measures that fall within the scope of Directive 98/34/EC [now Directive 2015/1535/EU] because they constitute draft technical regulations (e.g. as it may be the case for some national measures falling under Article 44 of the Regulation [i.e. national measures for non-prepacked foods]) must follow the general procedure laid down in the latter Directive before are introduced. Finally, national measures falling within Articles 40 and 43 of Regulation (EU) No 1169/2011 [i.e. national measures concerning certain derogations for milk and milk products presented in glass bottles intended for reuse and the voluntary indication of reference intakes for specific population groups] are only required to be communicated to the Commission without delay, once adopted. In the latter case, there is no prior evaluation of the measures.”

brings a threat of action in the European Court of Justice (ECJ) if a Member State does not end a perceived non-compliance. If a Member State’s response to the letter of formal notice is satisfactory, the Commission will not move to a reasoned opinion.

F. Exception from nutrition labelling (pre-packed food): the notion of “direct supply” (Article 16(3) and Annex V No. 19)

As of 13th December 2016, nutrition labelling is mandatory for pre-packed foods. This requirement in principle applies without regard of the possible SME character of the food business operator (FBO) many of whom may struggle to cope with the technicalities of nutrition labelling given their small scale. Neither does nutrition labelling pay regard to the methods of production used, which, because of their artisanal character, are ill-prepared to include nutrition labelling. Recognising these problems, and in a deliberate attempt to promote artisanal food production and short supply chains49, Annex V No. 19 states an exemption from nutrition declaration for food manufactured in small quantities and supplied directly to the final consumer or to local retail establishments. This clause favouring privileging small entrepreneurial manufacturers includes a number of rather vague terms and legal concepts (‘small amount’, ‘local’) that remain to be defined by national authorities, unaided, as it is the case, by guidance provided by the Q&A.

49 Cf. Article 55 of Regulation 1151/2012
I. Objectives pursued by national implementation measure

Belgian Act of 24 January 1997 regarding the protection of consumers’ health with respect to foodstuffs and other products constitutes the master legislation concerning the labelling and advertising of foodstuffs. This Federal Act forms the legal basis for the adoption of implementing rules on the subject-matter, through royal decrees. Up to the adoption of the FIR, Belgian horizontal rules on food labelling and advertising were embedded in two main Royal Decrees:

- Royal Decree of 13 September 1999 on the labelling of pre-packaged foodstuffs;
- Royal Decree of 17 April 1980 on the advertising of foodstuffs.

With the entry into application of the FIR, the large majority of the provisions contained in these pieces of legislation became redundant and/or inapplicable. As a consequence, a substantial part of the Royal Decree on the advertising of foodstuffs has meanwhile been repealed. It is expected that the same destiny will be reserved to the Royal Decree on the labelling of foodstuffs. In addition, Belgian authorities have implemented the rules on allergen declaration for non-prepacked foods in a separate Royal Decree of 17 July 2014, which will be discussed in section III.1. below.

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50 Belgian Gazette of 8 April 1977.
51 Royal Decree of 8 September 2015 (Belgian Gazette of 1 October 2015)
II. Notification procedure under TRIS

What is now Royal Decree of 17 July 2014 had been notified as TRIS 2014/154/BE. There are currently no relevant draft texts of legislation pending under the TRIS notification procedure.

III. Labelling requirements for non-prepacked food

1. Allergen labelling (Article 44(1)(a) FIR)

National implementing rules on allergen declaration for non-prepacked food have been adopted by Royal Decree of 17 July 2014\(^52\). It entered into force on 13\(^{th}\) December 2014.

In Belgium, allergens of non-prepacked foods may be declared either in writing or orally, although, for the latter, the obligations imposed on operators are stricter.

When the declaration is made in writing, the obligations of the food business operator are the following:

- A reference to the name of the allergen substance must be listed in a clearly readable manner on a physical or electronic medium at the location where the product is offered for sale, in order to be freely and readily available before the purchase is concluded.
- By way of exception, such declaration is not mandatory when the name of the food is provided in writing and a clear reference to the name of the substance or product is given (e.g. ‘eggs’).

If the operator chooses to communicate the allergen information orally, it

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\(^{52}\) Royal Decree of 17 July 2014 establishing provisions for the declaration of certain substances or products causing allergies or intolerances as regards non-pre-packed food, **Belgian Gazette**, 12 August 2014, p. 58654
will have to put a system in place which ensure safe and correct declara-
tion. The allergen declaration will have to be provided at the consumer’s
request by the operator or a staff member or by means of a suitable device,
without any additional cost for the consumer.

In addition, domestic procedures must be developed and implemented
at the point of sale to ensure that the declaration of allergens is provided
correctly. This implies that the allergens be listed in writing on a physical
or electronic medium in the establishment where the product is offered
for sale and in a place easily accessible to staff and supervisors. Further-
more, the staff must be trained as to the risks posed by allergies and food
intolerances, and the domestic procedure.

Finally, two additional written statements must be displayed to the con-
sumer, in each area where the food is offered for sale within the establish-
ment, and for both kind of declaration (written and oral):

• A statement indicating the location where, or the means by which, the
declaration of allergens is available and, where appropriate, an indica-
tion inviting the consumer to address their queries to the staff of the
facility, and
• Another statement warning consumers that the product mixture may
vary from one batch to another.

Such additional statements are however not mandatory if:

• the written declaration of allergens is listed in a clearly apparent lo-
cation such as to be easily available before the purchase is concluded
(this would not be the case if, for example, the allergen declaration is
made available to the consumer in a ‘closed’ register, not directly clearly
visible and identifiable for the consumer) ; or
• If the operator asked about the dietary needs of consumers in relation
to food allergies and intolerances in advance, and can offer food on
an individual basis in accordance with these dietary needs (e.g. when
booking a flight or at the hospital).
Since the adoption of the Royal Decree, the Federal Agency for the Safety of the Food Chain (which controls the application of the Royal Decree) published a circular related to allergen information\(^{53}\). Even though the circular is not binding as such, it provides food business operators with some guidance regarding the fulfilment of their obligations as regards allergen information for non-pre-packed food. In particular, the circular provides specific recommendations to help the operators to meet the legal requirements, notably in terms of traceability. It further provides specific guidance for the attention of the operators that provide the allergen declaration orally. In this respect, the authorities have established a standard form summarising the internal process to be put in place and allowing a personalisation of the process which fits with the situation of the operator on the field. Operators are nevertheless free to adopt their own procedure as long as it leads to the same result.

2. **Mandatory particulars (Article 44(1)(b) FIR)**

- *Fresh minced or milled meat* – A Belgian Royal Decree\(^{54}\) imposes to indicate, in a visible and an easily readable manner, and on a sign next to the foodstuff the sales name of the fresh minced or milled meat (which must comply with specific composition requirements), together with the animal species involved in the meat preparation (by descending order of weight).
- *Cheese* – The Belgian legislator foresees an obligation to declare, for both pre-packed and non-pre-packed cheeses\(^{55}\), the fat content of

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54 Art. 4 §2 Royal Decree of 8 March 1985 on the fabrication and the trade of fresh minced or milled meat (Belgian Gazette 16 April 1985, No: 1985013077, p. 5203

55 Art 2, 1° and 5 of the Royal Decree of 8 May 2014 on cheese (Belgian Gazette 19 May 2014, No 2014011226, p. 39877)
cheese, in grams of fat content per 100 grams of the product (unless the product already contains a nutrition declaration) and, when applicable, the inedible nature of the rind. This legislation, however, does not apply to cheeses legally produced and/or first placed on the market of another EU and EEA countries and in Turkey.

3. Means of expression and presentation (Article 44(2) FIR)

The means of expressions and presentations are included in each relevant Royal Decree dealing with mandatory information for non-prepacked food. As a matter of fact, one can note that the legislator takes as a rule the criteria of written information, displayed in a visible and easily readable manner.

IV. Labelling requirements for pre-packed food

1. National measures on additional mandatory particulars (Article 39 FIR)

- Identification of the packer:
Complying with its obligation to implement Directive 76/211/EEC relating to the making-up by weight or by volume of certain pre-packaged products\(^{56}\), Belgian law requires that each label of pre-packaged products bears a mark or an indication enabling to identify one of the following persons, depending on the place where the packing is made\(^{57}\):

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\(^{57}\) Royal Decree relating to the making-up by weight or by volume of certain pre-packaged products (Belgian Gazette 1 January 1980, No 1979122801, p. 33, and Ministerial Decree of 12 September 1980 fixing the arrangements for identifying the packer, the person arranging
• The packer or;
• The person arranging for the packing to be or;
• The importer in Belgium.

It must be highlighted that the definition of pre-packaged food under this legislation differs from the one laid down by the FIR. Indeed, legislation on the identification of the packer also applies when the pre-packaged foodstuffs do not constitute a sales unit.  

• Lot-marking:
In Belgium, just as in the other EU countries, all pre-packaged foodstuffs – safe some limitative exceptions – must be marked with an identification of the lot to which they belong. This requirement implements Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs, replaced since then by Directive 2011/91.

• Minced poultry meat and preparation of poultry meat:
When they are intended to be consumed cooked and sold in Belgium, the following indication must be mentioned on the label: “Cook well before eating” (“Bien cuire à cœur avant consommation”). This mention has to be indicated on a visible and clear place, and just below the

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58 The definition provided by both the EU Directive and Belgian Royal Decree on relating to the making-up by weight or by volume of certain pre-packaged products provide that a pre-packed product is a product ‘placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification’

59 Royal Decree of 9 February 1990 on the marks identifying the lot to which a foodstuff belongs (Belgian gazette 14 April 1990, No. 1990025061, p. 7110)


approval number of the producer of the meat, appearing in a specific format imposed by the legislation62.

- **Cheese:**
  In line with the requirements applicable to non-prepacked cheeses, prepacked cheeses must indicate the fat content of cheese, in grams of fat content per 100 grams of the product (unless the product already contains a nutrition declaration), and the inedible nature of the rind, where applicable. 63 This legislation does not apply to cheese legally produced and/or first placed on the market of another EU and EEA countries and in Turkey.

- **Raw milk sold to the final consumer via an automatic distributor:**
  The automatic distributor must indicate prominently64:
  
  - “Raw milk. Boil before use.”
  - “Store at a t° ≤ +6.0°C”, and
  - “Use before [date in DD/MM]”. This time limit may not exceed 72 hours after the first milking from which milk or colostrum remains in the batch from which milk is taken to supply the vending machine.

2. **Milk and milk products (Article 40 FIR)**

There is no specific Belgian measure applicable to milk and milk products presented in bottles intended for reuse.

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63 Art 2, 1° and 5 of the Royal Decree of 8 May 2014 on cheese (Belgian Gazette 19 May 2014, No 2014011226, p. 39877)
64 Royal Decree of 13 July 2014 on the hygiene of foodstuffs (Belgian Gazette 29 August 2014, No. 2014018271 p. 64857)
3. **Alcoholic beverages (Article 41 FIR)**

Belgian law does not require additional mandatory particulars for alcoholic beverages.

4. **Expression of net quantity (Article 42 FIR)**

In addition to the rules laid down by the FIR, Belgian law specifies that:

1) the net quantity of yoghurts and other fermented milks, as well as condiment sauces, may be expressed either in units of volume or in units of mass;
2) the units of mass of soups which are not ready for use may be replaced by the units of volume after preparation according to the cooking instructions;
3) the net quantity of ice creams must be expressed in units of volume. However, units of mass may be added.

5. **Indication of reference intakes for specific population groups (Article 43 FIR)**

There is no specific Belgian rules determining reference intakes for specific population groups.

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65 Art. 8, §1 of Royal Decree of 13 September 1999 on labelling of pre-packaged food (Belgian Gazette 29 October 1999, No. 1999022945, p. 40908 – as lastly amended on 5 October 2012)
V. Labelling requirements for both pre-packed and non-pre-packaged food: Use of language (Article 15(2) FIR)

Belgian law requires that any mandatory food information appears at least in the language(s) of the region where the product is marketed. Belgium comprises four linguistic regions:

- a Dutch speaking region in the north (Flanders);
- a French speaking region in the south (Wallonia);
- a German region in the east (Eupen-Malmedy);
- A bilingual regime of French and Dutch in the Brussels region.

As a consequence, the mandatory food information must be indicated in – at least – Dutch, French and German when the food is marketed in the whole Belgian territory.

VI. Exception from nutrition labelling: the notion of “direct supply” (Annex V No. 19)

Although no Belgian legislation directly defines and/or implements the notion of ‘direct supply’ under the scope of the FIR, specific definitions of ‘direct supply’ and ‘small production’ are provided by the Belgian Royal Decree of 7 January 2014 relating to the direct supply by a primary producer to the final consumer or of retail distribution of small quantities of certain foodstuffs of products of animal origin.

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66 Article 8 of the Law of 24 January 1977 on the protection of consumers’ health in relation to foodstuffs and other products (Belgian Gazette 08 April 1977, No. 1977012405, p. 4501 – as lastly amended on 30 April 2014)

67 Belgian Gazette of 21 January 2014
VII. Enforcement, incl. fines

When the authorities conclude to an infringement with labelling requirements on allergen information, they have the choice to send to the infringer:\[68:\]

- A warning letter, where the infringer is asked to cease the infringement. If the infringement is not brought to an end, an official report shall be then established; or
- An official report, directly. The infringer is then invited to present its defence.
- Further to that, and in addition to the seizure of the infringing goods, the relevant authorities have the choice between (without prejudice to the right for the public prosecutor to investigate and pursue the infringement by its own):
  - Propose the infringer to pay an administrative fine, whose amount varies between 150 EUR and 30,000 EUR. If the administrative fine is paid, the infringer may not be the subject of criminal prosecution anymore.
  - Immediately send the official report to the public prosecutor who will decide to start criminal proceedings or not.

If the public prosecutor starts criminal proceedings, the infringer runs the risk of being sentenced to an imprisonment from 8 days to 5 years and/or to a fine up to 90,000 EUR\[69:\] (depending on whether the infringement was intentional or not).

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68 Royal Decree of 22th February 2001 organising the inspections made by the Federal Agency for the Safety of the Food Chain, Belgian Gazette, 28 February 2001, p. 6403

69 Belgian law of 24 January 1977 on consumers protection related to food and other products, Belgian Gazette, 8 April 1977, p.4501; Royal Decree of 22 February 2001 organising the inspections made by the Federal Agency for the Safety of the Food Chain, Belgian Gazette, 28 February 2001, p. 6403
I. Objectives pursued by national implementation measure

The FIR was implemented by amendment to Act No 110/1997 Coll., on Foodstuffs and Tobacco Products (hereinafter as “Act on Foodstuffs”), which came into force on 1 January 2015. Besides FIR, it also transposed the Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs and the Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements. In this respect, further implementing decrees to Act on Foodstuffs shall be adopted as well, nevertheless none such act has been adopted so far.

II. Labelling requirements for non-prepacked food

Czech law provides for special regulation of labelling of food. Concerning food pre-packed for direct sale in the absence of the consumer it states mandatory information on the packaging for the following items:

- name of the manufacturer
- legal name of the foods
- net quantity
- list of ingredients
- the country or place of origin
- special storage conditions, if applicable
- the date of minimum durability or usability
- information according to Article 10(1) and Article 44(1)(a) FIR
- quality class, if mandatory according to special regulations
- other information, if mandatory according to special regulations
For non-prepacked food the law requires the following items of information to be placed in close distance to the place of offering for sale:

- name of the manufacturer
- quantity of the main ingredient, if ordered by law
- quality class, if mandatory according to special regulations
- legal name of the foods
- the country or place of origin
- information according to Article 10(1) FIR
- other information if applicable under special regulations

Information to be placed near the place of offering for sale includes:

- date of durability of ‘use by’ date
- information according to Article 44(1)(a) FIR
- other information, if mandatory according to special regulations

Information according to Article 9(1)(b) and Article 22 FIR shall be provided upon the consumer’s request or made easily accessible otherwise.

III. Labelling requirements for pre-packed food:

1. National measures on additional mandatory particulars (Article 39 FIR)

Apart from mandatory information according to FIR, pre-packed food shall be also labelled by information on:

- quality class, if mandatory according to special regulations
- other information, if mandatory according to special regulations
2. Milk and milk products (Article 40 FIR)

A new implementing decree on requirements on milk and milk products, frozen creams and eatable fats and oils has not been adopted yet; it is still in the legislative process.

3. Alcoholic beverages (Article 41 FIR)

In case of beverages containing more than 1.2 % of alcohol, information according to Article 9(1)(b) FIR (list of ingredients) and Article 22 FIR (quantitative indication of ingredients) are mandatory.

4. Expression of net quantity (Article 42 FIR)

National legal regulation stipulates requirements on labelling of net quantity of the product similar to FIR (Annex IX).

5. Indication of reference intakes for specific population groups (Article 43 FIR)

There are no national measures for indication of reference intakes for specific population groups (Article 43 FIR), only recommendations for the actual reference intakes.

IV. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

All mandatory information on the foods shall be provided to the consumer in Czech language.
V. Means of expression and presentation  
(Article 44(2) FIR)

According to Act on Foodstuffs, information must be provided visibly, easy to read. Special rules for means of labelling of foodstuffs are defined by Decree No 113/2005 Coll., on the method of labelling food and tobacco products, which has not yet been substituted by new legal regulation implementing FIR.

VI. Exception from nutrition labelling:  
the notion of “direct supply”

(Annex V No. 19)

According to the Act on Foodstuffs, a special implementing decree shall be adopted, which specifies “small quantities of products exempted from the requirement of the mandatory nutrition declaration.” None such regulation has been adopted yet.

VII. Enforcement

The State Agriculture and Food Inspection Authority control compliance with foods labelling requirements. The maximum amount of financial penalty, which can be imposed for violation of Act of Foodstuffs, is approx. EUR 36,000. The amount of the penalty imposed always depends on the character and seriousness of violation of law, facts of the case and its consequences. Such decision can be always appealed and final decision of the inspection authority can be brought to the court by filing an administrative lawsuit.
VIII. Miscellaneous

Legal regulation of labelling of foodstuffs in the Czech Republic was harmonised by the amendment to Act on Foodstuffs with FIR only partially. Remaining legal regulations implementing this act and reflecting FIR are still in the legislative process.
DENMARK

**Martin Dræbye Gantzhorn / Christian Marquard Svane, Horten Advokatpartnerselskab, Copenhagen**

I. **Objectives pursued by national implementation measure**

In Denmark, the Executive Order on the Labelling etc. of Foodstuffs is the act implementing the FIR.

II. **Notification procedure under the TRIS**

On 17 March 2015, the Danish Veterinary and Food Administration (the “DVFA”\(^\text{70}\)) submitted a notification (the “Notification” – 2015/123/DK) to the European Commission. The Notification relates to certain amendments, made to the existing Executive Order on the Labelling etc. of Foodstuffs. However, the DVFA had already implemented the notified amendments into Danish law by means of Executive Order No. 234 of 6 March 2015 on the Labelling etc. of Foodstuffs\(^\text{71}\) at the time of notification. During the notification procedure, the Commission submitted a detailed opinion. In response to the Commission’s detailed opinion, the DVFA decided to amend Executive Order No. 234 of 6 March 2015 on the Labelling etc. of Foodstuffs. On 29 October 2015, the DVFA initiated a public consultation\(^\text{72}\) of a new draft Executive Order on the Labelling of Foodstuffs\(^\text{73}\). The consultation period expires on 26 November 2015 and

\(^{70}\) www.foedevarestyrelsen.dk
\(^{71}\) https://www.retsinformation.dk/Forms/R0710.aspx?id=168739
\(^{72}\) https://hoeringsportalen.dk/Hearing/Details/58893
\(^{73}\) http://prodstoragehoeringspo.blob.core.windows.net/dd7753a9-bbb5-4a0f-8e59-6e1aa30b1e64/preview_M%C3%A6rkning.pdf
the amended Executive Order on the Labelling of Foodstuffs\textsuperscript{74} is set to enter into force as of 1 January 2016. The information in this chapter is based on the draft Executive Order on the Labelling of Foodstuffs, which was released for public consultation on 29 October 2015 (the “Draft Order”).

