



**NATIONAL IMPLEMENTING
REGULATION ON THE
EUROPEAN REGULATION
NO 1169/2011**



CONTENT

NATIONAL IMPLEMENTING REGULATION ON THE EUROPEAN REGULATION NO. 1169/2011

Austria <i>Andreas Natterer, Iliyana Sirakova</i>	3	Netherlands <i>Victor van Ahee, Natasja Brusik</i>	23
Belgium <i>Aude Mahy</i>	6	Norway <i>Marie Vaale-Hallberg</i>	24
Baltic States <i>Rauno Kinkar, Tadas Vilčinskas, Kaspars Linters</i>	8	Portugal <i>Francesco Montanari</i>	26
Croatia <i>Marko Kapetanovic</i>	12	Poland <i>Grażyna Osęka, Jowita Prokop</i>	27
Czech Republic <i>David Štros</i>	14	Romania <i>Oana Constantinescu</i>	29
Danmark <i>Martin Gantzhorn, Gundula Maria Kjær, Lise Aagaad</i>	15	Slovakia <i>David Štros</i>	30
France <i>Antoinne de Broses, Adrien Cairllavet</i>	17	Slovenia <i>Petra Smolnikova</i>	31
Germany <i>Bärbel Hintermeier</i>	20	Spain <i>Mónica Weimann</i>	32
Italy <i>Cesare Varallo</i>	21	Sweden <i>Magnus Friberg</i>	35
		UK <i>David Hetherington</i>	36

Edition
April 2017

Editor
Prof. Dr. Alfred Hagen Meyer
Bärbel Hintermeier

meyer .
rechtsanwälte

Sophienstrasse 5
D - 80333 Munich
Fon +49 (0)89 5506988-0
meyer@meyerlegal.de
www.meyerlegal.de

Graphic Design & Layout

Kullmanndesign
kullmann-design.com

This issue of our newsletter focuses on REGULATION (EU) No 1169/2011 and the provision of food information to consumers and the different national implementing regulations such as regarding:

- national regulations on allergens (Art. 44 Reg. 1169/2011)
- national regulation regarding non-prepacked food (Art. 44 para. 1 lit. b Reg. 1169/2011)
- national sanction system concerning Reg. 1169/2011
- further changes within national law concerning Reg. 1169/2011, f.ex. (national) law on cheese or beer

The newsletter aims at providing a useful compendium on this topic with open access. It comprises the collection articles regarding the legislation within 21 member states of Europe.

A big thank you goes to our colleagues from all over Europe for their support with regard to this comprehensive collection of articles.

We hope you enjoy reading.

Prof. Dr. Alfred Hagen Meyer

Bärbel Hintermeier

FIC AND THE AUSTRIAN IMPLEMENTING REGULATIONS

Authors: *Andreas Natterer, Iliyana Sirakova; schoenherr Österreich*

It has been six years since the Regulation on the provision of food information to consumers (EU) No 1169/2011 ("FIC") entered into force, and only a couple of months since it has become fully applicable (Art. 55 FIC); it is now time for a status check.

I. OVERVIEW OF THE CHANGES

While the FIC officially replaced the Austrian Labelling Regulation ("[LMKV](#)" – 1 January 2014 respectively 13 December 2014) and the Austrian Nutrition Labelling Regulation ("[NWKV](#)" – 13 December 2016) in almost all areas respective of the labelling of foodstuffs, it brought only minor changes to the Austrian legislation in place up to that point.

Most of the changes derive directly from the FIC provisions regarding¹:

- Extended and clarified responsibility of FBO²;
- Scope of application (all foodstuffs);
- Mandatory information for prepacked & non-prepacked food;
- Scope of application on all foodstuffs;
- Minimum font size;
- Obligatory nutrition labelling;
- Allergen labelling for non-prepacked food;
- Indication of the country of origin for fresh, chilled or frozen meat of swine, sheep, goats and poultry/indication of the primary ingredient;
- Date of freezing;
- Increased protection against misleading information/unfair competition;
- Nanomaterials.

Although the FIC harmonises European labelling laws to a large extent, it also authorizes Member States to adopt or maintain national measures for certain aspects of labelling (Art 38 FIC):

Article	Authorization to:	Status:
Art. 39	Adopt national measures on additional mandatory particulars	Nothing; no intention at the time to adopt measures for mandatory origin labelling
Art. 40	Adopt national measures on milk and milk products presented in glass bottles intended for reuse	No national measures
Art. 41	Maintain national measures as regards the listing of ingredients in the case of alcoholic beverages containing more than 1,2% alc. Vol.	The existing provision Sec.7 para. 1 subpara. 4 (1) LMKV was not maintained
Art. 42	Maintain national measures concerning the expression of net quantity for specified foods in a different manner to that provided for in Article 23(1)	No national measures
Art. 43	Adopt national measures on the voluntary indication of reference intakes for specific population groups	No national measures
Art. 44	Adopt National measures for non-prepacked food:	<ul style="list-style-type: none"> • No national measures; • Allergen Information Regulation (AllergeninformationsVO, BGBl. II No 2014/175)

Article	Authorization to:	Status:
Art. 15 para. 2	Adopt national provision on language	No explicit national provision
Art. 35 para. 2	Provide recommendations to FBO on additional forms of expression and presentation of the nutrition declaration	No national recommendation to FBO

¹ See also WKO, [Lebensmittelkennzeichnung NEU, 2011](#).

² Food business operators.

II. THE AUSTRIAN REGULATION ON ALLERGEN INFORMATION FOR NON-PREPACKED FOOD

The Regulation

Article 44 para. 2(a) FIC provides that where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale (e.g. restaurants, supermarkets, bakeries, etc.) information must be provided for any ingredient or processing aid listed in Annex II FIC or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form.

Thus, establishments such as restaurants, bakeries but also supermarkets that offer non-prepacked food have to provide information about allergens contained in the food they offer to consumers.

