EU-Food Information Regulation 1169/2011

Implementing Measures by Member States

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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 States[2]; national law incompatible with the Regulation became inapplicable. By moving from Directives to a Regulation in rulemaking on food labelling[3], 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 countries[4] 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.

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.[5] The principle of subsidiarity[6], 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"[7], specifically on non-prepacked foodstuffs, has prompted Union legislators to leave this area as exempt from coverage by full harmonisation.[8] This has been recognised by the European Commission in its "Better Regulation Package".[9] Hence, however insufficiently developed as an integration requirement[10], EU lawmakers' regard for the interests of small and medium sized enterprises (SMEs) in retail, crafts and gastronomy within the food sector[11] led to their allowing Member States to define the right degree of regulation. The concept of "micro-enterprise"[12] or "micro-entities"[13] may be borrowed from areas other than food law in the *acquis communautaire,* but the Commission's Guidance Document Regulation 853/2004[14] provides helpful references to defining what constitutes a "small business" as well as "marginal, localised and restricted activity." In this respect the FIR is a welcome example of SME interests being reflected in the "rather complete and mature"[15] – or saturated – legal framework of EU food law, which is often geared towards larger operators.

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 choses (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.[16] 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 prepacked is referred to as 'loose goods'. Union law defines what is 'prepacked' 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.

1. Definition of 'pre-packed food'

What had been defined as 'pre-packed foodstuff' in its predecessor Directive[17], is defined as 'pre-packed food' for the purposed 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":

Article 2(2) of Directive 76/211/EEC	**Article 2(2)(e) FIR**
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.”	‘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

Article 2(2)(e) FIR prevails as *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 Fitness and Performance Programme”[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 prepacked products. A stakeholder consultation has been conducted[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.[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[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 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.[22] 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).[23] 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 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 question[25]:

“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 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 alterative 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]

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 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[28] glass bottles with indelible (non-removable) marks (not labels[29]) already benefit from certain derogations under Article 16(1) FIR[30]. National law may further advantage producers by exempting them from displaying particulars[31] – which are otherwise mandatory for milk and milk products[32] – 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.[33] In order to determine whether such labelling would be appropriate, the Commission was required to issue a report by December 2014[34]. 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 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 Commission explains its approach in its answer to a parliamentary question[36]:

“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 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.