III. Scope of national implementation measure

The “Draft Order” applies to the promotion of foodstuffs in B2B-relations as well as in B2C-relations (cf. Chapter 11 of the Draft Order). The Draft Order covers the following matters:

- Labelling of non-prepacked foods, foods packed on the sales premises at the consumer’s request and foods pre-packed for direct sale (cf. Articles 44(1)(a) and 44(2) FIR);
- Mandatory particulars for certain foods pre-packed for direct sale (cf. Articles 44(1)(b) and 44(2) FIR);
- Expression of net quality (cf. Article 42 FIR);
- Language requirements (cf. Article 15(2) FIR), and
- Labelling requirements for pre-packed minced meat products (Annex VI, Part B, paragraph 3 FIR).

The DVFA has adopted a set of Guidelines (Guideline no. 9719 of 4 July 2015 – “Vejledning om mærkning af fødevarer”\textsuperscript{75}), which supplements the Draft Order. Please note that the Guidance Document has not been notified under the TRIS-directive and that the DVFA has not released a revised Guideline, which takes into account the amendments, which will be implemented by means of the Draft Order.

\textsuperscript{74} http://prodstoragehoeringspo.blob.core.windows.net/dd7753a9-bbb5-4a0f-8e59-6e1aa30b1e64/preview_M%C3%A6rkning.pdf
\textsuperscript{75} https://www.retsinformation.dk/Forms/R0710.aspx?id=173160
IV. Non-prepacked foods, foods packed on the sales premises at the consumer’s request and foods pre-packed for direct sale

1. Allergen labelling (Article 44(1)(a) FIR)

Pursuant to Article 44(1)(a) FIR, the particulars in Article 9(1)(c) FIR must be provided when ‘non-prepacked foods’, ‘foods packed on the sales premises at the consumer’s request’ and ‘foods pre-packed for direct sale’ are offered for sale. Pursuant to Article 44(2) FIR, Member States may adopt national measures concerning the means through which the particulars of Article 44(1) FIR must be provided/presented.

Pursuant to § 13(2) of the Draft Order, information on allergens (i.e. the ingredients and technical substances listed in Annex II FIR) must be provided to consumers by one of the following means of communication:

1. written information or similar in the immediate proximity of the foodstuff, or
2. other relevant methods, including information via electronic means.

The other relevant methods include e.g. making tablets or computers available to the consumer, containing information on allergens for all relevant products.

Pursuant to § 13(3) of the Draft Order, if the information on allergens is not stated on the foodstuff, on the menu (or similar), or in proximity hereof, the allergen labelling must, as a minimum, consist of e.g. a sign clearly stating that consumers may obtain information on allergens by contacting an employee.

Pursuant to § 13(4) of Draft Order, it is not required to provide separate information on allergens, if the name of the food is stated in writing,
insofar as the name of the product contains a clear reference to any and all allergens contained in the product\textsuperscript{76}.

Pursuant to § 13(5) of the Draft Order, it is required to provide information on allergenic ingredients, if the operator asks consumers in advance about their dietary needs in terms of food allergies and intolerances, provided that the operator is able to individually prepare/provide food in accordance with these dietary needs.

Pursuant to § 14(1) of the Draft Order, if any of the information (described above) is provided in writing, the requirements of Article 13(2) and (3) FIR (text size) do not apply. However, it is emphasized in § 14(2) of the Draft Order that the requirements in Article 21(1)(b) FIR, cf. Article 9(1)(c) FIR (emphasis of allergenic ingredients/technical aids) do apply.

2. Mandatory particulars (Article 44(1)(b) FIR)

Pursuant to Article 44(1)(b) FIR, Member States may adopt national rules, according to which the particulars of Article 9 FIR and Article 10 FIR (apart from allergens, cf. Article 9(1)(c) FIR) are mandatory for non-prepacked foods, foods packed on the sales premises at the consumer’s request and foods pre-packed for direct sale.

With § 15 of the Draft Order, the DVFA will adopt special labelling requirements for certain foods, which are ‘pre-packed for direct sale’. § 15 of the Draft Order applies to foods, which are prepared, packaged and offered for sale in the one and same retail shop, insofar as the foods are offered for sale for more than one “sales day”. As a matter of example, § 15 will apply to a sandwich, which is prepared by the «delicatessen»

\textsuperscript{76} Executive Order no. 234 of 6 March 2015 on the Labelling etc. of Foodstuffs (in § 13(4)) contained a provision, according to which, the operator was not required to comply with Article 21(b) FIR (emphasis of allergenic ingredients/technical aids). However, in response to the Commission’s detailed opinion, the DVFA proposes to delete this provision in the Draft Order.
department of a supermarket and packed in a plastic container on a Wednesday, if the sandwich is offered for sale during the Thursday as well.

Pursuant to § 15(1) of the Draft Order, such products must be labelled with the particulars of Article 9 FIR and Article 10 FIR, apart from the particulars stated in Article 9(1)(b)/Article 18 FIR (list of ingredients), Article 9(1)(d)/Article 22 FIR (QUID labelling) and Article 9(1)(l) FIR (nutrition declaration). Information on allergens must be provided in accordance with § 13 of the Draft Order, cf. Section 1.4.1 above.

Pursuant to § 15(2) of the Draft Order, the operator must – at the consumer’s request – be able to provide information on the ingredients contained by the food. The retail shop may provide this information verbally77.

Pursuant to § 15(3) of the Draft Order, if the operator provides the information under § 15(2) in written format to the consumer, the requirement in Article 18(1) FIR on providing the ingredients in descending order of weight does not apply78.

3. National mark for pre-packed minced meat products
   (Annex VI, Part B, paragraph 3 FIR)

Pursuant to Annex VI, Part B, paragraph 3 FIR, Member States may allow the placing on their national market of minced meat, which does not comply with the criteria laid down in point 1 of Part B, under a national

77 Executive Order no. 234 of 6 March 2015 on the Labelling etc. of Foodstuffs (in § 15(2)) contained a provision, according to which, the operator was not required to inform the consumer about allergenic ingredients/technical aids, if the full list of ingredients was provided to the consumer. However, in response to the Commission’s detailed opinion, the DVFA proposes to delete this provision in the Draft Order.

78 Executive Order no. 234 of 6 March 2015 on the Labelling etc. of Foodstuffs (in § 15(3)) contained a provision, according to which, the operator was not required to comply with Article 21(b) FIR (emphasis of allergenic ingredients/technical aids). However, in response to the Commission’s detailed opinion, the DVFA proposes to delete this provision in the Draft Order.
mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

The Order contains particular labelling requirements applicable to pre-packed mincemeat products that do not comply with the criteria of Annex VI, Part B, paragraph 1 FIR. Pursuant to § 7 and § 8 of the Order such pre-packed mincemeat products must be labelled with the Danish national mark, which must be a circular mark, on the top portion of which the company’s authorisation code is stated and on the bottom portion the number ‘1’ must be stated. If the above mark is used as a health mark, the circle must have an outer diameter of at least 4.5 cm, the figures in the approval number of the entity must be at least 0.8 cm high, and the figure ‘1’ must be at least 1.1 cm high. Such foodstuffs may only be offered for sale in Denmark.

V. Labelling requirements for pre-packed food: Expression of net quantity (Article 42 FIR)

Pursuant to Article 41 FIR, Member States may maintain national measures concerning the expression of net quantity for specified foods in a different manner to that provided for in Article 23(1) FIR.

Pursuant to § 4 of the Draft Order, expression of net quantity for pre-packed foods must be indicated in the metric system as net volume (i.e. litres, centilitres or millilitres) for liquid products and as net weight (i.e. kilograms or grams) for other foodstuffs.
VI. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

Pursuant to § 3(1) of the Draft Order, the mandatory particulars must be provided in Danish, or other languages which only differ slightly in spelling from Danish language. In its administrative practice, the DVFA has accepted labelling in Swedish and Norwegian. However, in certain matters, the DVFA has deemed Swedish and/or Norwegian labelling insufficient.

VII. Enforcement, incl. fines

Non-compliance with the Draft Order is punishable by a fine and – in exceptional cases – imprisonment. Furthermore, the courts may seize the profits made by a company by not complying with the legislation.
I. Objectives pursued by national implementation measure

In Finland the Regulation 1169/2011/EU on the provision of food information to consumers (hereinafter the “FIR”) did not bring about widespread implementation measures or significant changes in legislation as no new laws have been passed or existing laws amended. As FIR is directly applicable, certain ministerial decrees related to labelling of foodstuffs had to be repealed, however.

In addition, the Ministry of Agriculture and Forestry issued two new ministerial decrees in 2014, the Decree on the provision of particulars on food (834/2014) and the Decree on the labelling of certain foods as being high in salt (1010/2014). The first decree entered into force on 1 April 2015 and the latter will enter into force on 13 December 2016. Both decrees have been given on a national basis and concern matters that are not regulated by the FIR, such as language requirements. The first decree however, also includes the implementation of the Lot Directive 2011/91/ EU. Both decrees must be taken into account when assessing the food packaging and labelling requirements in Finland.

II. Notification procedure under TRIS

The Decree on the provision of particulars on food (834/2014) and the Decree on the labelling of certain foods as being high in salt (1010/2014) were notified under TRIS procedure. The first decree was commented on by the Commission and the latter by Estonia.
III. Labelling requirements for non-prepacked food

1. Allergen labelling (Article 44(1)(a) FIR)

According to Section 6 § of the Decree on the provision of particulars on food (834/2014) final consumers shall be provided with information on any ingredient or processing aid causing allergies or intolerances used in the manufacture or preparation of a non-prepacked food and still present in the finished product, even if in an altered form, as referred to in Article 9(1)(c) FIR. The ingredients shall be listed under the name of the food in a manner as to identify the name of the substance or product referred to in Annex II.

The information is, however, not required for food where the substance or product referred to in Annex II of FIR is obvious from the food name.

2. Mandatory particulars (Article 44(1)(b) FIR)

According to Section 7 § of the Decree on the provision of particulars on food (834/2014) the following information on non-prepacked food shall be provided to the final consumer on the retail sales premises:

- name of the food;
- food ingredients;
- country or place of origin; and
- necessary directions for use or storage.

Additionally from 31 December 2016 on, the following information shall be provided for non-prepacked food on retail sales premises:

- for cheese, the amount of fat and salt;
- for sausages, the amount of fat and salt;
- for other meat products to be used as cold cuts, the amount of fat and salt; and
- for bread, the amount of salt.
Furthermore, the following information on non-prepacked food shall be provided to the final consumer at food-serving establishments:

- the name of the food and
- country or place of origin

as laid down in the Food Particulars Regulation or provisions issued by virtue of it or in accordance with other legislation.

3. Means of expression and presentation (Article 44(2) FIR)

According to the Section 8 § of the Decree on the provision of particulars on food (834/2014) the information concerning non-prepacked food referred to above shall be provided to the final consumer in writing at the food’s point of transfer in the proximity of non-prepacked food, in an easily noticeable and clear flyer or table or other, similarly clear manner.

By way of derogation from the above-stated, the information may be offered orally, provided that

- at the food’s point of transfer in the proximity of non-prepacked food, it is communicated in an easily noticeable and clear flyer or table or by other clear means that the information is available from staff upon request and that the information is available to the consumer in written or electronic form prior to the purchasing decision without additional costs; and
- the information is easily available to staff and supervision authorities in written or digital form at the point of transfer of the food.
IV. Labelling requirements for pre-packed food

1. National measures on additional mandatory particulars (Article 39 FIR)

Finland has enacted a national requirement for labelling of certain foods as high in salt. The “high salt content” labelling rules are deemed as justified and proportionate measure for the protection of consumer health in Finland. The Decree on the labelling of certain foods as being high in salt (1010/2014) applies to both prepacked and non-prepacked food. According to Section 4 of said decree the following food packaging shall contain labelling stating “high in salt” or “high salt content” if the food’s salt content is:

- for cheeses, over 1.4 weight per cent
- for sausages, over 2.0 weight per cent
- for other meat products used in cold cuts, over 2.2 weight per cent;
- for fish products including salted, smoked and broiled fish, over 2.0 weight per cent;
- for breads, over 1.1 weight per cent;
- for crisp breads and sour dough crisp breads, over 1.4 weight per cent;
- for breakfast cereal products, over 1.4 weight per cent;
- for prepared meals and ready-to-eat meal components, over 1.2 weight per cent; and
- snack foods to which salt has been added, over 1.4 weight per cent.

The information referred to above shall be presented near the nutritional declaration, using the font size laid down in Article 13(2) FIR. If there is no nutritional declaration, the information shall be presented in an easily noticeable and clear manner.

The information referred to above shall also be provided for the following foods, even if they are sold or otherwise transferred to the final consumer on retail sale premises in a non-packed state:

- cheeses;
• sausages;
• other meat products used in cold cuts; and
• breads.

The information shall be provided to the final consumer in writing at the food’s point of transfer in the proximity of non-prepacked food, in an easily noticeable and clear flyer or table or other, similarly clear manner.

2. Milk and milk products (Article 40 FIR)

There are no national measures with regard to Article 40 FIR on milk and milk products.

3. Alcoholic beverages (Article 41 FIR)

There are no national measures with regard to Article 41 FIR on alcoholic beverages.

4. Expression of net quantity (Article 42 FIR)

There are no national measures with regard to Article 42 FIR on expression on net quantity.

5. Indication of reference intakes for specific population groups (Article 43 FIR)

There are no national measures with regard to Article 43 FIR on indication of reference intakes for specific population groups.
V. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

The language requirements are regulated in Finland by the Decree on the provision of particulars on food (834/2014) in accordance with the Finnish Language Act (432/2003).

According to said Decree the mandatory package labelling for pre-packed food to be sold or otherwise transferred in bilingual municipalities shall be at least in Finnish and Swedish. The package labelling for pre-packed foods to be sold or otherwise transferred in a monolingual municipality shall be at least in the language of the municipality.

VI. Exception from nutrition labelling: the notion of “direct supply” (Annex V No. 19)

According to the Decree on the provision of particulars on food (834/2014) the requirement to provide information about the amount of fat and salt in non-prepacked cheese, sausages and other meat products to be used as cold cuts, does not apply to food directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer.

VII. Enforcement

The Finnish Food Act lays down certain administrative enforcement measures that can be taken in case the provisions referred to above are not complied with.

For example, if the information given about food may cause a health hazard, endanger the accuracy or sufficiency of the information given on
the food, mislead the consumer, or otherwise violate the food regulations, the supervisory authority may order the deficiency to be removed. If there are reasonable grounds for suspecting that a serious health hazard may otherwise be caused, the control authority may also prohibit the primary production, manufacture, import, export, placing on the market, serving or conveyance of a foodstuff.

In certain cases, e.g. if the information on food violates the food regulations in an essential way, the supervisory authority may order a food business operator to withdraw food from the market and also, at the expense of the food business operator, inform the public about food that violates food safety requirements if the food business operator fails to do it.

In addition, the authority may prohibit a food business operator from continuing to conduct marketing that violates the food regulations or from resuming such or similar marketing.

The enforcement measures mentioned above can usually be reinforced by a threat of fine. The food business operator is also liable for the costs it incurs in complying with the decisions made by authorities.

Furthermore, the Finnish Food Act also includes penalty provisions, but those are not regularly applied, however, as they require deliberate act or negligence.
I. Objectives pursued by national implementation measure

The previous Labelling Directive 2000/13/EC was mainly implemented in France into the so-called « Code de la consommation » (Consumer Code). With the application of FIR, French authorities have taken several national implementation measures to review and adapted the Consumer Code to the FIR. These measures also incorporate into French law the provisions of the Directive 2011/91/EU on indication or marks identifying the lot to which a food belongs. As of today (14 September 2015), two decrees have been adopted to implement the FIR into French law. They deal with general and specific provisions of FIR (i.e. allergens for non-prepacked foods) and the penalties that can be pronounced in case of non-conformity:

- The first text was the decree n° 2014-1489 of 11 December 2014 modifying the French consumer code as regard to, notably, food information to consumers.
- The second text was the decree n° 2015-447 of 17 April 2015 regarding non-prepacked food and the information about allergens for non-prepacked foods.

The provisions of these decrees have been integrated into the Consumer Code, so in this paper references are made to the articles of the Consumer Code preferably to the references of the articles of the decrees.
II. Notification procedure under TRIS

There are currently no French texts pending under TRIS. Several draft texts were notified by the French authorities in 2014 (e.g. TRIS 2014/352/FR) but the standstill period has expired and is no longer relevant since the texts have been adopted.

III. Labelling requirements for non-prepacked food

National measures dealing with non-prepacked foods have been entirely adopted in France.

1. Allergen labelling (Article 44(1)(a) FIR)

French law states that the information on allergens « shall be indicated on the foodstuff itself, or in close proximity to it, leaving no doubt concerning the foodstuff to which it refers ». This provision is applicable to any kind of non-prepacked food (i.e. no packaging at all, packed on the sales premises at the consumer’s request or pre-packed for direct supply).

For any place like restaurants, canteens, etc. where meals are served (i.e., etc.) the information on allergen shall be indicated directly in writing, in a way that is legible and visible in the premises where the public is accepted. If the information about the allergens present in the meals is not directly given, it is possible to indicate where this information is freely and directly available in writing to the public (for instance a fact sheet at the cashier desk).

There is a derogation to the obligation to provide the information about the allergens contained in the meal when the consumer has indicated, before consuming the meal, that he refuses to eat specific ingredients listed as allergens in FIR. This derogation is applicable only to the so-called “collective caterers” that is to say restaurants or any kind of canteens
serving meals to a regular basis of consumers linked to the restaurants by an agreement or a contract (for instance company restaurants, school canteens, etc.). The information that the consumer refuses to consume certain allergic ingredients should be kept by the food operator for three years.

Lastly, French law states that any food supply to a restaurant shall be accompanied by a document (i.e. technical specifications) containing the information on allergens.

All the provision above are laid down in articles R 112-12 to R 11215 of the Consumer Code).

2. Mandatory particulars (Article 44(1)(b) FIR)

In France, in addition to the list of allergens, it is mandatory to indicate the product name as well as any other mandatory particular of the non-prepacked product pursuant to EU or French law (i.e. origin of fresh fruit of vegetables). This information « shall be indicated on the foodstuff itself, or in close proximity to it, leaving no doubt concerning the foodstuff to which it refers ».

This obligation is laid down by article R 112-10 of the Consumer Code.

3. Means of expression and presentation (Article 44(2) FIR)

French law is not very precise on the means of expression and presentation of the information about non-prepacked foodstuffs. It just indicates that this information should be « on the foodstuff itself, or in close proximity to it, leaving no doubt concerning the foodstuff to which it refers ». It gives room to implement different means of presentation depending on the type product, the type of business, the consumer relationship, etc. as long as the information is legible and the consumer can
easily make the link between the information available and the related non-prepacked product.

IV. Labelling requirements for pre-packed food

There are a lot of specific requirements in France for many pre-packed foods.

1. National measures on additional mandatory particulars (Article 39 FIR)

In France, there are plenty of legal texts requiring additional mandatory particulars for specific pre-packed food. Many of these texts have been adopted before FIR. For instance, yoghurts and fermented milks (French Order no 88-1203 of 30 December 1988), cheese (French Order no 2007-628 of 27 April 2007), truffles (French Order no 2012-129 of 30 January 2012), etc.

2. Milk and milk products (Article 40 FIR)

There is no specific French measure applicable to milk and milk products presented in bottles intended for reuse. French people do not consume milk and milk products that way.