According to Article 44 para. 2, Member States may adopt national measures concerning the means by which the particulars or elements of those particulars specified in paragraph 1 are to be made available and, where appropriate, their form of expression and presentation.

Subsequently, Austria adopted the [Allergen Information Regulation](#)³, which entered into force and became applicable on 13 December 2014.

This implementing regulation is complemented by two guidelines and one recommendations of the Code Commission published by the Austrian Ministry for Health and Women⁴:

1. [Personnel Training Guideline](#)⁵ for allergen information (on the competence of persons authorised to communicate information on allergens verbally);
2. [Allergen Information Guideline](#)⁶ for non-prepacked food ("bulk products") (general information on internal company measures);
3. [Recommendation for written information](#)⁷ for non-prepacked food ("bulk products") (on abbreviations and letter codes).

The Main Provisions

The provisions of the Austrian Allergen Information Regulation stipulate that the FBO have to ensure that the information relating allergens as listed in Annex II of FIC in non-prepacked foods are communicated to the final consumer (Sec. 2) and are based on written documentation (Sec 4). The information has to be available and easily accessible, and it must be provided to the consumer without an explicit request (Sec. 3, para. 1). It is, however, sufficient to indicate in a prominent place and in a clearly visible and legible way that the information can be obtained orally on request (Sec 3, para. 2). The oral information on allergens must be communicated by a person trained for this; the training is to be repeated at least every three years whereby the proof of the training must be documented (Sec. 3, para. 3).

In accordance with the text of the Allergen Information Regulation, the FBO might provide the information in both a written and/or oral manner.

The Written Form

Allergen information may be displayed on a sign on or in the vicinity of the related food, on a notice board/posting, the menu, the pricelist or in electronic form. If the name of the food or its presentation clearly indicate the presence of an allergenic ingredient, it is not necessary to provide separate information for this product. However, FBOs would be well-advised to restrain themselves from applying this exception too liberally as to avoid misleading or even false information.

Abbreviations, symbols and letter codes may be used. The meaning of such must be explained nearby. The abbreviations or symbols for an allergen must be stated only once per product, even if the product contains multiple ingredients from the same allergen-group.

If an FBO chooses to use abbreviations or alphabetic characters in reference to the 14 allergens, it may use the list prepared by the Austrian Chamber of Commerce (WKO) and published by the Austrian Ministry of Health (which can be found in the [Recommendation for written information](#) – see list below) and visibly clarify that it has done so using the phrase "Allergen information according to Codex Recommendation"):

Abbreviation	Letter code
Gluten-containing grains	A
Crustaceans	B
Egg	C
Fish	D
Peanut	E
Soy	F
Milk or lactose	G
Edible nuts	H
Celery	L

³ Verordnung des Bundesministers für Gesundheit über die Weitergabe von Informationen über unverpackte Lebensmittel, die Stoffe oder Erzeugnisse enthalten, die Allergien oder Unverträglichkeiten auslösen können und über weitere allgemeine Kennzeichnungsbestimmungen für Lebensmittel– AllergeninformationsVO, BGBl. II Nr. 175/2014)

⁴ At date of publishing, still called the Federal Ministry of Health.

⁵ Leitlinie für die Personalschulung über die Allergeninformation im Sinne der AllergeninformationsVO, BMG-75210/0017-IB/13/2014 vom 24.07.2014.

⁶ Leitlinie zur Allergeninformation bei nicht vorverpackten Lebensmitteln ("offene Ware") im Sinne der AllergeninformationsVO, BMG-75210/0017-IB/13/2014 vom 24.07.2014.

⁷ Empfehlung zur schriftlichen Allergeninformation bei nicht vorverpackten Lebensmitteln ("offene Ware"), BMG-75210/0029-II/B/13/2014 vom 07.10.2014.

Abbreviation	Letter code
Mustard	M
Sesame	N
Sulphites	O
Lupines	P
Molluscs	R

The Verbal Form

Information on allergens in foodstuffs may be communicated to a consumer orally if a clearly visible and easily accessible written notice states that information is available upon request. The information must be provided by a trained person who handles requests regarding allergen information. Every establishment must have at least one such trained person on staff during all business hours.

The allergen information will be based mainly on the information received from the supplier. If foods are produced by the FBO, the allergen information is based on the ingredients and the recipe. With regard to daily offers or changes in the recipes/ menu, trained personnel must be informed accordingly.

Trained Personnel

According to the above-mentioned guidelines, the FBO must determine the person(s) responsible for compiling the required allergen information. Trainings can be carried out by in-house or external experts who have the relevant knowledge to teach:

Conveying the meaning, importance and effect of food intolerances, allergens and allergen information;

Sensitivity training related to inducing allergic reactions or intolerances;

Knowledge of the list of allergenic substances according to Annex II of FIC;

Knowledge about communicating allergen information within the establishment and methods of conveyance to end consumers.

Documentation verifying the training of the personnel must be stored for 3 years in the establishment. The national Food Inspection Authority is responsible for examining training verifications and documentation upon which oral allergen information is based.

Miscellaneous Labelling Provisions

The Austrian Allergen Information Regulation also includes some additional – rather misplaced – labelling provisions.

According to Sec 5 para. 1, non-prepacked foods that contain aspartame or aspartame-acesulfame salt pursuant to Reg. (EC) No 1333/2008 shall bear the warning 'contains a source of phenylalanine'. Non-prepacked foods with more than 10% polyols added must bear the notice 'excessive consumption may induce laxative effects' (Sec. 5 para. 2).

This information always must be provided in a written form, even if the allergen information is otherwise oral. These notices must be legible and permanently posted on a clearly visible sign or price list on or in the vicinity of the food, in mass caterer establishments on food and beverage menus, or in other cases, as a notice posted visibly to the end-consumer.

Finally, according to Sec. 7, it is prohibited to extend the date of minimum durability of prepacked foods. If the date of minimum durability has expired, the seller must indicate this fact in a clear and easily understandable manner.

III. CONCLUDING REMARKS

In summary, Austria has adopted only one regulation that implements the FIC, namely the Allergen Information Regulation. This regulation is rather pragmatic and allows sufficient leeway for FBOs on how and by whom the information is communicated, while guaranteeing that allergen information is made available to any end consumer.

Otherwise no new regulations implementing the FIC (especially not for origin labelling) are contemplated at present. Rather, Austria relies on the provisions of the FIC to keep the consumers well-informed and the market well-functioning.

Andreas Natterer is partner at schoenherr attorneys in Vienna. He provides legal service to national and international clients in the branches of dispute resolution, Litigation, Food Law and Pharmaceutical Law.



Iliyana Sirakova is an Associate at schoenherr attorneys since 2014. The main focus of her work lies within dispute resolutions.



schoenherr

Dr. Andreas Natterer, Partner
Iliyana Sirakova,
Rechtsanwaltsanwarterin/ Associate
**Schönherr Rechtsanwälte GmbH/
Schoenherr attorneys at law**
Schottenring 19
A-1010 Vienna
Austria
www.schoenherr.eu

BELGIAN IMPLEMENTING MEASURES CONCERNING REGULATION 1169/2011

Authors: *Aude Mahy; Loyens & Loeff*

The Belgian Act of 24 January 1977 on the protection of consumer health with respect to foodstuffs and other products is Belgium's basic legislation on the labelling and advertising of foodstuffs.

This federal act forms the legal basis for the adoption of related implementation measures by Royal Decree. Until the adoption of the Regulation 1169/2011, 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-packed foodstuffs;
- Royal Decree of 17 April 1980 on the advertising of foodstuffs.

With the entry into force of Regulation 1169/2011, a large majority of these provisions became redundant and/or inapplicable. Consequently, a substantial part of the Royal Decree on the advertising of foodstuffs has since been repealed. It is expected that the Royal Decree on the labelling of foodstuffs will eventually be repealed as well.

In addition, the Belgian authorities implemented rules on allergen declaration for non-prepacked foods in a separate Royal Decree of 17 July 2014, which will be discussed further below.

LABELLING REQUIREMENTS FOR NON-PREPACKED FOODS

1. Use of language (Article 15(2) Regulation 1169/2011)

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

2. Allergen labelling (Article 44(1)(a) Regulation 1169/2011)

National implementing rules on allergen declaration for non-prepacked food were adopted by Royal Decree of 17 July 2014, which entered into force on 13 December 2014.

In Belgium, allergens in non-prepacked foods may be declared either in writing or orally, but the obligations imposed on food business operators are stricter in the latter case.

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

- Any allergen must be listed in a clearly readable manner on a physical or electronic medium at the place where the product is offered for sale, freely and readily available before the purchase is concluded, but
- Due to an exception, such declaration is not mandatory when the name of the food is provided in writing and clear reference to the name of the substance or product is made (e.g. 'eggs').

If the operator chooses to communicate the allergen information orally, it must also implement a system to ensure safe and correct declaration. The allergen declaration must be provided at no additional cost to the consumer at his or her request by the operator, a staff member, or by means of a suitable device.

Moreover, internal 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 must 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. Furthermore, the staff must receive instruction about the risks posed by allergies and food intolerances as well as training on the internal procedures.

Finally, two additional written statements must be displayed to the consumer in each area where food is offered for sale within the establishment for both types of declaration (written and oral):

- A statement indicating the location where, or the means by which, the declaration of allergens is available and, if appropriate, a statement inviting the consumer to address the establishment's staff with further questions, and

- Another statement warning consumers that the product mixture may vary from one batch to another.

However, such additional statements are not mandatory if:

- the written declaration of allergens is provided in a conspicuous location and as such easily accessible 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
- the operator asked about the dietary needs of consumers respective of food allergies and intolerances in advance and will offer food on an individual basis in accordance with these dietary needs (e.g. on a flight or at the hospital).

After the adoption of the Royal Decree, the Federal Agency for the Safety of the Food Chain (which enforces its application) published a circular related to allergen information. Even though the circular is not binding, it provides food business operators with guidance on how to satisfy their obligation to give allergen information for non-prepacked foods. In particular, the circular offers specific recommendations aimed at helping operators meet legal requirements, notably in terms of traceability. It further provides specific guidance for operators that choose to provide allergen information 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 procedures as long as they lead to the same result.

3. Mandatory particulars (Article 44(1)(b) Regulation 1169/2011)

- **Cheese** - The Belgian legislature foresees an obligation to declare, for both pre-packed and non-pre-packed cheeses, the product’s fat content in grams of fat per 100 grams of the product (unless the product already contains a nutrition declaration) and, if applicable, the inedible nature of the rind. However, this legislation does not apply to cheeses legally produced and/or first placed on the market in another EU or EEA country or in Turkey.
- **Beer** – In Belgium, a list of ingredients in beer is not mandatory.
- **Minced poultry and preparation of poultry** – When intended for consumption, cooking, and sale in Belgium, the statement “Cook well before eating” (“Bien cuire à cœur avant consommation”) must appear on the label of poultry products. The indication must be in a clearly visible place just below the producer’s approval number and in a specific format designated in the regulation.
- **Raw milk sold to the final consumer via an automatic distributor** – The automatic distributor must make the following indications prominently: i) “Raw milk. Boil before use”; ii) “Store at a $t^{\circ} \leq +6.0^{\circ}C$ ”, and iii) “Use before [date in DD/MM]”. The limit may not exceed 72 hours after

the first milking from which there were remains of milk or colostrum in the batch used to supply the vending machine.

EXCEPTION FROM NUTRITION LABELLING: THE NOTION OF “DIRECT SUPPLY” (ANNEX V NO. 19, REGULATION 1169/2011)

The Belgian authorities clarified the concepts of food prepacked for direct sale and food supplied in small quantities directly from the manufacturer to the final consumer or to local retail establishments directly supplying the final consumer.