3. Alcoholic beverages (Article 41 FIR)

There are several French provisions that require a list of ingredients for certain alcoholic beverages, for instance fruit based spirituous drinks, pastis, ouzo, liquors, wine based aperitifs, etc. These provisions are still in force and, therefore, may be maintained pursuant to Article 41 FIR pending the adoption of Union provisions.
4. **Expression of net quality (Article 42 FIR)**

There are three types of products for which France has decided to keep the expression of the net quantity in a different manner than provided in FIR. Snails, oysters and mussels:

«In the case of snails prepared in their shells and oysters, the quantity may be expressed as a number of units with an indication of the size. As regards to mussels in their shells, quantity may also be expressed in units of volume» (new article R 112-7 of the Consumer code).

This derogation results from the French Order no 2015-447 of 17 April 2015 on food information which was notified in TRIS before 13 December 2014 pursuant to article 42 FIR.

5. **Indication of reference intakes for specific population groups (Article 43 FIR)**

As of today (19 August 2015), there are no French reference intakes for specific population groups.

V. **Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)**

VI. Exception from nutrition labelling: the notion of “direct supply” (Annex V No. 19)

There is no legal act explaining the notion of “direct supply” referred to in annex V FIR relating the exceptions to the nutrition declaration.

French law, however, already contains several provisions creating exceptions to the full application of food for handcrafted foods that are supplied directly by the producer to the consumer in small quantities. In this case, the notion of “direct supply” refers to the situation where the consumer buys the food directly from the producer without any intermediary (i.e. farm stores).

VII. Application and enforcement

Under French law, it is necessary to adapt a special legal act in order to enforce European law. This has been done for FIR by the French decree no 2014-1489 of 11 December 2014 published the day before TRIS was applicable!

The new article R 214-24 of the Consumer Code created by this decree of December 2014 states that Articles 1, 2, 6 to 10, 12 to 28, 30 to 37, 44 and annexes I to XV of FIR are considered to be implementing measures of the French criminal offence of fraud/deception. It means that lack of compliance with the articles and annexes of FIR referred to above can be sanctioned under the criminal regime applicable to frauds and deception:

- An offence of fraud/deception can be pronounced against a food business operator if the lack of compliance with FIR was likely to mislead the consumer. In this case, the theoretical sanction is two years of prison and one maximum fine of 300,000 euros for individual (1,500,000 euros for companies that can be increased up to 10% of the average annual turnover of the three preceding years in proportion to the gain obtained from the fraud/deception).
• A labelling offence can be pronounced the lack of compliance with FIR was not likely to mislead the consumer (i.e. minor or non-important information missing on the packaging, information given in a non-compliant way, etc.). In this case, the theoretical sanction is a maximum fine of 450 euros for individuals (2.250 euros for companies) per non-compliant item. In practice, it means that the amount of the fine (to be chosen between 0 euros and 2.250 euros by the Judge) can be multiplied by the number of non-compliant items and can result in a significant total financial impact.

The French control services always take a pragmatic approach when they enforce a new legislative act. In this respect, they did not start enforcing FIR right away after 13 December 2014. They first paid attention to the global level of compliance of the food business operators and took into account the efforts made to ensure compliance with FIR. They also took into account the fact that many provisions of FIR are still incomplete because of missing European and national implementing measures. Now that FIR has been applicable for more than six months, they may start enforcing it progressively.

VIII. Miscellaneous / Comments

The French administration has published a note of information in November 2013 that explain in general terms the main provisions of FIR. This note does not give any precise indication on how certain provision of FIR should be interpreted. On the other hand, the French Association of Food Manufacturers (ANIA) has published Q&As for its members that contains very useful responses and responses on how to apply FIR in practice. This document, however, is purely indicative and has no legal value.
I. Objectives pursued by National Implementation Measures

1. Preliminary Regulation on Allergen Labelling of Non-prepacked Food

In Germany, the implementation of the Food Information Regulation (FIR) is not yet completed. A national Preliminary Regulation covers the information about allergen substances in the context of marketing non-prepacked food. The so-called “Verordnung zur Ergänzung unionsrechtlicher Vorschriften betreffend die Information der Verbraucher über die Art und Weise der Kennzeichnung von Stoffen oder Erzeugnissen, die Allergien und Unverträglichkeiten auslösen, bei unverpackten Lebensmitteln” (“Vorläufige Lebensmittelinformations-Ergänzungsverordnung – VorLMIEV”) of 28 November 2014 (published in the “Bundesgesetzblatt“, volume 2014, Part I No. 57, edited in Bonn on 12 December 2014, page 1994) is a preliminary regulation, because the German legislator intends to regulate on more food information issues than the information about allergens in non-prepacked foods.

2. Draft of a Comprehensive National FIR Enforcement Regulation

In July 2014, a draft of a national FIR-Enforcement Regulation was published which also included the principles concerning the use of the German language, the ingredient list of beer and a notification duty for food business operators who wish to make use of additional forms of expression and presentation of the information about the energy value
and the amount of nutrients according to Article 35 FIR. Furthermore, there are drafts of editorial adaptations concerning a number of national regulations which govern several specific product categories (vertical product category law), such as e. g. the national regulation on flavours or the national regulations on jam, sugar, honey, cocoa and so on. The national legislator has not decided on the afore-mentioned drafts yet, but accomplished its duty to govern the issue of information about allergens when selling non-prepacked food with the adoption of the respective preliminary regulation.

3. Maintenance of some Rules of the Existing National Regulation on Prepackages

Furthermore, the German legislator decided to maintain some principles laid down in the national regulation on prepackages (“Fertigpackungsverordnung – FPackV”). These principles concern some exemptions with regard to the information about the net quantity of a package.

II. Notification Procedure under the TRIS

There is no notification under the TRIS-procedure.

III. Labelling Requirement for Non-Prepacked Food

1. Scope of the Preliminary Regulation on Allergen Labelling of Non-Prepacked Food

The preliminary national regulation on the information about allergens (“VorLMIEV”) applies to food that is offered without packaging to consumers or mass caterers as well as food that is packed at the sales premises at the consumer’s request (compare Article 2(2)(i) FIR) or to food that is prepacked for direct sale, but that is not offered in self-services. This
means that the disposal of food which is prepacked for a direct sale and which is offered in self-service, is not regulated by the preliminary national regulation (“VorILMIEV”). For this kind of disposal there are not any national rules applicable yet, so that only Article 44(1) the FIR applies regulating the allergen information of non-prepacked food on EU-level. It is to be expected that coming national principles will govern this form of food offers in such a way that there will be further food information than information about allergens.

2. Provision of the Information about Allergens in Non-Prepacked Food

The information about allergen ingredients and processing aids has to be provided in an easily legible and visible way

- on a label on the food or near the food,
- on food and beverage menus or on price lists if the food is sold by mass caterers; this is also possible by easily legible footnotes or endnotes, if it is referred to these notes nearby the name of the food,
- on a notice board in the sales premises or
- by other written or electronic information to be provided by the food business operator which is easily accessibly to the final consumer or to mass caterers.

Additionally, the allergen information has to be provided in such a way that mass caterers can take notice of it before the purchase transaction or the sale of the food.

If the food business operators fulfils his duties by “providing information in written or electronic form“, it has to be indicated nearby the food or on a notice board in the sales premises how the allergen information is given.

In specific cases, the allergen information can also be given orally by the food business operator or by sufficiently informed staff members, if, at the final consumer’s request, the information is given immediately before the
purchase transaction and the sale of the food and if there is a written indication of the ingredients or the processing aids used during the production of the food and, finally, if this written indication is easily accessible to the competent authority and, upon request, also to the final consumer. In addition, it must be indicated nearby the food or on a notice board in the sales premises, at an easily visible place and in an easily legible way, that the allergen information is given orally and that a written information is accessible upon request. Due to the imponderables and risks related to the oral provision of information resulting from error susceptibility of this form of provision of information, an oral information is, in principle, not recommendable and the possibility of an oral allergen information has to be considered as a political concession to small businesses preparing handcrafted foods.

IV. Labelling Requirements for Prepacked Food

The German legislator has not yet established new and further national principles for the information about prepacked food. But the information about prepacked food is affected by the maintenance of some exemptions from the information about the net quantity, provided by the existing Regulation on Packages (“Fertigpackungsverordnung – FpackV”). With notice of 1 December 2014 (published in the “Bundesanzeiger” the 3 December 2014, ref. BAnZ AT 03.12.2014 B.1) the German Ministry of Economic Affairs and Energy informed following Article 42 FIR about the maintenance of § 6 (4) and (5), § 7 (1) and (2) No. 1 to 5, § 8 (1) to (3), §10 (1) and (2), first sentence No. 1 to 6, and second sentence as well as § 33a No. 3 FpackV. The afore-mentioned principles establish exemptions from the information about the net quantity provided by the FIR, e.g. the information about the net quantity of packages which include for their part other packages, or the information about the net quantity of certain products such as ice cream, honey or sauces.
V. Enforcement and Sanctions

With an adoption of § 11 (1) of the German Food and Feed Law (“Lebensmittel- und Futtermittelgesetzbuch – LFGB”) an infringement of Article 7 FIR can be sanctioned against the responsible FBO in the sense of Article 8 (1) FIR.
I. Executing the FIR in Hungary

The decree Nr. 36/2014. (XII. 17.) of the Minister of Agriculture which stipulates the provisions necessary to execution of Regulation (EU) No 1169/2011 on the provision of food information to consumers (hereinafter: „FIR”) entered into force in Hungary on December 20th, 2014 – 3 days after proclamation.

The new decree entered into force after the obligatory application of the FIR, which shows that adopting the regulation concerning the execution of FIR took longer in Hungary. Because of this the new decree will enter into force in multiple steps, in order to provide the participators of the economy with more time to comply with the decree. However the most important provisions entered into force on December 20th, 2014.

Due to the new decree most provisions of decree 19/2004 (II.26.) of the Ministers of Agriculture, Healthcare and Economy adapting Directive 2000/13/EC expired, but this decree regulates furthermore the date to be included on the pre-packed bread, and that the labelling on packaging of grocery marketed in Hungary shall be in Hungarian.

II. Effect of the new decree

The effect of the new decree concerns mainly the grocery designated for final consumers, but shall be applied for grocery marketed by catering traders or by mass caterers whose activity relates to informing the consumers about grocery.

The decree defines the definition of non-prepacked grocery and product.
1. **Non-prepacked grocery**

Non-prepacked grocery is according to the decree: grocery designated for final consumers

- offered to the final consumer, catering traders or mass caterers unpacked,
- packed at the sales premises at the request of the consumer,
- pre-packed at the sales premises in the absence of the consumer for indirect sale.

The decree orders as of December 20th, 2015 that in case of providing information according to Article 8(6) FIR the grocery business operator shall provide the participator buying the grocery with date of the non-prepacked grocery which shall be included due to the legal regulations of the EU and regulations released based on the Hungarian Codex Alimentarius. The final consumer shall be informed about these data at his request as of April 1st, 2015. (Allergens are also included.)

Information about certain substances or products causing allergies or intolerances

a. **Main rule: written information**

As of December 20th, 2015 in case of selling non-prepacked grocery to final consumer the consumer shall be informed about the content of substances or products causing allergies or intolerances (hereinafter as: substances or products causing allergies or intolerances) in the finished products according to Article 9(1)(c) FIR. Information shall be easily accessible for the final consumer without any additional costs for the final consumer.

The relevant information shall be provided on a physical or electronic data medium visibly referring to the name of the substance and product listed
in Annex II FIR at the sales premises of the non-prepacked grocery. The accessibility of the information shall be pointed out for the final consumer on a physical or electronic data medium well readable.

In case non-prepacked grocery is offered in more places for the final consumer in the sale premises, the information shall be displayed at every place. In case of written information the name and sign listed in Annex II of the FIR shall be included, in case of oral information the provision of oral information shall be applied.

The new decree was amended as of April 1st, 2015 by the obligation that the name of the grocery and the data stipulated in point 2.1., 2.2. of Annex III. of the FIR. Annex V of Regulation 1333/2008/EC about food additives shall be displayed at the selling premises well visibly.

b. Exception: Oral information

Information on content of substances or products causing allergies or intolerances in finished grocery may be provided orally if

- the person responsible for oral information is constantly present at the premises,
- the consumer receives the information at his request without delay at the selling premises before the purchase,
- the oral information is based on a written document accessible at the premises.

In case of oral information it shall be displayed at the selling premises of the non-prepacked grocery that oral information on the content of substances or products causing allergies or intolerances in finished grocery is available on request.

These rules are applicable rather for catering premises, because it is difficult for them to include the allergen content of grocery in writing,
however the co-workers of restaurants or catering premises shall provide the guests/customers at request with information.

The information may be provided as follows:

- guests are informed on the menu to notify if they are advised not to consume certain allergens,
- the co-workers of the premises shall receive proper education in order to being able to inform the guests at request.79

c. Provisions effective as of July 1st, 2015

The grocery business operator shall apply a procedure concerning oral information on content of substances or products causing allergies or intolerances in finished grocery and shall appoint the person responsible for the oral information. The procedure shall be documented on a physical or electronic data medium which shall be easily accessible for co-workers and authorities. Accordingly the business operators shall work out the rules of the appropriate procedures and drafting documentation.

The procedure shall include the education of co-workers concerned by marketing about the risks of substances or products causing allergies or intolerances which shall be proved by the grocery business operator with documents.

d. Exception to information about allergens:

Information about substances or products causing allergies or intolerances is not obligatory if

• the name of the grocery clearly refers to the name of the substances or products causing allergies or intolerances, or
• the grocery business operator provides consumer upon preliminary agreement with consumer with grocery which doesn’t contain such allergens.

According to the above the oral information is permitted under quite severe conditions. The government and the competent authorities haven’t released any public information about the application of the new decree since accepting the new decree. Presumably new information will be available about the interpretation of FIR based on the experiences during its application.
IRELAND

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I. Objectives pursued by national implementation measure

The main piece of legislation transposing Regulation 1169/2011 (the ‘FIR’) in Ireland are the EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014). In addition, on the issue of allergen labelling for non-prepacked foods the following legislation has been introduced – The Health (Provision of Food Allergen Information to Consumers in respect of non-prepacked food) Regulations 2014 (S.I. No. 489 of 2014).

II. Notification procedure under TRIS

EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014) were not notified under TRIS. The Health (Provision of Food Allergen Information to Consumers in respect of non-prepacked food) Regulations 2014 (S.I. No. 489 of 2014) were notified under TRIS on 11/07/2014 (TRIS 2014/339/IRL). No comments were made within the specified period which ended on 13/10/2014.

III. Scope of national implementation measure

The EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014) are a very comprehensive piece of legislation consisting of 26 pages. In addition it is written in the format of an Act that would be adopted by the Houses of the Oireachtas (Irish Parliament) rather than a typical Statutory Instrument which in the context of EU legislation usually states that the EU Regulation or Directive is accepted
under Irish law and the Statutory Instrument merely specifies who will enforce the legislation and what are the levels of fines & offences that can be introduced.

1. **Allergen labelling (Article 44(1) (a) FIR)**

There are national rules relating to Allergens – The Health (Provision of Food Allergen Information to Consumers in respect of non-prepacked food) Regulations 2014 (S.I. No. 489 of 2014).

On the issue of a definition of non-prepacked you would imagine that non-prepacked would be defined since it is mentioned in the title - not so - prepacked is defined - the Regulations cut & paste the exact wording from the definition in Article 2(2)(e) FIR. There is no definition of the term in any other Irish Regulations. Guidance documents from the Food Safety Authority of Ireland use the term as follows: non-prepacked food (loose).

The Regulations require that food allergen information for non-prepacked food must, as a minimum, be provided in written format, but can also be provided verbally at any time.

The food business operator must indicate the allergens in writing at:

a) the point of presentation, or
b) the point of sale, or
c) the point of supply,

The written information must be

a) freely and easily accessible before the sale or supply of the food,
b) at least in the English or in the Irish language and in the English language,
c) in a conspicuous place, such that it is easily visible and available to the final consumer or mass caterer,
d) in clear legible script, and
e) presented in a manner such that there is no possibility of confusion
as to which food the information relates

2. Mandatory particulars (Article 44(1) (b) FIR)

The Irish Regulations do not include any specific national provisions as provided for under Article 44(1)(b) FIR.

3. Means of expression and presentation (Article 44(2) FIR)

The Irish Regulations do not include any specific national provisions as provided for under Article 44(2) FIR.

IV. Labelling requirements for pre-packed food:

1. National measures on additional mandatory particulars (Article 39 FIR)

The Irish Regulations do not include any specific national provisions on additional particulars that must be provided to the consumer, as provided for under Article 39 FIR.

2. Milk and milk products (Article 40 FIR)

The Irish Regulations do not include any specific national provisions on the labelling of milk and milk products as provided for under Article 40 FIR.
3. **Alcoholic beverages (Article 41 FIR)**

The Irish Regulations do not include any specific national provisions on the labelling of alcoholic beverages as provided for under Article 41 FIR.

4. **Expression of net quality (Article 42 FIR) - UK, PL, DE, NL have made statements at Expert Group meeting of 20 March**

The Irish Regulations do not include any specific national provisions on the expression of net quantity as provided for under Article 42 FIR.

5. **Indication of reference intakes for specific population groups (Article 43 FIR)**

The Irish Regulations do not include any specific national provisions on the voluntary indication of reference intakes for specific population groups as provided for under Article 43 FIR.

V. **Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)**

Section 12 of the EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014) specifies that the mandatory food information must be in either:

- the English language, or
- the Irish language and the English language
VI. Exception from nutrition labelling: the notion of “direct supply” (Annex V No. 19)

Section 15 of the EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014) specifies that the nutrition declaration information listed at Article 35(1) (a) & (b) must be provided in the case of non-prepacked food provided by a food business operator.

VII. Enforcement, incl. fines

Infringement of the Regulations in Ireland is considered a criminal offence. Such offences are usually taken initially at the lowest court level – District Court.

Under the EU (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014) the following liabilities exist:

Upon summary conviction – a fine not exceeding EUR 5,000 and at the discretion of the Court a prison sentence of 6 months or both.

Upon conviction on indictment – a fine not exceeding EUR 500,000 or imprisonment for a term not exceeding 3 years or both.

An order for costs and expenses (relating to the taking of samples, testing of samples & other expenses incurred by the enforcement authorities) will be added to any fine or prison sentence unless the court is satisfied that there are special and substantial reasons for not including such an order.
I. Notification procedure under TRIS

The debate on the adaptation of Italian legislation to the indications contained in (EU) Regulation No. 1169/2011 (FIR) has witnessed a definite acceleration in recent months. On 18 December 2014 the Deputy Minister for Agriculture, Oliverio, confirmed the Government’s commitment to notify the EU Commission and the other Member States of the outlines of ministerial decrees during the planning stage. The XIII Commission of the Chamber therefore approved Resolution 8-00132 of Oliverio and others on 5 August 2015, which obliges the Government:

- to adopt all the appropriate measures at European level so that the European Commission is not confined to making its own indications deriving from the reports of the European Commission on the opportunity and possibility of extending the mandatory indication of the country of origin or place of provenance, seriously taking into account the needs expressed by the majority of consumers and producers in the agricultural sector on the subject of the origin of products, with particular reference to milk;
- to guarantee better and continuing institutional coordination, with particular reference to the stances to be taken at European level, to protect Italian interests, ensuring completeness and transparency with regard to the labelling of agro-food products;
- to take any action necessary to protect Italian dairy production (see paragraph IV.2 below);
- to undertake initiatives aimed at revising (EU) Regulation No. 1169/2011 in order to introduce the obligation to state as much information as possible on the label of dairy products, with particular regard to the use of fresh milk or curds or frozen curds or semi-manufactures in the initial product and the indication of the presence or absence of furoxin,
or to identify all necessary measures, taking their compatibility with Community law into account, which imposes the obligation, at least on a national level, to state these indications.