Regarding **food prepacked for direct sale**, the Belgian authorities have defined it as:

- Prepacked foodstuffs, on the package of which a best-before date or use-by date is indicated and which are sold either:
 - at the business where the food is produced – this expressly excludes processes such as cutting, slicing, portioning, defrosting, adding water to a dehydrated food, (re)conditioning, and other manipulations exclusively intended to enhance the presentation of the product; or
 - at a facility run by the same operator as where the food was produced, provided that the latter runs a maximum of five such entities.

OR

- Prepacked foodstuffs sold at the business where they were packed, provided that:
 - the product is sold no later than the day following the packaging; and
 - a packing date is indicated on the package, or the operator is able to prove to the authority that the food was sold the day following the packaging.

Food supplied in small quantities directly from the manufacturer to the final consumer or to local retail establishments directly supplying the final consumer is defined as:

- ‘**small quantities**’ means quantities produced by an operator that is either a micro-undertaking or a business that employs a maximum number of four persons;
- **local retail establishments** are retail establishments directly supplying end consumers within a radius of 80 km of the production establishment.

While this official explanation brings some clarity, it should be noted that the exceptions granted under Regulation 1169/2011 for these two categories of food may be implemented irregularly within the EU due to variations between such national guidance documents.

SANCTION SYSTEM (INCLUDING FINES)

When the authorities find a violation of labelling requirements for allergen information, they have the choice to send the offender:

- a warning letter, wherein the offender is asked to rectify the labelling violation. If the infringement is not corrected, an official report is made; or
- an official report, without warning. The offender may respond with a defence; and
- in addition to the report and seizure of the infringing goods, the relevant authorities may choose (without prejudice to the public prosecutor's right to investigate and prosecute the violation independently):
 - o to offer the offender resolution by means of paying an administrative fine of between 200 EUR and 40,000 EUR – if the administrative fine is paid, the offender may not be the subject of further criminal prosecution; or
 - o to send the official report immediately to the public prosecutor, who will decide whether or not to initiate criminal proceedings.

If the public prosecutor chooses to initiate criminal proceedings, the offender may be required ultimately to pay a fine of up to 96,000 EUR (depending on whether the violation was intentional or not).

Aude Mahy is attorney at law and counsel. She is a member of the Loyens & Loeff Litigation & Risk Management Practice Group in Belgium. She also heads the Benelux Food & Beverages Team.



LOYENS & LOEFF

Aude Mahy, attorney at law/counsel

LOYENS & LOEFF Advocaten

Woluwe Atrium

101-103 Rue Neerveld

1200 BRUXELLES

Belgique

www.loyensloeff.com

Baltic States

LITHUANIAN, LATVIAN AND ESTONIAN IMPLEMENTING REGULATIONS CONCERNING REG. 1169/2011

LITHUANIA

Author: *Tadas Vilčinskis; Lextal*

After the entry into force of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, the Government of Lithuania made appropriate changes to national legislation in the form of Hygiene Norm No. HN 119:2002 "Food labelling" (a consolidated version of 1 November 2016). The Hygiene Norm identified consumer information about food and food production labelling.

This article provides a short summary of the content of this Lithuanian implementing regulation.

STATE AUTHORITY

The State Food and Veterinary Service (SFVS) develops and implements the Government's policy in food safety and quality as well as in animal health and welfare. The SFVS is accountable to the Government of the Republic of Lithuania.

SCOPE OF APPLICATION AND GENERAL RULES

The above-mentioned Hygiene Norm indicates that the following data about a product should be included on its label:

- List of ingredients as established in Art. 17 of Regulation (EU) No. 1169/2011;
- Information on food additives as established in Art. 17 of Regulation (EU) No. 1169/2011;
- Certain substances or products causing allergies or intolerances as established in Art. 17 of Regulation (EU) No. 1169/2011;

- List of ingredients as established in Art. 18–20 of Regulation (EU) No. 1169/2011;
- Minimum durability date, “use by” date and date of freezing as established in Art. 24 of Regulation (EU) No. 1169/2011;
- other information as established by Regulation (EU) No. 1169/2011.

The information must be clear and easy to find on the label. It must be in Lithuanian, and if necessary, in any other language as well.

NON-PREPACKAGED FOOD AND INFORMATION ON ALLERGENS

In accordance with the Article 44 of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, beginning on the date mentioned below, there is a requirement to provide information on allergens or substances causing intolerances contained in non-prepackaged food.

There are 2 possible ways to provide information about allergens:

- Information on allergens may be supplied ***in writing*** by specifying the allergens that are present in a certain product;
- Information on allergens may be supplied by informing a consumer ***in writing*** by specifying that any staff or other representatives of a seller will give information on allergens present in a certain product verbally upon request.

The information may be presented on labels, in informational catalogues, on menus or any other places visible to the consumer.

BEER AND CHEESE

Requirements for beer labelling are contained in Order of the Minister of Agriculture No. 3D-882 from 21 November 2012 “Regarding the confirmation of technical regulation regarding the characterization, production and presentation of beer and beer cocktails”. This Order requires beer and beer cocktails to be labelled according to related provisions of the Hygiene Norm HN119:2002 “Food labelling” and other legal acts.

Requirements for cheese labelling are contained in Order of the Minister of Agriculture No. 3D-335 as of 13 June 2008 “Regarding the approval of cheese quality requirements and the replacement of some Orders of the Minister of Agriculture in connection with mandatory quality requirements”, which further references the above-mentioned Hygiene Norm HN 119:2002 „Food labelling” and other relevant legal acts.

SANCTION SYSTEM

In Lithuania, infringements of the provisions of Reg. 1169/2011 are prosecuted under the Administrative Violations Code of the Republic of Lithuania. According to Article 156(3) of the Administrative Violations Code of the Republic of Lithuania, in

the case of offering or selling goods or services not in compliance with labelling requirements specified in regulatory legal acts, a fine shall be imposed on natural persons engaged in private business from 16 to 30 EUR, on the employees of a legal person up to 150 EUR, and on managers of legal persons and other responsible persons up to 300 EUR.