II. Labelling requirements for non-prepacked food

1. Allergen labelling (Article 44(1)(a) FIR)

Under the provision of 6 February 2015, the Ministry of Health laid down the guidelines for indications regarding the presence of allergens in the foods delivered by mass caterers. In this document the Ministry specified that, with regard to the information on substances or on products that may cause allergies or intolerances, as listed in Annex II of (EU) Regulation No. 1169/2011, any operator that provides ready-to-eat foods for consumption inside an establishment, such as for example, in restaurants, canteens, schools or hospitals, or also via a catering service, or even via a vehicle or a fixed or mobile stall, must provide the final consumer with the requested information. Please see paragraph III.3 below for the methods of providing this information.

2. Mandatory particulars (Article 44(1)(b) FIR)

Under Legislative Decree No.109 of 27 January 1992, as amended by Legislative Decree No.181 of 23 June 2003, still in force in Italy, non-prepacked food products or those generally sold after being split, even if originally prepacked, as well as products packed at the points of sale on the request of the purchaser and products that are with the aim of being sold immediately, must be supplied with an appropriate label, which may be applied either to the product container or to the compartment where they are displayed. The following information must be stated on the label:

a. the name under which the product is sold;
b. the list of ingredients, unless an exemption applies;
c. the storage conditions for highly perishable food products, where necessary;
d. the “use by” date for fresh pasta or fresh filled pasta;
e. the actual alcoholic strength by volume for beverages with an alcohol content exceeding 1.2% in volume;
f. the percentage of glazing, considered as a tare weight, for glazed frozen products.

3. Means of expression and presentation (Article 44(2) FIR)

According to the above-mentioned guidelines of 6 February 2015 provided by the Italian Ministry of Health, information about allergens must be provided when food is served to consumers via mass caterers, for example on menus, or on special registers, or using any other equivalent systems, including technological ones. The main point of the legislature is, in fact, to ensure that this information is in plain sight, in order to enable the consumer to have easy and free access to it.

However, if the food business operator decides to provide the required allergen information via electronic devices, such as via Smartphone applications, bar codes, QR codes, etc., the notes provided by the Ministry highlighted that these instruments cannot be the only ones used. Indeed, such devices are not easily accessible to the whole population, nor can they be considered as an effective way of meeting the purpose of the European legislation.

On the contrary, it would be sufficient for the food business operator to place, one of the following indications in writing in a clearly visible place:

1. “the information about the presence of substance or products causing allergies or intolerance are available by contacting the staff in service”;
2. “for any information about allergens it is possible to consult the related document that will be provided, upon request, by the staff in service”,

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provided that in all of the previous cases, the information on allergens must also result from appropriate written documentation, readily available to both the competent supervisory Authority and the final consumer and that this information was previously approved by the company’s staff.

Finally, the Ministry decided to leave the choice concerning the means through which to inform consumers to the food business operator, who, in the end, is the real person responsible for the final products. However, this choice has to be based on his/her organization and on the company’s size, in order to offer the best solution to protect the health of consumers.

Above-mentioned Legislative Decree No.109/92 finally lays down the specific rules for special categories of bulk products, in particular:

- for ice-cream, pastry, bakery products and gastronomy, including food preparations, the list of ingredients can be reported on a single proper label that should be kept in plain sight, or, for individual products, on a special register or other equivalent system to be kept clearly in view, at the disposal of the purchaser, and close to the product’s display counters.
- for beverages sold on tap the label must be applied directly on the tapping system or next to it.
- prepacked confectionery products, but intended for sale individually or in bulk, generally intended for consumption immediately after purchase, may report the mandatory particulars for the bulk products only on the label or on the container, provided that they can be easily seen and read by the purchaser.
III. Labelling requirements for pre-packed food:

1. National measures on additional mandatory particulars (Article 39 FIR)

Article 3, paragraphs 7-9 of Legislative Decree No.91/2014 provided for a public consultation of consumers in order to understand extent to which the information on the origin of products and agricultural raw materials is capable of influencing consumer choices. This consultation ended in February 2015, involving more than 26,500 participants and reporting the following results. More than 96% of consumers declared that it is very important for the origin of the food to be written clearly and legibly on the label and 84% said that it was fundamental to state the place where the transformation process takes place. For 8 out of 10 Italians it is of utmost importance at the time of purchase that the product is manufactured using Italian raw materials and is transformed in Italy, and subsequently 54% check that the product is typical, 45% also check the presence of PDO and PGI certification, whereas for 30% it is essential that the product is organic. For 9 out of 10 Italians it is important to know the origin of the food for reasons related to compliance with food safety standards, whereas for 70% it is necessary for ethical issues, such as compliance with labour laws. Almost 22,000 people (82%) then declared that they would be willing to spend more in order to be sure that the origin and provenance of the product was Italy, with almost half ready to pay from 5 to 20% more.

Upon the outcome of the aforesaid consultation, the XIII Commission of the Chamber then approved Resolution 8-00132 of Oliverio and others on 5 August, which obliges the Government to adopt all the appropriate measures in Europe (see paragraph II above).

2. Milk and milk products (Article 40 FIR)

Following the initiation of the infringements procedure (procedure No. 2014/4170) involving Italy pursuant to Article 258 TFEU, the Italian government formally undertook to take all the necessary action to protect
Italian uncertified PDO and PGI dairy production in order to maintain in force the provisions laid down in Italian Law No. 138 of 1974 on the prohibition of using powdered milk in dairy production, including uncertified dairy production.

The commitment of the Italian government also concerns all the appropriate measures to introduce labelling on the place of origin, provenance and factory of production and packaging for fresh milk and medium to long-life milk, so that “100% Italian milk” and its derivatives are duly exploited for their high standards of quality and wholesomeness in the European and world markets.

3. **Alcoholic beverages (Article 41 FIR)**

In contrast with Article 16(4) FIR, which states that indications regarding the list of ingredients and the nutrition declaration are not mandatory for beverages with an alcohol content exceeding 1.2% in volume, Italian Legislative Decree 109/92 exempts only the following from the obligation to indicate the list of ingredients: “brandies and spirits, musts and wines, sparkling wines, liqueur wines and beers with an alcohol content exceeding 1.2% in volume”.

4. **Expression of net quality (Article 42 FIR)**

Alongside the rules already recently harmonised and transposed also in (EU) Regulation 1169/2011, Legislative Decree 109/1992 lays down that the indication of net quantity is not mandatory “[…] b) for confectionary products whose quantity does not exceed 30g” (art.10, paragraph 8, letter b).

As in the FIR, Legislative Decree 109/1992 also sets forth that in the case of prepacked products, consisting of two or more individual packages that are not regarded as units of sale, the net quantity is to be given by indicating the total net quantity and the total number of individual packages. Nevertheless, national legislation adds that “for bakery products, such
as rusks, crackers, biscuits, single dose leaven products and sugar-based products, it is sufficient to indicate the total quantity”.

5. **Indication of reference intakes for specific population groups (Article 43 FIR)**

There is no legal act relating to the indication of reference intakes for specific population groups

**IV. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)**

According to Italian Legislative Decree No.109/92, all mandatory requirements must be provided in Italian. The use of other languages is only allowed in the following cases:

- when a word is used by the majority of the population so that a translation is no longer required (e.g. Krapfen is the name used for a particular sweet); or
- when the original name of the foodstuff or the ingredient does not have any translation in Italian (e.g. whisky)

Food Business Operators are allowed to use other official languages of the EU, but in this case, these must be used in addition to Italian and not as a substitute for it.
V. Exception from nutrition labelling: the notion of “direct supply”

There is no legal act explaining the concept of “direct supply” referred to in Annex V No. 19 of Regulation (EU) 1169/2011.

VI. Enforcement, including fines

Under the provision of 6 March 2015 the Italian Ministry of Economic Development, in order to ensure continuity in the application of the penalties provided for in Article 18 of Italian Legislative Decree No.109/1992, pending the adoption of the new rules governing penalties, clarified the link between the provisions of the FIR Regulations and those of Italian Legislative Decree No.109/1992 on the basis of the following correlation table.

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THE NETHERLANDS

Gert-Jan de Jager, Kneppelhout, Rotterdam

I. National implementation measures

As a rule of law Regulation (EU) 1169/2011 on Food Information to Consumers (FIR) is applicable directly in the Netherlands. Nevertheless there is, of course, a need to lay down national rules on how this Regulation will be enforced according to Dutch Law. Furthermore, existing exceptions and new exceptions all set and allowed under the Regulation must be put in force.

Upon the FIR rules on information to consumers were set by two national decrees, based on the previous EC Regulations and Directives:

1. Commodities Act Decree Labelling Foods;
2. Commodities Act Decree Nutrition-Information Foods

As of 13 December 2014 a new Decree has come into force:

1. Commodities Act Decree Information Foods

1. Commodities Act Decree Information Foods\(^{80}\)

The Dutch government has chosen to alter as little as possible. Under the previous Regulations and Directives the Dutch government had already set several additional rules and exceptions as to labelling foods and providing information to consumers. All of these exceptions have been

\(^{80}\) The Dutch government has furthermore chosen to implement Directive 2011/91/EC on indications or marks identifying the lot to which a foodstuff belongs in this Commodities Act Regulation Information Foods.
remained in force within the scope of the provisions and exceptions of the new Regulation.

The main additional rule that already was set and that has been continued, is the rule that all labels on foods must be put in the Dutch language (besides the language of the country in which the foods has been manufactured).

Another exception that has been continued is the exception on non-labelling yoghurt. According to Article 19(1)(d) FIR Member States are not obliged to ask food business operators to label fermented milk and cream. Due to an error in the translation of the Regulation into Dutch a close read of the Dutch version of this Regulation seems to allow non-labelling only for soured milk or cream. Yoghurt is not soured but is fermented milk. That this is not what the EC has meant, show the English (fermented milk and cream), the German (fermentierter Milch und Sahne), the French (les laits et crèmes fermentés) and the Spanish version (la lecha y la nata fermentadas). The Dutch government therefore sees no obstacle in continuing this exception.

Based on the provisions made in Article 44 FIR labelling non-packed cheese can take place by putting the necessary information, such as the amount of fat on a label in the crust of the cheese, mentioned on a layer covering the cheese or on a label that is put on the cheese.

Based on the same provisions in Article 44 FIR the Dutch government continues its provisions as to packed foods (please note that according to Dutch law packed foods are not meant for the end consumer, only prepacked foods are meant for the end consumer) and non-packed food. Information on non-packed foods such as its name can be put on the food, but that is not obligatory. It can be put above the product, for example when sold on a food market, and information can be given by other means such as leaflets, product books, and ‘speaking’ information points.

The Dutch government makes use of Article 40 FIR. Under this article Member States can allow its food business operators to put only the date of
minimum durability of the ‘use by’ date and the name of the food business operator on glass bottles intended for reuse.

Finally there are two separate national regulations, based on the Commodities Act Decree Information Foods:

2. Commodities Act Regulation Net Quantity of Enhanced Sustainable Mushrooms and Sauerkraut;
3. Commodities Act Regulation Allergen Information for Non-Prepackaging Foods

As mentioned before the Dutch government has chosen to change as little as possible in the provisions and exceptions that were put into force under the previous Regulations and Directives, provided that these provisions and exceptions are still allowed under the new Regulation. The latter is nevertheless a new provision.

a. Commodities Act Regulation Net Quantity of Enhanced Sustainable Mushrooms and Sauerkraut

This regulation has been based on the exception the FIR allows in its Article 42. As long as the European Commission has not yet put into place a manner for the expression of the net quantity other than the one laid down in Article 23(1) FIR (in units of volume in the case of liquid products and in units of mass in the case of other products), Member States may maintain national measures that have been adopted before 12 December 2011.

In the Netherlands such measures existed regarding enhanced sustainable mushrooms and sauerkraut (since 2007). Because of the sustainable way in which these products are grown, the products do not have an uniform shape and form. To protect the consumer but also to give clear guidelines to the food business operators the Dutch government has put into force very specific and complicated rules on how the net quantity of these
products can be measured and how this net quantity can be clarified to the consumer. These measures are now maintained under the new Regulation. According to the commentary of the Ministry of Public Health on this regulation in 2014, maintaining these measures has not been reported to the European Commission. However Article 42 FIR clearly stipulates that this should be done.

b. Commodities Act Regulation Allergen Information for Non-Prepackaging Foods

The latter (new) regulation is based on the provision mentioned in Article 44(2) FIR. According to Article 9(1)(c) FIR any ingredient that causes allergies or intolerances present in the finished product should be indicated.

However based on Article 44(2) FIR Member States may adopt national measures concerning means through which foods are offered for sale to the final consumer or mass caterers without pre-packaging (or packed on the sales premises) or pre-packaged for direct sale. The Dutch government has seen fit to adopt such measures for non-prepackaged foods. The measures make sure that the allergen information is always present at the premises where the food is sold and can be provided for by various ways to both the consumer and the Netherlands Food and Consumer Product Safety Authority (NVWA). This can be done through electronic means, in written form and last but not least, orally by the staff of (for example) the restaurant.

2. Enforcement

Violation of the rules set in the FIR and the supplementary rules set in and by the Commodities Act Decree is penalized with fines of EUR 525 (small company, less than 50 employees) and EUR 1,050 (larger companies, over 50 employees) for each violation.
Please note that the Dutch parliament has passed an act that will penalise violation of all rules set in or by the Commodities Act with administrative fines that can amount to EUR 810,000.00.

The government has asked to pass this act because of the large food fraud cases that has taken place in the last few years in the Netherlands. For example the horsemeat scandal, in which the Netherlands Food and Consumer Product Safety Authority (NVWA) has decided to destroy 50,000 tons of beef that was mixed with horsemeat. Because it was not entirely clear what the origin of this horsemeat was, the authority decided (based on Article 14 of Regulation 178/2002) to destroy this meat. The Dutch government wants to ensure food safety and quality as good as possible. On fining violation far more severe it seeks extra means to ensure these goals.81

3. **Correlation table**

In the correlation table below one will find how the various articles of the FIR (as far as necessary) have been put into force in the Netherlands.

<table>
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81 The CEO of the company that was involved in this horse meat scandal has recently been sentenced to imprisonment for 2.5 years because of forging documents. In other words general criminal law remains one of the means for reaching these goals.
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<td>Art. 2.7</td>
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<td>Art. 38</td>
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<td>Art. 39</td>
<td>Art. 2.2 and 10 sub a</td>
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<td>Art. 40 1° paragraph</td>
<td>Art. 9</td>
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<td>Art. 40 2° paragraph</td>
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<td>Art. 41</td>
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<td>Art. 42</td>
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<td>Art. 43</td>
<td>Art. 2.2 and 10 sub d</td>
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<td>Art. 44.1.a</td>
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<td>Art. 44.1.b and 44.2</td>
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<td>Art. 7 (packed)</td>
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<td>Art. 8 (non-packed)</td>
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<td>Art. 10, sub e</td>
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<td>Art. 30, sub b</td>
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<td>Art. 44.3</td>
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<td>Art. 45</td>
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<tr>
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<td>Art. 2.7</td>
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<td>Art. 54.3</td>
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<td>Art. 55</td>
<td>Art. 32</td>
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<tr>
<td>Annex VI.B.3</td>
<td>Art. 2.2 and 10 sub f</td>
</tr>
</tbody>
</table>
I. The FIR in an EEA country

While Norway is not a member of the EU, a brief introductory note on the relationship with the EU is appropriate. Norway is linked to the EU in the European Economic Area agreement of 1992 (the EEA Agreement) between EFTA (of which Norway is a member) and the EU. The EEA Agreement implies that Norway, Iceland and Lichtenstein (EEA/EFTA Member States) participate in the internal market established in the EU, for all goods and services designated under the agreement, and as such, most EU rules on food are EEA relevant.

Whilst the EU Member States have passed on their legislative power to EU bodies, the legislative powers of the EEA/EFTA Member States remain unaltered. Any alteration to the EEA Agreement is de facto a new international agreement which by implication requires the consent of all EEA/EFTA Member States. In order to secure a smoother decision-making process, the EEA Agreement lays down the principles of development and interaction between the EU law of relevance to the EEA Agreement and how such legislation is to be adopted also by the EFTA Member States. The EEA Joint Committee – a committee where both the European Union and the EEA/EFTA Member States are represented – makes decisions regarding incorporation of new EU legislation into the EEA Agreement; after which the EEA/EFTA Member States implement the legislation into domestic law through legislative or regulatory decisions.

As regards the (EU) 1169/2011 on food information (FIR), the EEA Committee formally included it on 24 October 2014. Despite the late inclusion, the Norwegian authorities had prepared for the coming incorporation and were thus able to incorporate FIR shortly after. FIR is now binding law in Norway by way of the Regulation on food information of 28 November
2014 no 1497 (Norwegian Regulation), which was brought into effect simultaneously with the EU.

The purpose of this booklet is to pinpoint the national differences in implementing FIR, and the way it was implemented in Norway may be adequately described as follows: The authorities did not use any of the possibilities outlined in the FIR to adopt national rules\textsuperscript{82}. Certain comments nevertheless are appropriate, and particularly with regard to allergen labelling.

II. Allergen information

The preparatory works reveal that the Norwegian Food Safety Authority (NFSA) first was of the opinion that the allergen information according to Article 44(2) FIR could be provided orally\textsuperscript{83}. Whereas the former regulation on food labelling made it possible to fulfil the mandatory information requirements orally upon request\textsuperscript{84}, the first draft regulation section 6 outlined that when selling non-pre packed food over the counter, at restaurants or similar, mandatory information could be provided in the menu or orally. However the “upon request” requirement was not included, by implication meaning that the business operator had to ensure

\textsuperscript{82} We are informally informed that it is not likely that additional requirements will be made according to article 39-43. For Article 39 FIR (measures on additional mandatory particulars), the NFSA has expressed that it is unlikely that it will take any measures in regard to this because – in its view- of the difficulties to prove required necessity. Measures taken according to Article 43 FIR (voluntary indication of reference intakes for specific population groups) are according to NFSA not likely to be taken because of the amount of work required to establish specific reference group. Further, as today, it is not regarded as necessary with such specific reference groups.

\textsuperscript{83} See NFSA’s first hearing statement pp. 14-15. The hearing statements and more information on the implementation work may be found at http://www.mattilsynet.no/mat_og_vann/merking_av_mat/generelle_krav_til_merking_av_mat/merkeforskriften_revideres.4711 (in Norwegian). Direct link to the hearing statement is http://www.mattilsynet.no/om_mattilsynet/regelverksutvikling/akteve_prosesser/horingsbrev.4712/dinary/Høringsbrev (in Norwegian).

\textsuperscript{84} The Norwegian regulation on labelling of 21 December 1993 no 1385 (repealed) section 7
that the information was provided always and not just upon request. The proposed provision proposal also addressed which format could be used when the information was provided in writing (in addition to signs and other notices).

Due to discussions at EU/EEA level, and the interpretation of Article 44(2) FIR provided by the Commission’s Health and Consumer Directorate General in the Q&A-document, the NFSA re-examined whether the first proposal was in compliance with FIR. It decided to remove the option referred to above in full, based on an overall assessment, underpinning e.g. that the intention was to strengthen consumer rights.  

The NFSA has provided little guidance on how to comply with the requirements on allergen information for non-pre packed food. Principally it is up to the business operators themselves to decide how to give the mandatory information within the framework of FIR. Late October last year, the NFSA provided a brief guidance – principally a fact sheet - shedding some light on the interpretation of FIR Article 12(1) and Article 13(1) regarding non-pre packed food. E.g. it is stated that the information shall be available in a written format directly to the consumer. The requirement “directly” is interpreted so that the consumer should have access to the information without having to ask the staff first. In addition, the information must be specific and not possible to misunderstand. According to the view of the NFSA, the relevant allergen must be named, and simply referring to e.g. «nuts» is not acceptable.