Tadas Vilčinskas is an associate at LEXTAL and has 10 years of legal practice in various institutions and companies. During his nearly 3 years of legal practice in LEXTAL, Tadas has been involved in various legal international and local projects, prepared numerous consultations for clients in the field of competition law, employment law, commercial law, public procurement and other areas, and he has represented clients in courts and other institutions.



LEXTAL

Tadas Vilčinskas, Associate
LEXTAL Vilnius
 Etmonų str. 6
 LT-01305 Vilnius
 Lithuania
www.lextal.lt

LATVIA

Author: [Kaspars Linters](#); [Lexal](#)

Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers¹ (hereinafter – FIC Regulation) came into force on 12 December 2011. It combines two main areas within the scope of labelling regulation: general food labelling and nutrition labelling. This article provides a brief summary of the

¹ Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004; OJ L 304, 22.11.2011.

implementation of the FIC Regulation in Latvia with respect to general food labelling requirements.

Requirements on food handling and labelling in the Republic of Latvia are prescribed by the Law on the Supervision of the Handling of Food (hereinafter "LSHF"), which adopted necessary changes on 26 November 2014 in order to meet the requirements of Article 38 para. 1 of the FIC Regulation.

In accordance with Article 20 of the Latvian Consumer Rights Protection Law, information on a product label must objectively reflect its safety or harmlessness and quality, and must comply with Latvian laws and regulations on the use of the state language. Moreover, in accordance with Article 13 para. 1 of the LSHF, information provided on the label as well as advertising information must not be misleading. Likewise, on the label or product description, it is impermissible to indicate the presence of a specific food or ingredient naturally existing in the product that has been replaced by another. Therefore, a company that manufactured or prepackaged food or a food distributor that has changed the original product packaging, labelling or affixed a new label is responsible for accurate labelling.

The Cabinet of Ministers of the Republic of Latvia issued or supplemented a number of Cabinet Regulations (hereinafter "CR") which contain both directions of directly applicable FIC Regulation provisions and developed provisions that are not specifically harmonized with the FIC Regulation.

1) In accordance with CR No. 115 - "Labelling requirements of the prepackaged food" issued on 03.03.2015 - when distributing prepackaged foods in Latvia, compliance with the requirements contained in the FIC Regulation must be ensured. Therefore, Latvian regulatory enactments for prepackaged food labelling is in full compliance with the EU requirements.

2) In accordance with CR No. 595 - "Requirements for the provision of information on non-prepacked foods" issued on 20.10.2015, a non-prepacked food is a food offered for sale to the end consumer or to mass caterers without packaging, or which is packed on the sales premises at the consumer's request and/or which was packed for direct sale in accordance with Article 44 of the Regulation. Furthermore, CR No. 595 contains requirements for sellers on what information on non-prepacked food should be provided if prepacked food on sales premises is sold without packaging, if it is packed at the consumer's request or prepacked for direct sales. Similarly, the provisions contain exceptional cases where such information from the seller can be provided orally. Furthermore, substances or products causing allergies or intolerances should be noted in writing in accordance with requirements mentioned in Annex II and Article 21, para. 1(b) FIC Regulation.

3) In accordance with CR No. 97 - "Regulations regarding requirements for the classification, quality and labelling of milk products and composite milk products" issued on 01.02.2011, the trade name of product "cheese" shall be supplemented only with a cheese variety name or traditionally used name. This provision is directly aligned with the requirements of the Regulation and entered into force on 13.12.2014. In addition, CR No. 97 states that if the indicators of cheese quality,

composition and technology are appropriate to the particular cheese variety in accordance with international standards², the trade name of the product may only contain the cheese name without the word "cheese" (for example, mozzarella, cheddar, etc.). On the cheese label, the type of cheese may be indicated as well (for example, soft, hard, fat content, etc.).

4) Although these were not harmonized with the FIC Regulation, the Cabinet of Ministers of the Republic of Latvia on 12.08.2014 issued CR No. 461 - "Requirements for food quality schemes, arrangements of their implementation, operation, monitoring and control", which contains specific quality requirements for inter alia beer, kvass and malt drinks, as well as regulated certification rules for food producers to participate in some of the national food quality schemes. CR No. 461 states that beer's raw materials are only water, malt and hops, while for the fermentation process (which may not be less than 15 days) a beer yeast must have been used. Sugar, syrup or a substitute for malt is not allowed. Beer, kvass and malt drink's quality must be controlled by the operator, and its quality must comply with the requirements of CR No. 461. In turn, the final product's compliance with high quality requirements may be indicated with the popular Latvian food quality scheme trademarks "green spoon" and "burgundy spoon"³, which currently as a whole are allocated to more than 600 Latvian produced foods, including several beers such as Bauska and Mezpils.

Kaspar Linters is an Attorney at Law focusing his practice on civil law, commercial law, competition law, consumer law, individual's and legal person's insolvency law, debt recovery.



LEXTAL

Kaspars Linters, attorney at law

LEXTAL Riia

Republikas laukums 2A

LV-1010 Riia

Latvia

www.lextal.lv

² Cheese production standards developed by the Food and Agriculture Organization of the United Nations (<http://www.fao.org/home/en>) and the World Health Organization (<http://www.who.int/en>).

5) In accordance with CR No. 142 - "By-law of the Food and Veterinary Service" issued on 22.02.2005 - food business monitoring and inspection in the Republic of Latvia is conducted by the Food and Veterinary Service (hereinafter - FVS). The FVS is competent both to issue appropriate orders and decisions, as well as to hold violators liable administratively, including by imposing sanctions for noncompliance with regulatory acts. According to Article 24, para. 5 of the LSHF, appeals of orders and decisions made by the FVS may not suspend their execution, with the exception of decisions on the imposition of an administrative penalty for specific cases prescribed by the Latvian Administrative Violations Code. According to Article 1669 of the Latvian Administrative Violations Code, if one offers or sells goods or services not in compliance with the quality requirements specified in regulatory enactments, a fine of up to 350 EUR may be imposed on natural persons, and up to 1400 EUR on legal persons.

Law firm "LEXTAL" provides advice and legal assistance to local and international food producers in relation to regulatory requirements as well as representation before FVS, Latvian administrative courts and the Latvian consumer protection authorities.

ESTONIA

Author: *Rauno Kinkar; Lextal*

This article addresses the implementation in Estonia of EU Regulation 1169/2011 on the provision of food information to consumers ("FIC Regulation").

IMPLEMENTATION OF THE FIC REGULATION

The basic regulation on the provision of food information to consumers in Estonia is the Food Act (FA)⁴.

The FIC Regulation was implemented by means of the Food Act Amendment Act (FAAA), which entered into force on 13.12.2014. The FAAA aimed to directly implement the FIC Regulation and nullify national provisions that previously regulated areas sufficiently covered by the new provisions.

GENERAL RULES AND IMPACT OF THE FIC REGULATION

The implementation of the FIC Regulation did not bring about any fundamental changes under Estonian law.

Pursuant to the FA, the following general principles regarding food product labelling apply:

1. Food information must be true, comply with requirements established by applicable legislation, and must not mislead the handler or the consumer (Art. 38 (2) of the FA);

2. Food which is sold or transferred in some other manner to the consumers must be labelled in a manner that ensures the provision of necessary information about the food (Art. 38 (2) of the FA);
3. For food sold or otherwise delivered to the consumer in Estonia, food information must be provided in Estonian unless the information provided in another language or in another manner is understandable to the consumer (Art. 38 (3) of the FA).

NATIONAL REGULATIONS OUTSIDE THE SCOPE OF THE FIC REGULATION

While the FIC Regulation is directly applicable in Estonia, it leaves room for national regulation in some areas. As such, the FAAA and the Food Act include provisions delegating authority to regulate in areas not sufficiently addressed by the FIC Regulation. Such areas may, in accordance with the FIC Regulation, be regulated by EU directives or by national law of the Member States.

Rauno Kinkar's main area of work as an attorney is in resolving disputes in civil proceedings focusing on legal issues related to IT solutions and smart technologies. Rauno is the author of the first Estonian broad-based and legal theoretical approach to self-driving vehicles. Looking for and finding a modern and functional solution for a client is what inspires Rauno.



LEXTAL

Rauno Kinkar, attorney at law
LEXTAL Tallinn
 Rävåla pst. 4
 EE-10143 Tallinn
 Estonia
www.lextal.ee

³ "Green spoon" was introduced in 2004 and is given to products which are produced in Latvian from local raw materials and meet higher quality requirements. Similarly, "burgundy spoon" was introduced in 2014 and is given to products on which full production cycle is carried out in Latvian, product meet higher quality requirements, but necessary raw materials for the production can be imported.

⁴ The official English translation of the Food Act can be found here: <https://www.riigiteataja.ee/en/eli/520122016005/consolide>.

In Estonia, the Minister of Rural Affairs was granted the authority to establish such requirements by a Regulation of the Minister:

1. For provision of food information per food group or treatment (Art. 38 (4) of the FA);
2. For provision of food information on non-prepackaged food (Art. 38 (5) of the FA);
3. Specifications for identification of a batch of foodstuffs (Art. 38 (6) of the FA).

Since receiving this authorisation, the Minister has issued various Regulations of the Minister regulating provision of food information to consumers in relation to food groups, non-prepackaged food and lots of foodstuffs. A more specific overview of the exceptions and specifications for marking of

specific food groups cannot be provided in this short article. However, the law firm LEXTAL is happy to further advise anyone who requires legal aid in this matter.

SANCTIONS

Pursuant to FA Art. 53, the penalty for a violation of food information regulations (incl. provisions of the FIC Regulation) is a fine of up to 150 fine units (currently 600 EUR), whereas the penalty for the same act committed by a legal person is a fine of up to 1300 EUR.

Croatia

CROATIAN IMPLEMENTING REGULATION ON REG. (EU) 1169/2011

Author: [Marko Kapetanović](#); [schoenherr Croatia](#)

INTRODUCTION

Regulation (EU) 1169/2011 (the "**Regulation**") has been implemented into the Croatian legal system by way of the Act on Provision of Food Information to Consumers (*Zakon o informiranju potrošača o hrani*; Official Gazette No. 56/13, 14/14, and 56/16) and Regulation on Provision of Non-prepacked Food Information to Consumers (*Pravilnik o informiranju potrošača o nepretpakiranoj hrani*; Official Gazette no 144/14).

The former concerns the implementation of the Regulation in general (establishing competent authorities and their tasks, official controls, administrative measures and fines), whereas the latter concerns exclusively the regulation of non-prepacked foods.

In general, food placed on the Croatian market must be labelled in accordance with the Regulation and other applicable laws. Related information must be provided in the Croatian language using Latin letters, but multilingual labelling is also allowed.

The authorities responsible for the enforcement of such laws and regulations are the Ministry of Agriculture and the Ministry of Health, in accordance with their respective competencies and scopes of authority.

NON-PREPACKED FOODS

Food business operators offering or selling non-prepacked foods to end consumers (e.g. retail stores, mass caterers)

are obliged to provide information in accordance with Article 9 para. 1 point c of the Regulation.

In general the method of indicating information required by Article 9 para. 1 point c is the same as that for the labelling of prepacked foods, thus provisions of Article 21 of the Regulation apply. Namely, the information must be provided in written form, must be easily visible and legible, and if applicable indelible, and provided at the selling place close to the food it relates to (e.g. catalogues, booklets, menus, etc.) or on the packaging if applicable (i.e. food label). It should be noted that the font size requirements prescribed by the Regulation do not apply to non-prepacked foods.