85 See NFSA’s second and final hearing statement p. 6-8. The hearing statement is found at http://www.matillsynet.no/mat_og_vann/merking_av_mat/generelle_krav_til_merking_av_mat/oppsummering_og_vurdering_av_horingsuttalelsene.8714/binary/Oppsummering%20og%20vurdering%20av%20høringsuttalelsene (Norwegian).
III. Other comments

The Norwegian Regulation states that all labelling must be in Norwegian or a language which in spelling is similar to Norwegian, cf. Provision 2. Swedish and Danish do – to some extent – fulfil the language requirements, but case-by-case assessment is necessary. Aligned with the wording in FIR, the mandatory information may be provided by using another language to the extent that the phrases used are principally written in the same way as Norwegian and are therefore easily understood by Norwegian consumers.

Worth noting is that the Norwegian Regulation also includes some additional criteria for food groups which do not have EEA relevance (specific labelling requirements for fresh fruit, berries, vegetables and potatoes), or which have not been adopted into the EEA (genetically modified food). Labelling requirements in various regulations for specific food still apply and the implementation of FIR did result in some other editorial amendments in relation to regulations for specific food groups.

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86 Agriculture products fall outside the scope the EEA-Agreement cf. EEA-agreement article 8, but intra EU/EEA trade is encouraged according to the EEA-Agreement article 19. Section 3 of the Norwegian Regulation on food information states that fresh fruits, berries, vegetables and potatoes that are not pre-packed shall be labelled with/accompanied by a trade description. Both pre-packed and non-pre-packed food shall be labelled with/accompanied by information on country of origin. Apples, pears, plums, cherries and strawberries which are not pre-packed, shall be accompanied by information on the species.

87 Both packed and non-packed genetically modified food shall, as a main rule be labelled with either the term "genetically modified" or "produced from genetically modified [name of organism]“. Any genetically modified food must be pre-approved by the NFSA before it may be sold on the Norwegian market. As of 11 May 2015, no such approval has been given for foodstuff to consumers. The NFSA has stated that when and if Regulation 1829/2003/EC on genetically modified food and feed is incorporated in Norway, the labelling requirements will be regulated by a new regulation on genetically modified food.

88 In example, the previous Norwegian regulation on labelling also included labelling requirements for foodstuff treated with ionising radiation (Directive 1999/2/EC) and for quick-frozen foodstuffs for human consumption (Directive 89/108/EEC). FIR does not amend or annul these provisions, but NFSA has decided to move these provisions to the regulations regarding the specific food group.
IV. Violation and sanctions

Violation of a provision of the Norwegian Regulation may be fined. Also imprisonment up to 1 year is possible (2 years for particularly aggravating offences), but imprisonment is very rare. The NFSA is authorized to make any decision required in order to ensure compliance under the scope of the Food Act and the regulations attached thereto. Thus, depending on the violation’s degree of severity, the NFSA will decide what sanction is deemed most appropriate and effective in each case.

The most common form of sanctioning is an injunction that requires amendment of the labelling/advertisement, or an injunction that requires that the foodstuff’s content is changed so that it corresponds with the current labelling. The NFSA may also give compulsory fines for each day that the company does not comply with such injunctions, but this happens rarely and when it happens the fines are normally low (between NOK 2,000 – 20,000).

Furthermore, the authority may impose administrative fines, but this is not often used. Of practical interest is the fact that the NFSA may prohibit the sales, or impose withdrawal of the foodstuffs in question. The Food Act moreover gives legal basis for criminal prosecution, which means criminal fines and imprisonment. However, such reactions are reserved for NFSA’s more serious cases—e.g. cases of animal maltreatment. When a sanction is prepared by the authorities, the entity is normally entitled to comment, and moreover, when the sanction is made, there is a complaint procedure in place. The case may thereafter be brought before the courts.
I. Labelling requirements for non-prepacked food (Article 44 FIR)

Labelling of non-prepacked foods delivered to the final consumer is regulated in Poland by means of the Regulation of 23 December 2014 of the Ministry of Agriculture and Rural Development on labelling of specific types of foodstuffs (hereinafter, the Regulation). Paragraph 19 of the Regulation lists the mandatory particulars that need to be delivered to the final consumer and specifies the way they should be delivered.

II. Labelling requirements for expression of the net quantity (Article 42 FIR)

Regulation of 23 December 2014 of the Ministry of Agriculture and Rural Development on labelling of specific types of foodstuffs sets forth the requirements concerning the expression of net quantity for specified foods in a different manner to that provided for in Article 23(1) FIR. Pursuant to Paragraph 2 of the Regulation the labelling of ice cream, mayonnaise, seasoning in liquid form, thick sauces, and fermented dairy products and of condensed milk can be expressed in units of volume or in units of mass. The above provision had been in place prior to the date of application of the FIR.
III. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

Pursuant to Article 6 of the Act of 21 December 2000 on the commercial quality of agricultural and food products, agricultural and food products which are being placed on the market are labelled at least in Polish language. The obligation to label the foodstuffs in Polish does not apply in case of agricultural and food products which are intended for export outside the territory of Poland. The above provision had been in place prior to the date of application of the FIR.
PORTUGAL

JENS KARSTEN, BXL-LAW, BRUSSELS / RAQUEL FERREIRA CORREIA, LISBON

I. Objectives pursued by national implementation measure

Portuguese implementation measures remain incomplete. The draft Decreto-Lei nº ../2015 de … 2015 or Decree-Law No. ../2015 of … (hereinafter: the DL) remains a project so far (state of November 2015). It is designed to be the instrument of Portuguese law dedicated to the implementation, and completion, of Regulation 1169/2011 (FIR) for the national jurisdiction. The DL also includes a renewed transposition of Directive 2011/91/EU on indications and marks identifying the lot to which a foodstuffs belongs89, taken aboard from a law abrogated by the DL.

Under the Portuguese constitution, legislative acts may come along either as ‘Laws’ (enacted by parliament) and as ‘Decree-Laws’ (enacted by government), both vested with equal binding force.90 The government is entitled to issue Decree-Laws in matters not belonging to the prerogatives of parliament, the Assembleia da República.91 While the constitution

89 OJ L 334, 16.12.2011, p. 1
90 Constituição da República Portuguesa, (CRP) Article 112. Explicar competência legislativa governo 198(1a) questão da possibilidade AR 10 deputados nos 30 dias seguintes fazerem cessar a vigência do DL. Competência exclusiva e relativa. Distinguir dos regulamentos do governo que visam implementar...
91 Art 198 CRP establishes the legislative competence of the Government. Decree-laws should not be mistaken with other Decrees also enacted by the Government that aim at the implementation of laws within the habitual government executive powers, like regulatory Decrees (Articles 199(c) e 112(6) and (7)). Articles 164 and 165 CRP list the absolute and relative legislative competence of the Parliament – Assembleia da República. However, it should be noted that in the first 30 days after publication of a Decree-Law, it may be submitted to the appreciation of the Assembleia da República for purposes of amendment or revocation, by request of only 10 Members of Parliament.
provides for transpositions of acts of Union law to be enacted as Laws or Decree-Laws\textsuperscript{92}, most of Portuguese consumer law and food law are issued by way of Decree-Law. Also relevant in food law are so-called \textit{Portaria}; these are implementing acts of a law, issued by the Ministry of Agriculture.


II. Notification procedure under the TRIS

The Portuguese government notified a draft Decree-Law on 9.12.2014 to the European Commission under the TRIS-procedure, registered as 2014/596/PT. The three-month standstill period was prolonged by a further three months to expire on 11.6.2015 after the Commission issued a detailed opinion (Article 9 of Directive 98/34/EC) and Slovakia tabled comments (Article 8 of Directive 98/34/EC). The Commission criticised the absence of a mutual recognition clause\textsuperscript{93} that would require Portuguese authorities to admit onto their territory non-prepacked foodstuffs which are lawfully manufactured or marketed in the Internal Market and which, although they may fail to meet the requirement of the DL, offer a sufficient and suitable safety for the Portuguese consumer.

\textsuperscript{92} Article 112(8) CRP.

\textsuperscript{93} Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (OJ C 265, 4.11.2003, p. 2)
III. Labelling requirement for non-prepacked food

The scope of the DL is defined in its Articles 1 and 2. In transposing Directive 2011/91/EU the DL is of horizontal application covering all foodstuffs. In implementing the FIR the DL is limited in scope to food information on non-prepacked food, establishing labelling requirements on allergens and an enumerated number of other particulars. The definition of non-prepacked food names five categories:

1. Non-prepacked food for sale to the final consumer
2. Non-prepacked food for sale to mass caterers (Article 2(2)(d) FIR)
3. Non-prepacked food sold by mass caterers (Article 2(2)(d) FIR)
4. Food packed at the request of the consumer
5. Pre-packed food for direct sale

The Decree-Law defines the exemption of “pre-packaged foodstuffs for direct sale” of Article 2(2)(e) FIR as meaning “foodstuffs which are pre-packaged at the establishment where they are offered for sale to the final consumer.” Insofar as no time limits are set by this definition, it does not apply only to packages for immediate sale or those to be sold on the same day (or, for instance, in 48 hours) but to all food packed at the same premises where sale occurs where the packaging has not been requested by the consumer.

1. Allergen labelling (Article 1(2)(a) DL)

Easily accessible allergen labelling (Article 9(1)(c) FIR) of non-prepacked food is mandatory under Union law (Article 44(1)(a) FIR and Article 12(1) FIR); it is discretionary for the national regulator to adopt measures concerning the means of informing on allergens (Article 44(2) FIR).

Under the Decree-Law allergen labelling is stipulated by its Article 4(1)(b) DL for non-prepacked food for sale to mass caterers, by Article 5(1)(b) DL for non-prepacked food sold by mass caterers, by Article 6(1)(b) DL
for food packed at the request of the consumer and by Article 7(1)(b) DL for pre-packed food for direct sale. The competent national authority, the Direção-Geral de Alimentação e Veterinária (cf. VII below), has issued a formal note to clarify the issue of allergen information regarding non-pre-packed food (Esclarecimento 2/DAH/2014 - Comunicação de alergénios em géneros alimentícios não pré-embalados) that states what is contained in the notified draft law and additional information.

The DL requires allergen information of non-prepacked food intended for mass caterers to appear on the document accompanying the products or be printed on the labels and tags respectively. Also for pre-packed food for direct sale information has to be provided on the label. More flexibility is permitted for non-prepacked food sold by mass caterers and for food packed at the request of the consumer where allergen information must be displayed “in a prominent place” and by way of written, visual, electronic or other material communication. Alternatively, the FBO may indicate how this information may be obtained.

The “Esclarecimento” adds that the information may be provided by word of mouth in case:

1. the referred to indication is clearly visible and instigates the consumer to request the information on allergens to the workers;
2. the information on allergens may be directly and in an appropriate way transmitted to the consumer by the owner or worker at the premises of sale before the sale; and
3. the information on allergen in permanently available in a written or electronic format to the workers and to the inspecting authority.
4. It also states that whenever products containing allergens are for sale in several places of the sale premises, the information must be available in all those places. The information must be provided for free, be easily understandable and clearly readable.

Insofar as Article 44(1)(a) FIR is directly applicable and creates an obligation for FBOs to inform on allergens for non-prepacked food, the
lack of guidance provided by the national legislator is likely to increase legal uncertainty while crucial information still needs to be displayed easily available for the consumer under Article 12(1) FIR. The FIR Q&A states that in the absence of national rules this means that the information should be given in written form. This document has been put in the Portuguese competent authority website for information to the public.

2. Mandatory particulars

The DL provides for a number of requirements for the declaration of mandatory particulars in accordance with Article 44(1)(b) FIR.
<table>
<thead>
<tr>
<th>MANDATORY PARTICULARS</th>
<th>Product name (Articles 9(1)(a) and 17 FIR)</th>
<th>Storage conditions (Article 9(1)(g) FIR)</th>
<th>Country of origin (Article 9(1)(i) FIR)</th>
<th>Instructions for use (Article 9(1)(g) FIR)</th>
<th>Net quantity (Article 9(1)(e) FIR)</th>
<th>Packaging date/use-by date (Article 9(1)(f) FIR)</th>
<th>Name of FBO responsible for food information (Article 9(1)(h) FIR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-pre-packed food for sale to mass caterers (Article 4)</td>
<td>Yes</td>
<td>Yes, If applicable</td>
<td>No</td>
<td>Yes, “whenever applicable”</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Non-pre-packed food sold by mass caterers</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Food packed at the request of the consumer</td>
<td>Yes</td>
<td>Yes, “whenever applicable”</td>
<td>Yes, “whenever applicable”</td>
<td>Yes, “whenever applicable”</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Pre-packed food for direct sale</td>
<td>Yes</td>
<td>Yes, “whenever applicable”</td>
<td>Yes, “whenever applicable”</td>
<td>Yes, “whenever applicable”</td>
<td>Yes</td>
<td>Yes(^1)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
3. Means of expression and presentation

In the case of pre-packed food, mandatory food information shall appear directly on the package or on a label attached thereto (Article 12(2) FIR). For non-prepacked food the national regulator has to elaborate on the form of presentation to the final consumer and the mass caterer. Where the Portuguese legislator provides details on the “means through which the particulars are to be made available and their form of expression and presentation” (Article 44(2) FIR) it refers to a whole range of communication tools: accompanying documents, labels, tags, menu or by means of a writing, visual, electronic or other material support. Although the DL does not provide for definitions, a formal note from the national competent authority (Esclarecimento 2/DAH/2014) clarifies that the expressions written or electronic form enables businesses to make the information available through websites, IT applications, electronic boards, catalogues, brochures, posters, among others.

The FIR allows for flexibility, suggesting food information to be provided “also by other means than the label” (recital 14) and permitting “certain particulars to be made available thorough alternative means” (recital 23). The FIR’s definition of food information (Article 2(2)(a) FIR) itself integrates a notion of the means that in abstract could be used to provided it: “made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication.”

<table>
<thead>
<tr>
<th>WAY INFORMATION MUST BE PROVIDED</th>
<th>Accompanying documents</th>
<th>Labelling (also just a tag?)</th>
<th>Written, visual, electronic or other material form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-prepacked food for sale to mass caterers</td>
<td>Acceptable both for voluntary and obligatory information</td>
<td>Acceptable both for voluntary and obligatory information</td>
<td></td>
</tr>
<tr>
<td>Non-prepacked food sold by mass caterers</td>
<td>Acceptable for product name, allergen information and voluntary information. Allergen information has to be placed in a prominent place but it is possible to indicate there only the way to obtain the detailed information.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food packed at the request of the consumer</td>
<td>Acceptable for product name, storage, country of origin, instruction for use and for allergen information, as well as voluntary information. Allergen information has to be placed in a prominent place but it is possible to indicate there only the way to obtain the detailed information.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-packed food for direct sale</td>
<td>Both for obligatory and voluntary information.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Voluntary labelling for non-prepacked food (Article 8 DL)**

The DL also makes provision for optional information for non-prepacked food. Article 8(1) DL states the obvious, that is, that FBOs may label their products with particulars (Article 9 and 10 FIR) not made mandatory by the DL. This includes nutrition declaration (Article 9(1)(l) FIR).

Should the FBO decide to include a nutrition declaration, the DL stipulates
that it should in principle be expressed per 100mg or 100ml. The FBO may choose to use per portion or per consumption basis but those references can be limited to the amount of fat, saturates, sugars, salt, and energy value or energy value alone, in accordance to Article 8(2) DL.

The rules on placement of the nutrition declaration under Article 8(3) DL restrict the rules under Article 5(2) DL (non-prepacked sold by mass caterers) and 6(2) DL (packed at the request of the buyer) concerning the placement of general voluntary information (see table above). Mass caterers who wish to present a nutrition declaration have to do so in the menu or by a tag and the nutrition declaration for food packed at the request of the buyer has to be presented by poster or tag. Regarding non-prepacked food for sale to mass caterers Article 8(3b) DL actually repeats Article 4(2) DL.

However, Article 8(3) DL is unclear. First it uses the concept food “non-prepacked for direct sale” (paragraph 3d) which one may assume is a mistake but if it means “prepacked food for direct sale” then it simply repeats once more what is already stated in Article 7(2) DL. Paragraph 3d also adds “in accordance to Articles 30 to 35 FIR and it is unclear what it is supposed to mean in particular as it seems to apply only to direct sale situations. Then finally paragraph 3a) stipulates the use of a poster or a tag to “non-prepacked food and food packed at the request of the buyer in the sale premises”, which is unclear on what the legislator actually wishes to cover in the first concept: all non-prepacked food (which does not seem to make sense taking into account the other paragraphs) or non-prepacked food sold to consumers (which is included in the definition of non-prepacked food but is not otherwise mentioned in chapter II).

IV. Labelling requirements for pre-packed food

The DL does not introduce specific rules on pre-packed food where permitted by the FIR. So far no national measures on additional mandatory particulars (Article 39 FIR) have been notified to the Commission (Article
45 FIR). However, a number of national laws remain in place that go further than what is mandatory under the FIR.

1. **Alcoholic beverages (Article 41 FIR)**

Concerning alcoholic beverages, by virtue of Decree-Law 126/2005 adding a new Article 14a to Decree-Law 560/99, the Ministry of Agriculture is entitled to establish rules regarding the labelling of ingredients of alcoholic drinks with alcohol content superior to 1.2% by *Portaria*. Article 7(3) of Decree-Law 257/87 makes an ingredient list for liqueurs mandatory. The same applies for beer on the basis of Article 9(2a) of *Portaria 1/96* (authorised by Decree-Law 93/94).

Less obvious is the situation for “aguardente de medronho”. While no specific requirement of ingredient lists exists under the general regime applicable to spirits, Article 7(1) of Decree-Law 238/2000 applicable to “aguardente de medronho” states that the labels of products to be marketed to the final consumer should follow the legislation applicable to food law labelling. As the general rule of Decree-Law 560/99 assumes that there should be an ingredient list but makes a remission on alcoholic drinks to a specific *Portaria* and none establishes in general the issue of this ingredients lists, it is unclear what was the applicable regime before the entry into force of the Regulation. As the FIR supersedes Decree-Law 560/99 in what concerns pre-packed food, at present there seems to be no legal obligation to provide an ingredients list for “aguardente de medronho”.

2. **Indication of reference intakes for specific population groups (Article 43 FIR)**

Concerning voluntary indication of reference intakes for specific population groups, that is, children, pregnant women, sportsmen, diabetics (et al.) a guide on reference intakes was in elaboration in 2014 within several bodies of the Ministry of Health but appears as yet not to be approved.
V. Labelling requirements for pre-packed and non-prepacked food: Use of language

The DL does not replicate Article 24 of the abrogated Decree-Law 560/99 instituting a tailor-made language regime for food labelling. This absence has unclear consequences. Under general consumer law (Article 7(3) of Decree-Law 24/96) any business-to-consumer (B2C) commercial communication has to be issued in the Portuguese language. Furthermore, Decree-Law 10/2015 regarding the exercise of the economic activities of commerce, services and mass caterers (restauração) expressly reiterates the application of Decree-Law 238/86 that establishes in its Article 1: “The information about the nature, characteristics and guarantees of goods or services offered to the public in the domestic market, whether referring to labels, packaging, brochures, catalogues, books of instructions for use or other information means or those provided at point of sale or broadcasted or otherwise advertised“. This obligation applies to “the manufacturer, packer, service providers and all other staff who undertake wholesale or retail trade activities” (Article 4 of Decree-Law 238/86).

The consequences of not maintaining Article 24 of Decree-Law 560/99 are difficult to gauge given that the language requirement of general consumer law, albeit similar, do not entirely concur. Firstly, the permission under Article 24(2) of Decree-Law 560/99 allowing that product denominations that cannot be translated or which are internationally well-known do not need to be stated in Portuguese, would vanish. Secondly, for labels originally written in a foreign language, Article 24(3) of Decree-Law 560/99 obliged the translation only of mandatory information.

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94 **Direito à informação em geral:** “A informação ao consumidor é prestada em língua portuguesa”.