However, the information may also be provided in a different way such as oral communication, provided that: (i) there is a visible notice indicating the place where available information is located or there is a notice directing consumers to address the staff regarding the presence of substances or products causing allergies or intolerances; (ii) information is available where food is sold in written or electronic form in the product; (iii) information is available before food is offered for sale, and that without incurring additional costs to consumers.

All in all, there is no prescribed universal method for providing information about allergens or foods which cause intolerances. Any facility operating with food may design its own method in accordance with their capabilities.

If a non-prepacked food is accompanied by an ingredients list, information from Article 9 para. 1 point c of the Regulation has to be included in the ingredients list, whereas in other cases

the information must be indicated obviously following the word "Sadrži" ("Contains").

Food business operators offering or selling non-prepacked foods are also obliged to provide (i) the name of the food, (ii) additional declarations as prescribed by Annex III and Annex VI of the Regulation, (iii) the name or business name and address of the food business operator, (iv) the country of origin or place of provenance if omission thereof could mislead the consumer, (v) an ingredients list for confectionery, frozen products, meat preparations, and bakery and pastry products, as well as in cases where a consumer cannot intuit the real nature of the food from its name or where a food name could mislead the consumer, and (vi) a "use by" date. Food business operators providing catering services (except for pastry shops) are not bound to provide this information. Regardless of the above, an ingredients list may be provided on a voluntary basis for other non-prepacked foods as well.

In cases where a non-prepacked food is sold by means of distance communication, the required information discussed above must be made available to the consumer before a purchase is concluded and at the time of delivery (e.g. on an invoice), except for the "use by" date which has to be indicated at the time of delivery. Information may be provided on a web page, flyer, catalogue or by oral communication (e.g. telephone). No additional costs may be incurred by consumer for receiving such information.

ADMINISTRATIVE MEASURES

During official inspections, the competent authorities may: (i) order elimination of nonconformities and give appropriate deadlines for their elimination; (ii) temporarily or permanently prohibit placement of food on the market and/or order withdrawal from the market and/or end consumer; (iii) prohibit all forms of informing consumers about food which does not comply with requirements stemming from the applicable laws and regulations; and (iv) order other appropriate measures.

In cases of nonconformities which do not affect consumers' health, food business operators may be given an appropriate deadline for their elimination: (i) a maximum of six months, taking into consideration the quantity of food on the market and stocks of packaging if (a) ingredients are not indicated in descending order of weight; (b) synonyms are used instead of specifically designated names; or (c) food name, net weight and alcoholic strength are not in the same field of vision, respectively (ii) two months if nonconformities may mislead consumer, such as (a) food name, net weight or ingredients' net weight are not indicated, (b) there is no nutritive declaration, (c) information on substances or products which cause allergies or intolerances are not indicated appropriately, etc.

Nonconformities which may affect the safety and health of end consumers and/or may mislead consumers and which require measures of temporary or permanent prohibition of placement on the market and/or withdrawal from the market and/or end consumer are as follows: (i) information is not indicated in Croatian language and Latin letter; (ii) indicated information is not in accordance with fair information practi-

ces; (iii) ingredients list is not indicated; (iv) ingredients which cause allergies or intolerances are not indicated; (v) minimum durability date or "use by" date is not indicated; (vi) there is no information on special storage conditions and/or instructions for use where needed; (vii) name and address of food business operator are not indicated; (viii) actual alcoholic strength for beverages which contain more than 1.2% of alcohol is not indicated; (ix) additional mandatory information is not indicated.

FINES

Food business operators may be imposed with monetary fines ranging between HRK 10,000 (approx. EUR 1,340) for minor violations (e.g. usage of synonyms instead of specifically designated names) to HRK 100,000 (approx. EUR 13,405) for severe violations (such as failure to indicate ingredients which cause allergies or intolerances). Authorised persons acting on behalf of such food business operators may also incur fines ranging from HRK 2,000 to HRK 20,000 (approx. EUR 270 to EUR 2,680). However, fines are not imposed for first offenses as long as the food business operator eliminates detected nonconformities within a given deadline except in cases where nonconformities may affect the safety and health of consumers.

Marko Kapetanović is an attorney at Law in cooperation with Schoenherr attorneys in Zagreb. His legal service focuses mainly on corporate issues and M&A.



schoenherr

Marko Kapetanović, odvjetnik / attorney at law

Schoenherr attorneys at law

Branimirova 29/I

HR-10000 Zagreb

Croatia

www.schoenherr.eu

CZECH NATIONAL IMPLEMENTING REGULATION CONCERNING REG. 1169/2011

Author: *David Štros, Štros Kusák Attorneys at law & Patent attorneys*

The Czech regulation adapting national law in conformity with Regulation (EU) 1169/2011 on the provision of food information to consumers is included in Act No. 110/1997 Coll., on foodstuffs and tobacco products (*Zákon o potravinách a tabákových výrobcích*, abbr. ZOP). ZOP provides general rules for the labelling of foodstuffs as well as sanctions for violation of mandatory provisions of Regulation 1169/2011 and mandatory provisions of national food labelling law.

Specific details about providing mandatory information about foodstuffs are prescribed in the national Decree No. 417/2016 Coll., on certain rules on the labelling of foodstuffs issued by the Ministry of Agriculture of the Czech Republic (*Vyhláška o některých způsobech označování potravin*, abbr. VZOP). The VZOP has been in effect since 1 January 2017.

This article provides a short summary of the national regulations for allergen labelling and labelling of non-prepacked foods, as well as an overview of the national sanction system and changes to national law with respect to Regulation 1169/2011. It also includes a summary of the pending draft amendment to the VPOP.

SCOPE OF APPLICATION AND GENERAL RULES

The ZOP and the VZOP address the sale of foodstuffs directly to consumers and to mass caterers (Article 2(2)(d) Reg. 1169/2011).

According to Section 3 para. 1 letter e) ZOP, food information must be provided in the Czech language.