95 The extent to which translations have to be provided is not always evident and Decree-Law 238/86 as well as Decree-Law 24/96 seem to promote a broad interpretation of this obligation. As regards the need to translate the expression “made in” see the opinion from the Public Prosecution Office: http://www.dgsi.pt/pgrp.nsf/0/53623e84c299cf3e802566170041f0c9?OpenDocument
a specific food-related language clause it appears that the full label needs to be translated, taking a way a welcome degree of flexibility.

However, the sanctions regime applicable to the violation of obligations under DL 238/86 is Article 64(1c) of DL 28/84, that just like present Article 28(1a) of DL 560/99 governs the “lack, inaccuracy or deficiency of obligatory information” in labels. The first applies to all labels while Article 28(1a) and Article 24 of DL 560/99 applied only in food law labelling.

VI. Exception from nutrition labelling: 
the notion of “direct supply”

Favouring local farming and direct sales schemes (Article 55 of Quality-Regulation 1151/2012) and other forms of SME artisanal food production, Article 16(3) FIR exempts from the requirement of mandatory nutrition labelling among other things “food, including handcrafted food, directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer” (Annex V, No. 19 FIR). The small quantities of products that should be submitted to an exceptional regime are established by Portaria 699/2008. The activity of producing handcrafted food is submitted to the “Estatuto do artesão”- Decree-Law 41/2001 - which requires registration. It is defined in its Article 4 as an “economic activity of recognised cultural and social value that relies on the production or repair of goods of artistic or utility value, traditional or contemporary, or on the performance of services of the same kind, as well as the production of traditional food.” The conditions applying to this status are regulated in the same law.
VII. Application and Enforcement (Articles 3 and 11 to 14 DL)

The competent authority (Article 3 DL) for both the purposes of the FIR and the DL is the Direcção Geral de Alimentação e Veterinária – DGAV (www.dgv.min-agricultura.pt). The DGAV is the authority domestically competent for the policies of food safety, in accordance with Decree-Law 7/2012 of 17.1.2012 and Regulatory Decree (Decreto Regulamentar) 31/2012 of 13.3.2012. In this function the DGAV supervises implementation as a whole, receive feedback concerning its application, answer questions from FBOs, provide clarifications or propose any amendments and adaptations to the national system.

The task of market inspection, however, is given to a different body, the Autoridade de Segurança Alimentar e Económica – ASAE (www.asae.pt). Instituted by Decree-Law 237/2005, of 30.12.2005, the Food Safety and Economic Authority (ASAE) unifies in a single structure the competence for the assessment and risk communication in food matters, the inspection of economic agents and their activity in both food and economic areas, from manufacturing to commercial and industrial establishments. With the aim of centralisation, the following administrative bodies were merged in ASAE: the IGAE (General Inspection of Economical Activity), the DGFCQA (Directorate General of Inspection and Control of Food Quality), further integrating the inspection functions of the DRA (Regional Directorates of Agriculture), DGV (Veterinary Directorate), IVV (Institute of Wine and Vineries), DGPC (Directorate-General for Crop Protection) and DGP (General Directorate of Fisheries). The DGFCQA and the DRA were the authorities competent under the Decree Law 560/99 (see above) with competence to inspect, and instruct the enforcement procedure against FBOs. As these functions were included in ASAE, the DL implementing the FIR falls within the ambit of this authority (Article 12 DL).

The decisions on enforcement procedure should in principle be made by a different entity from the one that inspects and instructs them. The notified
draft Decree law established the competence of the Director-General of the DGAV to decide the enforcement procedures that have been opened and instructed by ASAE.
I. Objectives pursued by national implementation measure

In Slovak Republic, there were no major changes of national laws in relation to FIR in terms of its adoption.

II. Labelling requirements for non-prepacked food

Apart from rules of FIR, when offering for sale to consumers, non-prepacked food shall be labelled by its legal name. In case of food sold in units, it shall be labelled also by its weight, except the case of fruits and vegetables.

Special rule applies for non-prepacked finished or semi-finished pastry products, where the list of ingredients must be displayed on an accessible place.

As far as it concerns putting non-prepacked food on the market, it shall be labelled by the following information:

- legal name of the food quantity
- the date of minimum durability or the “use by” date
- information about the origin in case of GMO
- information about foods treated with ionising radiation
- information about possible adverse effect on human health
III. Labelling requirements for pre-packed food:

1. National measures on additional mandatory particulars (Article 39 FIR)

National rules of labelling do not exceed rules stipulated by FIR. Special rule applies for beverages containing more than 150 mg/l of caffeine, which shall carry the notice “contains higher amount of caffeine” in the same field of vision as the legal name of the food.

2. Milk and milk products (Article 40 FIR)

No special legal regulation was adopted following FIR. As for labelling, national law stipulates rules for legal names of milk products as far as it concerns means of preservation and amount of fat.

3. Alcoholic beverages (Article 41 FIR)

According to national labelling rules adopted before FIR, information on amount of alcohol and main ingredient shall be presented on the product under the conditions stipulated by the decree on labelling of foods.

4. Expression of net quantity (Article 42 FIR)

National legal regulation stipulates requirements on labelling of net quantity of the product similar to FIR (annex IX).
5. **Indication of reference intakes for specific population groups (Article 43 FIR)**

There are no national measures for indication of reference intakes for specific population groups.

6. **Means of expression and presentation (Article 44(2) FIR)**

In case of pre-packed food, source of information shall be connected to the food without being easily detached from it. Information shall be clear, irremovable and easy to read under usual marketing conditions, its colour shall contrast with the background; it shall not be hidden or disturbed by other signs or symbols.

**IV. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)**

All mandatory information on the foods shall be provided to the consumer in Slovak language.

**V. Exception from nutrition labelling: the notion of “direct supply” (Annex V No. 19)**

None such regulation has been adopted yet.
VI. Enforcement

Compliance with foods labelling requirements is controlled by State Veterinary and Food Administration Authority. The maximum amount of financial penalty, which can be imposed for violation of Act of Foodstuffs, is approx. EUR 500,000. The amount of the penalty imposed always depends on the character and seriousness of violation of law, facts of the case and its consequences. Such decision can be always appealed and final decision of the inspection authority can be brought to the court by filing an administrative lawsuit.
1. Objectives pursued by national implementation measure

“Real Decreto 126/2015 de 27 de febrero, por el que se aprueba la norma general relativa a la información alimentaria de los alimentos que se presenten sin envasar para la venta al consumidor final y a las colectividades, de los envasados en los lugares de venta a petición del comprador, y de los envasados por los titulares del comercio al por menor”

Royal Decree 126/201596 (hereinafter RD) is the instrument of Spanish law dedicated to the implementation and completion of Regulation 1169/2011 on food information to consumers (FIR). As a draft it was notified by the Spanish government to the European Commission on 3 June 2014 (TRIS 2014/255/ES). The three-month standstill period ended on 4th September 2014.

Shortly after its publication in the Official Gazette on 4 March 2015 the Spanish Health Authority (“AECOSAN”) published a guidance note97 on the interpretation of the RD. In addition, some Autonomous Regions have also published their respective Guidance98 on the interpretation of the RD.

97 “Guía de aplicación de las exigencias de información alimentaria de los alimentos que se presenten sin envasar para la venta al consumidor final y a las colectividades, de los envasados en los lugares de venta a petición del comprador y de los envasados por los titulares del comercio al por menor”. http://aesan.msssi.gob.es/AESAN/docs/docs/notas_prensa/guia_aplicacion_informacion.pdf
98 Some examples are the Guidance published by the Autonomous Regions of Madrid and Catalonia (http://www.gencat.cat/salut/acsa/html/ca/dir1307/guia_alimentaria.pdf)
2. Scope of the RD

The RD sets forth the requirements for the provision of food information for the following foods:

- foods that are offered unpacked for sale to the final consumer and mass caterers (Article 4 RD)
- foods from suppliers to mass caterers (Article 4 and Article 6 RD)
- foods packed at points of sale at the request of the buyer (Article 4 RD)
- foods packed by the owners of retail businesses for immediate sale in the establishment or establishments they own (Article 5 RD)
- foods referred to in the previous points and offered for sale through distance communication (Article 9 RD)

The RD also defines the means through which information on the presence of allergenic substances or substances causing intolerances may be provided on non-prepacked foods.

3. Operators affected by the RD

The RD applies to food business operators (FBOs) at all stages of the food chain, inasmuch as their activities affect food information provided to consumers. Therefore, the following operators or establishments could be affected:

- Operators or establishments which supply food to mass caterers (bars, cafeterias, restaurants, school cafeterias, companies, hospitals, residences, etc.)
- Operators or establishments which supply foods which are packed or not packed and made available at points of sale at the request of the consumer (such as cold cuts, breads, sandwiches, cakes, ready-made meals, etc.)
- Operators or establishments who sell or supply non-prepacked foods to other establishments such as schools, hospitals, residences for the elderly, etc.; or
• Owners of retail businesses who pack their own products for immediate sale in their establishment or establishments (article 2.1 RD and point 3 of Aecosan Guidance).

4. **Allergen labelling**

Pursuant to Article 44(1)(a) FIR, Member States had to enact national measures regarding allergen labelling (Article 9(1)(c) FIR) for non-prepacked food; whilst they could at their discretion adopt national measures concerning the means of informing consumers on allergens (Article 44(2) FIR).

The RD stipulates that allergen labelling is mandatory for:

• Non-prepacked foods for sale to the final consumer (article 4.1.b RD)
• Non-prepacked foods for sale to mass caterers (article 4.1.b RD)
• Foods packed at the request of the consumer (article 4.1.b RD)
• Pre-packed foods for direct sale (article 5.1 RD)
• Non-prepacked foods sold by mass caterers (article 6.5 RD)

It is required that allergen information of non-prepacked food intended for mass caterers appears on the document accompanying the products as well be printed on the labels. For the other three categories of non-prepacked food, allergen information must be displayed “in a prominent place” and by way of written, visual, electronic or other material communication. Alternatively, the food business operator may indicate how this information may be obtained upon request.
## 5. Mandatory information (table)

<table>
<thead>
<tr>
<th>Product name (9.1.a FIR)</th>
<th>Allergens content (9.1.c FIR)</th>
<th>QUID (9.1.d FIR)</th>
<th>Alcoholic content (9.k FIR)</th>
<th>List of ingredients (9.1.b FIR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-prepacked foods for sale to final consumers (article 4.1 RD)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-prepacked foods sold to mass caterers (article 4.1 RD)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Foods packed at the request of the consumer (article 4.1 RD)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Foods packed by retail business (article 5.1 RD)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Foods sold by mass caterers (article 6.5 RD)</td>
<td>Yes</td>
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<tr>
<td>Fruits and Vegetables (article 5.2 RD)</td>
<td>Yes</td>
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<tr>
<td>Net quantity (9.1.e &amp; j FIR)</td>
<td>Storage conditions / Instructions for use (9.1.g FIR)</td>
<td>use-by date (9.1.f FIR)</td>
<td>Name of FBO (9.1.h FIR)</td>
<td>Country of origin (9.1.i FIR)</td>
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6. Means of expression and presentation

In the case of pre-packed food, mandatory food information shall appear directly on the package or on a label attached thereto (Article 12(2) FIR). For non-prepacked foods the RD establishes (article 6 RD) that foods which are non-prepacked or packed at the request of the consumer must comply with general requirements regarding the availability and information (i.e. the information must be made available and be indicated in an easily visible, clearly legible and accessible manner to the consumers).

This information must be provided in writing either (i) on the labels attached to the food; or (ii) on a sign. If the information is displayed directly on the package or label, then the requirements regarding the font size set forth in Article 13 FIR must be complied with. On the other hand, if signs are relied on, then these must be positioned (i) at the place where the food is offered for sale; (ii) directly on the food; or (iii) near the food in question.

There are specific cases that must be considered:

a) Mass Caterers

Mass caterers (such as restaurants, bars, cafeterias and similar establishments) may provide the information regarding the ingredients likely to cause allergies and intolerances either in writing, or orally (article 6.5 RD). If the information is transmitted in writing, then it can be made available on means such as menus, for example. If transmitted orally:

- The information can be provided by the establishment’s personnel (or by other means that will not result in an additional monetary cost for the consumer) but always prior to the moment when the food is purchased;
- The information must be physically registered (either in writing or by electronic means) at the establishment, in a way that it will be easily accessible to the establishment’s personnel, to consumers and to the supervisory authorities.
In addition, in the areas where the food is made available, the following information must be indicated:

- The place in the establishment where the information may be obtained; or alternatively
- The fact that consumers may address the establishment’s personnel in order to obtain the information.

If the establishment has several sections, the indications must be available in each different section, except if:

- The foodstuffs have labels; or
- The information is made available on signs placed next to the food.

All of the above will not be necessary if the establishment provides meals which are specifically adapted to the needs of consumers affected by allergies or intolerances. However, the information regarding the ingredients likely to cause allergies and intolerances must always be available, and provided to any consumers or supervisory authorities upon request.

b) Fruits and vegetables

A retailer selling fruit and vegetables (vegetables of any type), tubers or dried fruits or nuts, and using packaging enabling the product to be identified normally with the naked eye must, as a minimum, indicate:

- The sales designation accompanied, as appropriate under the requirements of the specific regulations, by the category and variety or commercial type and the country of origin;
- The net amount; and
- Identification of the food business in accordance with the provisions of FIR.

This type of sale is referred to as a sale under “a self-service system”. As
with other sales categories, the mandatory information provided during a sale under “a self-service system” must respect the general requirements of availability and information\textsuperscript{99}. This information must appear on the package or on the label (respecting any font size requirements pursuant to FIC). However, the sales designation may appear on signs positioned in the place where the food is offered for sale, near the food in question (article 6&7 RD).

c) Distance selling

Any food business operator who sells products which are subject to the RD by means of distance communication (internet, telephone, food businesses selling products outside of their establishment, etc.) must also provide the information required for each of these sales channels (article 9 RD and 4.c.4 AECOSAN guidance), and particularly the information regarding the ingredients likely to cause allergies and intolerances. This information must:

- be made available through the means where the sale takes place (for example, on the web page or on other appropriate means depending on the food business operator);
- be provided without any additional monetary costs to the consumer;
- be provided prior to the purchase being made; and
- accompany the food at the time of its delivery

Notwithstanding the foregoing, the particulars relating to the country of origin or place of provenance, as well as the particulars that, being mandatory, are not listed in Article 9(1) FIR, may be unavailable before the purchase is made but must always be available at the time of delivery.

\textsuperscript{99} Basically that the information available must be indicated in an easily visible, clearly legible and accessible manner to the consumers
7. Voluntary labelling for non-prepacked food

The RD expressly envisages that other voluntary information may be additionally provided. This voluntary information may refer to any of the particulars referred to in Articles 9 or 10 FIR, or to any other type of information that is not considered mandatory pursuant to FIR. For instance, non-prepacked foods do not have to display a nutrition declaration. However, should the information be displayed on a voluntary basis, then it must be done pursuant to FIR (article 8 RD).

8. Language regime

All the information displayed on foods which are subject to the RD must be expressed at least in Spanish. Nonetheless, in the case of traditional foods which are produced and distributed exclusively in an Autonomous Region with an official language other than Spanish, the information may be displayed in the language of that region (this would be the case of the Basque Country or Catalonia). The only exception to this applies to any ingredients likely to cause allergies and intolerances, which must always appear in Spanish (article 10 RD).

9. Responsibilities of the FBO

In addition to any responsibilities set forth in FIR, the RD emphasises one in particular: food business operators must provide the information on ingredients likely to cause allergies and intolerances to any restaurants, bars, canteens or the like, so the latter may in turn communicate the information to the final consumers (article 11 RD). The RD adds a further responsibility: food business operators must keep the information; and make it available to any consumers or supervisory authorities upon request, during a “reasonable time period”. “Reasonable time period” is further defined as a time period during which it can be reasonably assumed that the food has been consumed (article 12 RD).
10. Enforcement

The authorities enforcing FIC and the RD are the supervisory authorities at Autonomous Region level where an infringement takes place. This would not prevent the Central Health Authorities from also intervening in specific cases.

11. Provisions on pre-packed food

The RD does not provide specific rules on pre-packed foods where permitted by the FIR. However, some national laws are maintained. No national measures on additional mandatory particulars (Article 39 FIR) have been notified to the Commission by Spain (Article 45 FIR) to date.
1. Introduction

The Swedish National Food Agency (“NFA”) has implemented primarily two main national regulations relating to the FIR.

- NFA regulation (LIVSFS 2014:4) on food information, and
- NFA regulation (LIVSFS 2015:1) on the use of a particular symbol (Keyhole)

Both have been submitted within the notification procedure TRIS. Both have passed the standstill and the final texts have been adopted and entered into force. In addition to this, a number of national regulations have been repealed as a consequence of the FIR, and consequential changes have been made in regulations remaining in force. These will be dealt with below in relation to the review of the regulation on food information.

2. National Food Agency regulation (LIVSFS 2014:4) on food information

The content of the regulation and its support in FIR

The provisions of the Swedish national regulation contain national supplementation of the FIR as well as provisions for non-packed food. In its Consultation paper, the NFA made the following observations with regard to the scope in the FIR for national requirements concerning further compulsory details.

The following provisions have been used:
Article 15: The article allows the Member States to prescribe that food information shall be provided in the languages of one or more members of the Union. This option is used in the proposed new regulations.

Article 42: The article allows the member states to adopt different expressions of net quantity. The regulation uses this option with regard to decilitre and net quantity food supplements, sweeteners and similar.

Article 44: The article provides for compulsory requirements for foods that are not pre-packed and how they are to be supplied. The following were deemed not relevant to Sweden or the NFA declared that it would not at present use the options provided by FIR.

Article 39: On the protection of public health, consumers, prevention of fraud, prevention of unfair competition etc. The NFA has decided not to use said option but does not rule out that this could happen in the future.

Article 40: Exceptions for returnable bottles made of glass for milk and dairy products. This was deemed not relevant to the Swedish market.

Article 41: Ingredient requirements for drinks with more than 1.2% by volume of alcohol. The NFA has decided to await the European Commission’s report on whether alcoholic drinks will be covered by lists of ingredients and nutritional declarations in the future.

Article 43: Inclusion of references for certain groups. The NFA deemed this not relevant to Sweden at the moment.

The regulation’s scope and content
The regulation primarily concerns the following areas:

- Information regarding allergens which, according to the information regulation, are to be indicated for non pre-packed foods.
- Compulsion to state the name (type) of the food in the case of all foods that are not pre-packed where requested by the consumer.
• An obligation for certain not pre-packed foods (food packed at the request of the customer or pre-packed food for direct sale) where the details that are compulsory for pre-packed foods are to be provided upon request (nutritional information excepted).
• The requirements already present in the previous legislation regarding language (food information shall be provided in Swedish), net quantity, and regarding the labelling and presentation of veal and potatoes are being retained and transferred from the present labelling regulations to the new ones and are largely unchanged.
• The provision on information on unpacked veal is being simplified.
• The provision concerning the name, fruit drink, is being repealed.
• The provisions regarding packaging date and date of manufacture (including date of baking and baked) are repealed.

Swedish regulations repealed
The following regulations are repealed as a result of the new regulations:

• the general Swedish national labelling regulations (LIVSFS 2004:27)
• the regulations on certain labelling, (LIVSFS 2002:47), and
• the regulations on nutritional declarations. (LIVSFS 1993:21)

Non pre-packed food and allergens

2.0.1 Required information and methods of communication for all foods

The name of the food shall be provided on request for all foods that are not pre-packed foods. The provision applies to restaurants as well as food purchases over the counter in a grocery store. The new provision has a broader scope than the previous provisions as it include pre-packed filled/open sandwiches and ready-made food for immediate consumption.

The following information as stipulated in article 9.1b and e-k (FIR) shall, where the consumer so requests, be provided with regard to food which is
• packed at the point of sale at the consumer’s request, or
• pre-packed for direct sale.

Namely:
• List of ingredients
• Quantity of certain ingredients or categories of foods
• Net quantity
• Minimum shelf life (best before) or date to be consumed by
• Special storage/use conditions
• Name and address of company
• Country of origin or place of origin where required under the infor-
mation regulation
• User instructions
• Actual alcohol content expressed in % by volume.

It should be noted that this provision does not apply to food served at
restaurants but it does apply to takeaway food that a restaurant deliv-
ers – takeaway pizza for instance. It should also be noted that nutritional
declaration is not required.

The “consume by dates” shall be provided for food that is highly per-
ishable microbiologically instead of the best by date.

When it comes to the list of ingredients, the ingredients need not to be
provided in the same order as stipulated in article 18 FIR as long as it is
clear to the consumer which ingredients are concerned.

2.0.2 Allergens

Compulsory information about allergens that must be provided, in ac-
cordance with Article 44 FIR, shall be provided for all foods that are not
packed foods. This may be done in writing, with certain requirements
regarding legibility, verbally or through other methods if the information
can also be provided verbally where required. Here the regulation opens
for the use of modern technical solutions, such as QR codes or applica-
tions for mobile phones.
If the food manufacturer decides to provide the details only once requested to do so by the consumer, the food manufacturer is obliged to ensure that it is clearly stated how the consumer can get access to the details. The food manufacturer cannot just provide information if requested to do so. If the consumer’s allergy has been investigated and written down in advance and the food is provided to the consumer on the basis of this information, the requirement does not apply. Examples where this might apply are schools and hospitals.

The same methods of communication stated for allergens can be used for other information required.

**Comments on national net-weight rules**

Decilitres may be used as net quantity with regard to liquid products.

The net quantity of products in the form of capsules etc. may be indicated by stating the number of capsules instead of information about weight or volume. This applies to sweetener capsules, dietary supplement capsules and capsules of food for special medicinal purposes.

**Language**

Compulsory food information shall be provided in Swedish or in a language that is only slightly different to Swedish. It is often thought that the Scandinavian languages are sufficiently similar to allow use of either in replacement of the national language for instance Swedish. However this cannot be relied on. There are discrepancies in the languages and the terminology which cannot be considered slight.

The information may be provided in several languages at the same time. This provision does not diverge from what previously applied.

**Certain comments made concerning potatoes**

The previously applicable provisions on the labelling of potatoes sold loose according to which information should be given on variety name, date of packaging and storage instructions are repealed and replaced in the regulation with the following:

- The variety name of the potato in connection with the denomination
• Information that the potatoes should be stored in a dark and cool place
• Date of packaging

The information concerning variety name for potatoes soled loosely can be given on a placard in the close vicinity to the potatoes. The provision does not apply to products legally produced in other EU Member States, states party to the EEA or Turkey.

Consequential changes in national regulations on certain products
The Swedish regulation entails consequential changes to the following regulations:

• SLVFS 1997:27 (grain-based foods and baby food for infants and small children)
• SLVFS 1997:30 (certain food intended for use in low-calorie diets for weight reduction)
• SLVFS 2000:14 (food for special nutritional purposes)
• SLVFS 2000:15 (food for special medicinal purposes)
• SLVFS 2000:22 (coffee and chicory extract)
• LIVSFS 2003:9 (dietary supplements)
• LIVSFS 2003:10 (honey)
• LIVSFS 2003:11 (sugar)
• LIVSFS 2003:13 (cocoa and chocolate products)
• LIVSFS 2003:16 (condensed milk and milk powder)
• LIVSFS 2003:17 (jam, jelly and marmalade)
• LIVSFS 2003:18 (fruit juice and nectar)
• LIVSFS 2003:45 (mineral water, spring water)
• LIVSFS 2005:20 (food hygiene)
• LIVSFS 2006:12 (frozen food)
• LIVSFS 2008:2 (infant formula)
3. Conclusive remarks

The Swedish regulation has taken into account both the consumers’ interest in disclosure of clear and concise information about the food products including non-prepacked foods. It has acknowledged the danger of over-informing the consumers, that is, inundating consumers with information and the danger of pertinent information getting lost. In addition to this, industry concerns about an increased administrative burden on the food manufacturers and other companies in the chain have been acknowledged and supposedly effective ways and possibilities of providing information implemented. One interesting step is of course the acceptance of modern information technology as means of communication.

It is also of certain interest to note that the NFA at this stage does not use the option to implement national rules addressing food fraud and other misleading practices. However, Sweden often awaits measures to be taken on the EU-level rather than implementing national special regulations.

4. Keyhole regulation

Background

The Keyhole symbol was introduced on the Swedish market in 1989. The idea was to create an easily recognizable and observed symbol whereby the consumer could find better alternatives in terms of nutrition – i.e. healthier foods. It is a registered trademark owned by the Swedish National Food Agency (“NFA”). The use of the symbol is well-established as a voluntary measure open to all the products of that comply with the stipulated requirements.

The conditions of the are based on the Nordic Nutrition Recommendations 2012 (NNR 2012) which among other things emphasises the reduction of the most significant lifestyle-related diseases, primarily heart and circulatory diseases, type 2 diabetes and osteoporosis through changing eating habits.
The Keyhole has been introduced in other countries as well – Denmark and Norway in 2009. During 2012-13, the conditions for the Keyhole symbol were discussed and revised in a working party containing participants from Denmark, Norway and Sweden. In January 2013, Iceland also joined the Nordic working party. In 2013, Lithuania adopted the use of the Keyhole symbol, but is not part of the Nordic working party.

**The Keyhole regulation LIVSFS 2015:1**

The Keyhole symbol can be used for pre-packaged food the composition of nutrients of which is in accordance with the conditions stipulated in the regulation. It also applies to certain non-prepackaged foods such as certain unprocessed vegetables for instance potatoes, root vegetables, leguminous plants, fruit and berries, crisp bread and crisp rolls, cheese, fish and mussels and unprocessed meat.

The Key-hole regulation does not apply to pre-packaged foods provided at restaurants and restaurant-like establishments. These kinds of foods may be covered by a new system for “The keyhole symbol at restaurants”, which is currently being developed in a project group.

Food intended for children under 36 months of age cannot be labelled with the Keyhole.

Products containing sweeteners or for instance “Stevia” are not eligible for the Keyhole. There are also restrictions concerning plant sterols, plant sterol esters, plant stanols and plant stanol esters.

**Nutritional declaration**

The Keyhole symbol includes a number of nutrition claims. Whenever used, the Keyhole symbol shall be accompanied with a nutritional declaration. This applies to pre-packed foods and non-prepacked foods with the exception of unprocessed vegetables, fruit and berries, and fishery products, live mussels and prepared fishery products. As regards non-prepacked foods, the nutritional declaration shall be provided optionally,
provided the consumer is in a position to receive the relevant information before the purchase has been made. The nutritional declaration shall be on the packaging in the case of food prepacked for direct sale.

In December 2012, the European Commission published guidance on permissible deviations from a nutritional declaration. The European Commission’s guidance shall be applied to nutritional declarations on products bearing the Keyhole symbol.

**Food groups covered**

The following food groups are covered by the regulation
- Vegetables, fruit, berries and nuts etc. (groups 1-3)
- Flour, grains and rice etc. (groups 4-6)
- Porridge, bread and pasta (groups 7-10)
- Milk, fermented products and vegetable alternatives etc. (groups 11-14)
  It should be noted that fermented flavoured milk products are not eligible for the Keyhole.
- Cheese and similar vegetable products (groups 15-17)
- Fat spreads and oils (groups 18-19)
- Fishery products and products derived from these (groups 20-21)
- Meat and meat products (groups 22-23)
- Vegetable products (group 24)
- Ready meals (groups 25-30)

In the current regulations, there is one group for soups (17).

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New groups are

- Soups containing meat and fish (28)
- Soups without meat or fish (group 29)
- Ready meals that do not constitute a complete meal (group 30).

- Dressings and sauces (groups 31-32)
  Two new groups have been added:
  - Oil and vinegar dressings (31)
  - Sauces (32).

Conclusive remarks

The Keyhole-symbol is a well-established symbol on the Swedish market both with consumers and food companies. A high percentage of the consumer knows the Keyhole-symbol and what it stands for. Many companies use the Keyhole symbol. According to a survey conducted by the Swedish NFA, concerning the Keyhole symbol’s effect on innovation, it seems as if it has positive effects on the companies. Many companies use the Keyhole criteria for benchmarking quality assurance in the development of new products.

However, there are drawbacks. The industry’s interest in the symbol depends on the consumers’ demand. It has been acknowledged in surveys made over the years that the consumers’ confidence in the symbol varies. The NFA concludes that it must focus on resurrecting the meaning and confidence of the Keyhole among consumers. It is important to remind the consumers of the purpose and benefits of choosing a Keyhole marked product by continuous and clear presence, visibility and communication. In addition, it is important to achieve a political impact and sustainability which Keyhole put in a larger context in relation to the role of diet in human health.101

101 [Link](http://www.livsmedelsverket.se/globalassets/rapporter/2015/nyckelhalets-paverkan-produktutveckling-2015.pdf?_t_id=1B2M2Y8AsgTpgAmY7PhCfg%3d%3d&_t_q=nyckelh%c3%a5let&_tags=language%3asy%2csiteid%3a67fa9c486-281d-4765-ba72-ba3914739e3b&_t_ip=212.247.16.98&_t_hit.id=Livs)
I. Objectives pursued by national implementation measure

The Swiss Food Labelling Law has undergone two major revisions with respect to the Regulation (EU) No. 1169/2011 (FIR). The Federal Office for Public Health from the Federal Department of Home Affairs waited until December 3, 2013, before first mentioning the FIR as a reference in the revision documents. It explained as “important changes” the new “BIG 7” form and order of the nutrition declaration as follows:

The current order of the nutrition labelling will change with this revision, so that “unfavourable” nutrients for the consumers are visible first. So the energy value will newly be followed in descending order by the content of fat, carbohydrates and protein. If the salt content is specified in the nutrition labelling, it will be reported as salt and not as sodium in the nutrition table - which improves the understanding for consumers.102

However, this revision in contrast to the FIR did not make the nutrition declaration mandatory. In 2013 Switzerland also adopted the obligation to label “formed meat” (Annex VI 7. FIR), and regulated that allergenic ingredients must be emphasized in the ingredients list (Article 21 FIR). Other provisions from the FIR have been left aside arguing that they did represent neither necessary information for the Swiss consumer nor barriers for trade.

This approach of the Swiss legislator is called “autonomous implementation” and gave Switzerland the picture of the “cherry picking” country with respect to EU Food Law.

In 2013 Switzerland started to revise its Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA): “The EU system recognizes today’s globalization of the food market and is based on a single European economic area without border control from. Strict requirements for imports from third countries apply. If Switzerland wants to facilitate trade in goods with the EU, they must create the necessary legal framework and harmonize technical regulations with those of the EU.”103 As the National Council began with the consultations on the revision of the Food Act, he was under the impression of the “Lasagne-scandal” with undeclared horsemeat. The call for stricter rules for the declaration of the origin of raw materials in food was a major concern during the debate and prolonged the time for the adoption of the Act in June 2014. With the new FSA the declaration of origin of raw materials will stay a non-mandatory provision, but may be regulated in implementing ordinances, as it is the case already today.

As a follow up the second revision of the Ordinances of 2015 is still ongoing. The consultation for the proposal of the new Food Law Ordinances ended on October 31, 2015. Even though the assessment of the consequences of this new revision foresees an elevated financial burden for the Swiss Food Industry, the Swiss Food Industry supports the adoption of the revision, if it is in harmonization with the FIC-Regulation. Nevertheless, several provisions in compliance with the FIR have been criticised by other stakeholders. It is at date unclear, if this revision will finally be adopted and enter into force in 2016.

II. Notification procedure under TRIS

Some Ordinances being part of the 2015 Revision have been notified in the TRIS procedure:

<table>
<thead>
<tr>
<th>Switzerland</th>
<th>2015/9507/CH</th>
<th>• Ordinance on materials and articles intended for contact with foodstuffs (OMACF, unofficial translation)</th>
<th>2015-10-12</th>
<th>2016-01-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>2015/9508/CH</td>
<td>• Ordinance on hygiene during the handling of foodstuffs (OHF, unofficial translation)</td>
<td>2015-10-12</td>
<td>2016-01-13</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2015/9509/CH</td>
<td>• Ordinance on dietary supplements (ODS, unofficial translation)</td>
<td>2015-10-12</td>
<td>2016-01-13</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2015/9504/CH</td>
<td>• Ordinance concerning information relating to food (OIF, unofficial translation)</td>
<td>2015-10-05</td>
<td>2016-01-06</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2015/9505/CH</td>
<td>• Ordinance on foodstuffs and commodities (OFC, unofficial translation)</td>
<td>2015-10-05</td>
<td>2016-01-06</td>
</tr>
</tbody>
</table>

With respect to the Ordinance concerning information (OIF) relating to food the message of the notification states: “This ordinance constitutes a harmonisation with the legislation of the main economic partner (the EU). The proposal contains an obligation to declare the country of production and the origin of main raw materials on every foodstuff. In the EU, the country of production must only be declared in cases where its absence could deceit the consumer.”

With respect to TBT and SPS aspects the drafts have been considered to have no significant impact on international trade.
IIII. Labelling requirements for non-prepacked food

Today non-prepacked foodstuffs are exempted from the mandatory labelling requirements, if the information of consumers is guaranteed in other ways (e.g. by oral information), article 36 para. 1 Ordinance on Food Labelling (SR 817.022.21). There are three exemptions to this: 1. Health or nutrition claims with regard to a foodstuff may not be made, if the mandatory information for such claims like the recalling of the importance of a varied and balanced diet and a healthy lifestyle are not made in a written form. 2. The treatment of ionizing radiation and the use of GMOs, and 3. the country of production of meat, meat preparations and meat products need to be indicated in written form. This written information needs to be provided “in an appropriate manner”. In restaurants, hospitals, canteens or similar establishments, it can be mentioned in the menu or be attached to a poster (article 36 para. 2 Ordinance on Food Labelling).

The new article 5 OIF requires for non-prepacked foods the following information in written form: the origin of meat and fish, the allergens, the use of GMOs, the application of specific technological processes such as ionizing radiation and the use of hormonal or non-hormonal growth promoters. All other information can be given orally, as it is the case today.

The explanatory note of the legislator to this proposal states: “Basically, for consumers of non-prepacked foods the same information has to be available as for pre-packaged foods. However, this information can be given orally and does not necessarily take place in writing. But there are details that are so important for reasons of health or the protection against misleading, that they should be available in written form in any case. Several events and parliamentary interventions carried out with stakeholders (consumer organizations, trade, food industry, law enforcement, etc.) have shown that written information is desired in particular for foods of animal origin regarding the origin of the animals, for fish regarding fishing areas, for foods of animal origin regarding performance enhancers, and for all foods regarding allergens, the treatment with ionizing radiation and the use of genetically modified organisms. These concerns were accommodated.”
IV. Labelling requirements for pre-packed food

1. National measures on additional mandatory particulars (Article 39 FIR)

The aim of the latest Food Law Revision (2015) is described as follows: “Materially, now the newly proposed provisions are based largely on EU law. The aim is to achieve in Switzerland at least the same high level of protection for consumers as in our neighbouring countries. At the same time existing barriers to trade should be reduced and the creation of new barriers should be avoided. With regard to the obligation to indicate the country of production, the Parliament has derogated from this principle and has decided to implement specific Swiss rules. According to this the country of production for prepacked foods must be indicated, while in the EU this only needs to be specified, if the consumers would be misled without this information.”

2. Alcoholic beverages (Article 41 FIR)

Switzerland abandoned the obligation for an ingredients list on beverages containing more than 1.2 % alcohol content with the Revision in 2013.

3. Expression of net quantity (Article 42 FIR)

The Ordinance on the expression of net quantity in open sales and on pre-packed foods (SR 941.204) regulates the Swiss provisions for this food labelling requirement.
V. Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

In Switzerland, it has been a general rule that food labelling can be made in one of the three national languages (German, French, Italian) and this all over Switzerland, independent from the place where the product is marketed. In praxis and exceptionally, information may also be made in a language other than an official language, if the consumers are thereby sufficiently and unequivocally informed (article 26 para. 4 Ordinance on Food and Utility Articles, SR 817.02).

With the revision 2015, the Swiss legislator introduces the requirement to label “warning indications” in the official language or the official languages of the place, at which the food is placed on the market. For products that are marketed all over Switzerland this means that such warnings must be labelled in all three official languages, while all the other information can be only in one official language. This seems to be contrary to the aim of the Federal Act on technical trade barriers (THG; SR 946.51) reducing trade barriers. The concerned “warning indications” are not defined and can probably not be conclusively defined. If, for example, the “emphasised” allergens in the list of ingredients constituted warning labels. It is not clear either, if for example the reference to the importance of a varied and balanced diet and a healthy lifestyle for a health claim constitutes such a warning. The provision is not tangible and cannot be implemented in practice, as long as the legislator does not precisely define and restricts the concerned warnings to all those indications that are indispensable for the protection of public health.

VI. Application and enforcement

Today he who deliberately or negligently delivers wrong or deceiving information on foods or omits or incorrectly indicates mandatory labelling information concerning food, commits a criminal offence punishable
with imprisonment or penalties up to 50,000.00 CHF Euros (article 48 FSA). In most of the (minor) cases the authorities issue a caution without a charge (article 48(3) FSA). A criminal complaint will be reported in the case of grave misleading or recurrence. In the area of advertising, a criminal procedure is also possible against media, publishing houses or outsourced advertising agencies for aiding and abetting (article 48(2) FSA).

The New FSA foresees better coordination and harmonization of the national food control operations and the new opportunity for the federal government and the cantonal enforcement authorities to specify control frequencies. It stands for facilitated conditions for small food business operators, which may be exempt from fees and penalties for minor violations and have to respect a simplified self-control. In the case of a violation of the Food Law the food control authorities can issue orders, which may contain sales bans, prohibitions of names or advertisements and brochures.

VII. Miscellaneous / Comments

The coming into force of the revised FSA and the new Ordinances is planned for 2016. However, today it is not clear, if the latest revision of 2015 will pass the newly constituted Swiss Parliament. A final report on national implementing measures with respect to the FIR will only be possible after this.
UNITED KINGDOM

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Introduction

The UK national measures for Regulation (EU) No 1169/2011 on the provision of food information to consumers (‘FIC’\(^{104}\)) are found in four statutory instruments; one for each UK nation:

i. The Food Information Regulations 2014 SI 2014/1855, which apply in England;
ii. The Food Information (Wales) Regulations 2014, SI 2014/2303;
iii. The Food Information (Scotland) Regulations 2014, SI 2014/312; and

There are no material differences between the provisions of each statutory instrument as each nation endeavoured to take a common approach to the derogations available under FIC; therefore, the following commentary is applicable to the statutory instruments of all four nations unless we specify otherwise.

For the sake of convenience, therefore, we will refer to the four statutory instruments collectively as the Food Information Regulations or ‘FIR’ for the remainder of this chapter.

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Objectives pursued by national implementation measure / Scope of national implementation measure

The two principle objectives of FIR are to introduce national enforcement measures and to exploit certain derogations contained in FIC.

The provisions of FIR can be split into three main groups:

1. national measures as permitted under FIC in relation to non-pre-packed food\textsuperscript{105}, Milk and Milk Products\textsuperscript{106} and minced meat\textsuperscript{107};
2. national enforcement measures\textsuperscript{108}; and
3. revocations and consequential amendments to existing statutory instruments\textsuperscript{109}.

The authorities given responsibility for food labelling policy and enforcement under FIR differ across the UK. We set out below which authorities have responsibility for labelling policy and which have enforcement responsibilities in each of the nations; hereafter referred to collectively as the ‘Enforcement Authority’:

v. England: the Department for Environment, Food & Rural Affairs (DEFRA) is responsible for food labelling policy and local authorities (including non-metropolitan district councils) and port health authorities have responsibility for enforcement.

\textsuperscript{105} FIC, Article 44
\textsuperscript{106} FIC, Article 40
\textsuperscript{107} FIC, Article 17 and Annex VI
\textsuperscript{108} Approaches to enforcement may differ between nations, in particular, enforcement notices are not used in Scotland (see below for more details)
\textsuperscript{109} The most significant being the revocation of almost all of the Food Labelling Regulations 1996 (in respect of England, Wales and Scotland) and the Food Labelling Regulations (Northern Ireland) 1996.
vi. Wales: the Food Standards Agency (FSA) Wales is responsible for food labelling policy and local authorities have responsibility for enforcement.

vii. Scotland: the FSA Scotland is responsible for food labelling policy and local authorities have responsibility for enforcement.

viii. Northern Ireland: the FSA Northern Ireland is responsible for food labelling policy and district councils have responsibility for enforcement.

Notification procedure under TRIS

The UK duly notified the Commission of the envisaged FIR on 18 July 2013 in accordance with Article 45, FIC\textsuperscript{110}.

In accordance with Article 44 ‘National measures for non-prepacked food’, the UK used its authority to introduce national measures relating to non-prepacked food. The notified draft indicated that the UK proposed to introduce the following national measures:

- the provision of allergen information for non-prepacked foods;
- additional mandatory particulars in relation to the name of the product on non-prepacked food;
- Quantitative Ingredient Declarations on the meat content/ingredient of meat products sold non-prepacked.

The Commission did not issue a detailed opinion on the notification, but did issue comments in relation to the proposed provisions relating to Quantitative Ingredient Declarations on non-prepacked meat, Regulation 7 and Schedule 2\textsuperscript{111}, which specifies food products to which Regulation 7 doesn’t apply.

\textsuperscript{110} Notification number: 2013/394/UK

\textsuperscript{111} UK Observations - Communication from the Commission - TRIS/(2013) 02693
The Commission commented on Point 1 of the Schedule, which states that ‘Raw meat to which no ingredient other than proteolytic enzymes has been added’ is one of the exempted products. In respect of the term ‘proteolytic enzymes’, the Commission asked the UK authorities for clarification regarding their function (i.e. whether they are processing aids, additives or other).

The UK authorities replied as follows:

“Proteolytic enzymes can be added in very small quantities to some raw meats as ‘meat tenderisers’ to help the meat become tender and palatable when it is cooked. Once the food is cooked (heat treated) the enzymes no longer exert a technological function in the final food.

The function of the proteolytic enzymes on meat is as a processing aid as defined in EU legislation on food additives (EC) No. 1333/2008. Once the positive list of food enzymes is established, such use will also need to be in compliance with Regulation (EC) No 1332/2008 on food enzymes.”

The Commission’s response was:

‘Following these explanations it is clear that ‘proteolytic enzymes’ fall within the scope of Regulation (EC) No 1332/2008 on food enzymes pursuant to Article 3 defining the scope of the Regulation. However, there are certain food enzymes exempted from the scope of this Regulation pursuant to its Article 2(2).

Therefore in order to ensure clarity and correct application of Regulation (EC) No 1332/2008, the UK authorities are kindly invited to indicate in the notified draft regulations that ‘proteolytic enzymes’ fall within the scope of Regulation (EC) No 1332/2008 on food enzymes and shall comply with the requirements contained therein.

It should also be noted that when the EU list of food enzymes is
established pursuant to Article 17 of Regulation (EC) No 1332/2008, Article 4 of this Regulation provides that only food enzymes included in this list may be placed on the market as such and used in foods.’

FIR was adopted on 15 August 2014. The adopted legislation remains fundamentally the same as the notified draft regulations, albeit with some revisions to the language and presentation.

The reference to ‘proteolytic enzymes’ in Point 1 of the Schedule112 is currently unchanged and no indication is given in FIR that ‘proteolytic enzymes’ fall within the scope of Regulation (EC) No 1332/2008 on food enzymes as recommended by the Commission.

**Commencement dates**

The dates for compliance with FIC are staggered over a number of commencement dates, albeit the majority of provisions came into force on 13 December 2014.

The other key dates for FIR compliance are/were:

- 19 September 2014 when the derogation relating to minced meat came into force (in all nations except Scotland);113
- 13 December 2016 when the mandatory requirements relating to nutrition declarations under FIC must be met;
- 13 December 2018 when the remaining national rules contained in the Food Labelling Regulations 1996114 and the Food Labelling Regulations (Northern Ireland) 1996 will be revoked; and
- 13 December 2021 when Regulations 5, 6, 7 and 12 of FIR will cease to have effect in England.

112 Now Schedule 3 in FIR
113 Regulation 4, FIR (see also section 7 below)
114 For England, Wales and Scotland
The remaining national rules contained in the Food Labelling Regulations, referred to above, relate to the composition of cheese and cream and descriptions of drinks with less than 1.2% alcohol, however, they are only applicable to food produced within the UK. These national rules provide for:

- compositional requirements for traditional UK cheeses (Cheddar, Blue Stilton, Derby, Leicester, Cheshire, Dunlop, Gloucester, Double Gloucester, Caerphilly, Wensleydale and White Stilton)
- compositional requirements for certain creams (Clotted cream, Double cream, Whipping cream, Whipped cream, Sterilised cream, Cream or single cream, Sterilised half cream and Half cream); and
- conditions of use when using the terms alcohol-free, dealcoholized, low alcohol or non-alcoholic.

Products that are on the market or labelled prior to 13 December 2014 can be sold through until stocks are exhausted under transitional arrangements. The Competent Authorities have indicated that they are aware that this could take some time, even years, in the case of products with a long shelf life, such as frozen, dried and canned products.

National measures as permitted under FIC

Allergen labelling (Article 44(1)(a) FIC, Regulation 5 FIR)

Mandatory allergen information should be provided for all non-pre-packed foods. The information can be communicated in a variety of ways, including orally, but it must be made easily available to the consumer at the place where they make their food choice. It is not sufficient to say all foods ‘may contain allergens’.

This information can be provided in writing by way of food labels, menus, chalkboards and/or electronic or web-based tools, but it must be clear and conspicuous, not hidden away, easily visible, legible and accurate.
If information is to be provided orally, there must be a written notice signposting that details of the relevant allergens can be obtained by asking a member of staff. A suitable system must be in place to ensure that allergen information provided orally is accurate, consistent and verifiable when challenged. Verification should be provided in writing, e.g. a recipe book, ingredients chart or matrices.

In catering establishments, allergen information can be provided for an entire dish or with components separated to give consumers more choice, e.g. BBQ Chicken Burger without coleslaw for a customer allergic to mustard: **BBQ Chicken Burger and coleslaw** *(Chicken burger: wheat; BBQ sauce: celery, fish; Bap: wheat, eggs and sesame; Coleslaw: egg, celeriac, mustard).*

Where non-prepacked food is sold by means of distance selling (e.g. home delivery orders by telephone or online), allergen information must be made available before the purchase is concluded. This can be done orally or in writing but must be provided in writing upon delivery (e.g. via a menu or a sticker on the packaging).

**Mandatory particulars (Article 44(1)(b) FIC)**

In addition to the provision of allergen information, FIR contains two further national measures in respect of non-prepacked foods. These relate to:

- The name of the food; and
- **QUID** on meat products.

**Name of Food (Regulation 6 FIR)**

There is a mandatory requirement to provide the name of non-prepacked foods in accordance with Article 9(1)(a) and Article 17 of FIC.

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115 Quantitative Ingredient Declaration
This requirement applies to:

- any non-prepacked food (also referred to as loose food) that is offered for sale to a final consumer or a mass caterer; and
- food packed on the premises at the consumer’s request (e.g. sandwiches made and sold from the premises in which they are made).

The requirement doesn’t apply to food offered by a mass caterer (as part of their business as a mass caterer), which is prepared ready for consumption.

Except in the case of sales by means of distance communication, the name must be provided:

- ‘on a label attached to the food, or
- on a notice, ticket or label that is readily discernible by an intending purchaser at the place where the intending purchaser chooses that food’ – i.e. it must be visible in close proximity to the food where the consumer makes the decision to purchase. For example, in a bakery selling fresh cakes, the name of the cake could be provided on a label at the front of the shelf where the cakes are displayed.

QUID on meat products (Regulation 7 FIR)

Any non-prepacked foods and foods packed on the premises at the consumer’s request that contain meat and any other ingredient must be accompanied by a declaration of the quantity of meat in accordance with Article 9(1)(d), as read with Article 22 and Annex VIII of FIC.

There are certain exceptions to this requirement, including raw meat to which no ingredient has been added; Sandwiches and filled rolls which are ready for consumption without further processing (except burgers) and pizzas, amongst others.\textsuperscript{116}

\textsuperscript{116} Schedule 3, FIR
The conditions for presentation of this information are the same as those for the name of the food (i.e. a label attached to food or a ‘readily discernable’ notice, ticket or label) and do not apply to sales by distance communication\textsuperscript{117}.

Again, this regulation does not apply to food prepared to be ready for consumption by a final consumer sold by a mass caterer (as part of their business as a mass caterer).

**National measures on additional mandatory particulars (Article 39 FIR)**

The following national measures also apply to pre-packed foods:

**Minced meat (Regulation 4 FIR):**

In the UK minced meat that doesn’t comply with the compositional requirements in Annex VI of FIC can still be sold under the national mark, ‘For UK Market Only’. This mark must also be provided on non-pre-packed minced meat that does not meet the Annex VI requirements.

This derogation, which permits UK market minced meat to contain higher levels of fat and collagen, is subject to a review after three years.

**Milk and milk products (Article 40 FIC, Regulation 3 FIR):**

It is still common place in the UK for some consumers to purchase milk from a milk rounds man (commonly referred to as a milkman). The milk is delivered by the milkman in reusable glass bottles, which are taken away by the milkman to be sterilised and refilled at the dairy.

\textsuperscript{117} Note this distance communication exception does not apply in Scotland.
Accordingly, Regulation 3 provides that the requirements laid down in Articles 9(1) and 10(1) do not apply to milk or milk products presented in a glass bottle where the glass bottle is intended for reuse.

Expression of net quality (Article 42 FIR):

Prior to the commencement of FIC, quantity labelling was governed by national law, however, any conflicting or overlapping national rules on quantity labelling have been revoked.

National rules have been retained for loose foods, foods sold in open containers, foods sold for direct sale or certain wholesale transactions.

The enforcement of the net quantity provisions of FIC are treated differently in that they are enforced under the Weights and Measures Act 1985 (in the same way as the previous national rules) rather than FIR. Section 31A of the Act makes it an offence to fail to comply with Article 8, Article 9(1)(e) or Chapter V of FIC to the extent they relate to net quantity.

Irradiated Food (Regulation 8 FIR):

Regulation 8 provides that foods which have been irradiated must be labelled as ‘irradiated’ or ‘treated with ionising radiation’. Similarly, irradiated food ingredients must also be indicated in the in the list of ingredients.

Irradiated food sold in bulk must have the indication on a display or notice above or beside the container in which the products are placed.

Labelling requirements for pre-packed and non-prepacked food: Use of language (Article 15(2) FIR)

Mandatory food information must be given in English as this is the language that is most easily understood by consumers in the UK. However,
information can be provided in other languages in addition (for example, Welsh) on a voluntary basis.

If only marketed in the UK, information voluntarily given in another language will not have to be given in the minimum font size. However if it is to be marketed in another Member State with a different national language, the minimum font size requirement must be met.

NATIONAL ENFORCEMENT MEASURES

Enforcement in England, Wales and Northern Ireland

Failure to comply with FIR can be a criminal offence. There are two principle offences under FIR which could result in a criminal prosecution being brought against the food business:

5. Regulation 10: Failure to comply with the allergen requirements under FIC and Regulation 5 of FIR\textsuperscript{118}; and
6. Regulation 12(1)(b): Failure to comply with an improvement notice.

For the first time, FIR affords Competent Authorities (typically Trading Standards Officers (“TSO’)) the power to use improvement notices to deal with food labelling breaches that are not safety related. A TSO may issue an improvement notice where he/she has reasonable grounds for believing that there has been failure to comply with any of the provisions of FIC listed in Schedule 5 of FIR\textsuperscript{119} or Regulations 5, 6, 7, or 8 of FIR.

\textsuperscript{118} Specifically, Article 9(1)(c) of FIC as read with Annex II; Article 21(1)(a), as also read with Articles 9(1)(c) and 18(1) and Annex II; the second subparagraph of Article 21(1), as also read with Articles 9(1)(c) and 19(1) and Annex II; and Article 44(1)(a), as also read with Article 9(1)(c) and Regulation 5 of FIR

\textsuperscript{119} i.e. Articles 6 – 10 (excluding Article 9(1)(l) until 13 December 2013), 12 - 15, 17 – 18, 21 – 22, 24 – 28, 30 – 37, 44 and 54.
The notice must:

- state the TSO’s grounds for believing that there has been a failure to comply with the relevant EU FIC provision;
- specify what the failure is, including what provision(s) have been breached;
- specify what measures need to be taken in order to secure compliance; and
- specify the date by which the measures must be put in place.

There is a right of appeal to the First-tier Tribunal in England, and to the Magistrates Court in Wales and Northern Ireland and the improvement notice will detail this. If there is no successful appeal there is no alternative but to comply with the improvement notice, as indicated above, it is a criminal offence not to comply.

A person found guilty of an offence under FIR will be liable to an unlimited fine.

While there are limited offences under FIR, there are a wide range of offences in other legislation that may be used to bring a prosecution where the failure gives rise to a breach of that other provision, for example, where the failure to comply with FIC results in a food being unsafe. For food safety offences, there has been a recent trend for an increase in fines for food safety prosecutions. New guidelines have been created by the Sentencing Council, which advises the judiciary on the appropriate way to approach sentencing, covering ‘Health and safety offences, corporate manslaughter and food safety and hygiene offences guidelines’, which are anticipated to come into force in early 2016 and are expected to increase the levels of fines for food safety offences, including those relating to food labelling, even further.

Typically, however, most food labelling challenges are resolved without the regulator proceeding with a prosecution or formal enforcement action. It is common for food businesses to be given the opportunity to
rectify the non-compliance, for example, by ‘over-labelling’ or ‘over-sticking’ the incorrect product label with a corrected version or by replacing the incorrect label with a correct one.

**Enforcement in Scotland**

The enforcement regime is different in Scotland in that there is no provision for improvement notices to be issued. Instead, the Food Information (Scotland) Regulations 2014 create five offences. These are failure to comply with:

- Any specified FIC provision\(^{120}\);
- Regulation 5(3), (4) or (5);
- Regulation 6(1) as read with 6(4);
- Regulation 7(1) as read with 7(5); and
- Regulation 8(1) or (3).

The sanctions are the same as for the other nations; an unlimited fine if found guilty.

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\(^{120}\) As above, Articles 6 – 10 (excluding Article 9(1)(l) until 13 December 2013), 12 - 15, 17 – 18, 21 – 22, 24 – 28, 30 – 37, 44 and 54
### ANNEX I: TRIS NOTIFICATIONS

<table>
<thead>
<tr>
<th>Member State</th>
<th>Law or draft law</th>
<th>TRIS reference</th>
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<tr>
<td>Austria</td>
<td>Decree on Allergen Information of 10.7.2014</td>
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<tr>
<td>Belgium</td>
<td>Royal Decree establishing provisions for the declaration of certain substances or products causing allergies or intolerances as regards non pre-packaged foods 2014/154/BE</td>
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<td>Bulgaria</td>
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<td>Croatia</td>
<td>Rules concerning the provision of information on non-prepacked food to consumers 2014/396/HR</td>
<td>2014/396/HR</td>
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<tr>
<td>Cyprus</td>
<td>The Foodstuffs (Control and Sale) (Amendment) Law of 2015 The Foodstuffs (Control and Sale) (Amendment) Law</td>
<td>2015/44/CY 2014/648/CY</td>
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<td>Czech Republic</td>
<td>Draft of the Decree of the Ministry of Agriculture of the Czech Republic on certain arts of food labelling requirements</td>
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<tr>
<td>Denmark*</td>
<td>Order concerning the use of the Keyhole symbol</td>
<td>2014/306/DK</td>
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<td>Estonia</td>
<td>Draft Minister for Agriculture Regulation entitled “Requirements for the provision of food information on non-prepacked foods”</td>
<td>2014/559/EE</td>
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<td>Finland</td>
<td>Decree of Ministry of Agriculture and Forestry on the provision of particulars on food Decree of Ministry of Agriculture and Forestry on the labelling of certain foods as being high in salt</td>
<td>2014/208/FIN 2014/231/FIN</td>
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<td>France</td>
<td>Decree amending the Consumer Code with particular regard to consumer information on allergens and non pre-packaged foods</td>
<td>2014/352/F</td>
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<tr>
<td>Germany</td>
<td>Vorläufigen Verordnung zur Ergänzung unionsrechtlicher Vorschriften betreffend die Information der Verbraucher über die Art und Weise der Kennzeichnung von Stoffen oder Erzeugnissen, die Allergien und Unverträglichkeiten auslösen, bei unverpackten Lebensmitteln (Vorläufige Lebensmittelinformations-Ergänzungsverordnung – VorlLMIEV) v. 28.11.2014</td>
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</table>
|              | Preliminary Decree on the completion of Union law on consumer information on the way of labelling of non-prepacked food of substances or products triggering allergies and intolerances  (Vorläufige Lebensmittelinformations-Ergänzungsverordnung- VorlLMIEV)  
(no notification)  
<p>| Greece       | Joint ministerial decision concerning the adoption of national implementing measures for Article 44 of Regulation (EU) No 1169/2011 on the labelling of allergens on non-prepacked food                                         | 2014/120/GR     |
| Hungary      |                                                                                                                                                                                                                 |                 |
| Ireland      | Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations 2014                                                                                                  | 2014/339/IRL    |
| Italy        |                                                                                                                                                                                                                 |                 |</p>
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<tr>
<td>Latvia</td>
<td>Requirements for the provision of non-prepacked food information</td>
<td>2015/126 /LV</td>
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<td>Commodities Act (Allergen Information for Non-Prepackaged Foodstuffs) Regulation</td>
<td>2014/176/NL</td>
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<td>Romania</td>
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<td>Decree of the Ministry of Agriculture and Rural Development of the Slovak Republic on food labelling requirements</td>
<td>2015/18/SK</td>
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<td>Decree implementing Regulation (EU) on the provision of food information to consumers</td>
<td>2014/186/SI</td>
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<td>Spain</td>
<td>Draft royal decree adopting the general standard on food information for non-prepacked food intended for sale to the final consumer and mass caterers, for food packed at the point of sale at the request of the buyer and for food packed by owners of retail businesses</td>
<td>2014/255/E</td>
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<td>Sweden*</td>
<td>Regulations amending the National Food Administration’s regulations (LIVSFS 2005:9) on the use of a particular symbol</td>
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<td>United Kingdom</td>
<td>The draft Food Information Regulations 2013</td>
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<td>The draft Food Information Regulations (Northern Ireland) 2013</td>
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<td>The draft Food Information (Wales) Regulations 2013</td>
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<td>Norway*</td>
<td>Amendment of the regulation on voluntary labelling of foods with the Keyhole</td>
<td>2014/9007/N</td>
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<td>Iceland*</td>
<td>Regulation on the use of the Keyhole label in the marketing of foodstuffs</td>
<td>2014/9016/IS</td>
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<td>2012/9008/IS</td>
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<td>Non-EU countries</td>
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<td>Albania</td>
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<td>Serbia</td>
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<tr>
<td>Switzerland</td>
<td>2015/9504/CH</td>
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</tbody>
</table>
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<thead>
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<th>Firm Name</th>
<th>Contact Person</th>
<th>Website</th>
<th>Email</th>
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<tbody>
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<td>Italy</td>
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