NON-PREPACKED FOOD AND INFORMATION ON ALLERGENS

Non-prepacked foodstuffs must be labelled with certain mandatory information as prescribed in Article 9(1)(c) Regulation 1169/2011.

According to Section 8 para. 2 letter b) ZOP, required information about allergens must be placed near the non-prepacked foodstuff to which it relates. The information may be provided on the price label or on or near the display of non-prepacked foods for sale.

Permissible methods for providing information on allergens in a prepared meal are prescribed in the VZOP. One of the possible ways is to state in writing that allergen information will be

provided by the staff upon request. Another way is to state the allergens present in foods on the menu of the restaurant.

ALCOHOL

According to Section 6 para. 1 letter b) ZOP, a statement including an ingredients list and a quantitative indication of ingredients is mandatory on the packaging of alcoholic beverages containing more than 1,2 % vol. alcohol.

SANCTION SYSTEM

Sanctions applicable in prosecuting violations of the labelling requirements of Regulation 1169/2011 and of national law are provided for in the ZOK.

In the event that a foodstuff is not labelled in accordance with European or national law or is not labelled at all, a fine of up to 10,000,000 CZK (370,000 EUR) may be imposed.

Dr. David Štros is attorney-at-law and patent attorney. His work focuses on intellectual property rights, industrial rights, competition law, and civil law. He assists with all aspects of Czech law issues and offers essential and specialized advice on Slovak law.



ŠTROS & KUSÁK

Dr. David Štros
Národní 32
CZ-110 00 Praha 1
Czech Republic
www.stroskusak.cz

DANISH FOOD LABELLING REQUIREMENTS: IMPLEMENTATION OF REGULATION (EU) NO. 1169/2011

Author: *Martin Dræbye Gantzhorn & Gundula Maria Kjær & Lise Aagaard*

INTRODUCTION

In addition to the adoption of the “Food Information to Consumers” Regulation (EU) No. 1169/2011 (FIC), the Danish authorities have adopted Executive Order No. 1355 of 27 November 2015 on the labelling of foods (the Executive Order), which came into force on 1 January 2016. The Executive Order covers issues relating to the labelling of food products marketed to consumers as well as in B2B-relations and complements FIC on several matters.

In April 2016 the Danish Food and Veterinary Administration (DVFA) additionally issued a labelling guideline describing the authorities’ interpretation of FIC and other labelling requirements (“Vejledning om mærkning af fødevarer”).

DANISH FOOD LABELLING REQUIREMENTS

The Danish special provisions with respect to food labelling cover the following topics:

- I. Language requirements
- II. Expression of net quantity
- III. Allergen labelling
- IV. Labelling of non-prepacked foods, foods packed on sales premises at the consumer’s request and foods prepacked for direct sale
- V. Labelling requirements for prepacked minced meat products

LANGUAGE REQUIREMENTS

Pursuant to section 3(1) of the Executive Order, the mandatory particulars must be provided in Danish, or other languages which only in spelling differ insignificantly from the Danish language. This means that Swedish or Norwegian may be acceptable, however, there are some Swedish and Norwegian words that are not easily understood by Danish consumers.

EXPRESSION OF NET QUANTITY

Pursuant to section 4 of the Executive Order, the net quantity for prepacked foods must be indicated in the metric system as net volume for liquid products (i.e. litres or millilitres) and as net weight (i.e. kilograms or grams) for other food types.

ALLERGEN LABELLING

Pursuant to section 13(2) of the Executive Order, information about allergens in non-prepacked foods must be provided to the consumers.

Access to this information should be given as a) written information or similar in the immediate vicinity of the foods, or b) through other relevant methods, i.e. normally informed verbally by the staff. Therefore, the requirements for labelling of foods depend on the circumstances of the sale in Denmark (see figure 1).

Labelling of non-prepacked foods, foods packed on the sales premises at the consumers’ request and foods prepacked for direct sale

For prepacked foods, mandatory labelling requirements in the FIC must be observed.

For foods prepacked in a retail shop and intended for direct sale within the same day (≤ 24 hours), no labelling requirements exist. However, the staff is required to provide information about allergens (Executive Order section 13).

Foods prepacked by the retail store intended for direct sale over a period of several days (Executive Order, section 15) should be labelled with mandatory particulars according to FIC, except for information about ingredients, nutrition declaration and QUID labelling.

Pursuant to Executive Order section 15(2), the food business operator must provide information about the ingredients at the consumer’s request. The retail shop may provide this information verbally (Executive Order, section 15(2)). Consumers should also be able to receive information about allergens upon request (Executive Order, section 13(1)), either written or verbally.

For foods packed on the sales premises at the consumer’s request, e.g. take away food, pizza, or food packed by the consumer, no labelling requirements exist, but information about allergenic ingredients should be provided if requested (Executive Order No. 1355/2016, section 13). The DVFA normally allows this information to be provided on a sign in the store located near the products for sale. Alternatively, a sign with information about the possibility of receiving this information verbally from the staff is permitted (see the Danish Guideline on labelling of foods).

NATIONAL ALLERGEN CONTROL CAMPAIGN 2017

In general the DVFA focuses greatly on allergens, and from April to May 2017 the DVFA will conduct a so-called “inspection campaign” to inspect food business operators and ensure that they, particularly those responsible for preparing food for direct sale and restaurants, are compliant with FIC and national labelling requirements.

LABELLING REQUIREMENTS FOR PREPACKED MINCED MEAT PRODUCTS

Pursuant to sections 7 and 8 of the Executive Order, prepacked minced meat products must be labelled with a circular mark with the company’s authorization code appearing at the top and the number “1” at the bottom.

If the mark is used as a health mark, there are specific requirements concerning the size of the mark. Only products labelled with this mark may be offered for sale in Denmark.

ENFORCEMENT

DVFA conducts inspections of food business operators on a regular basis in order to ensure that the marketing of foods is compliant with applicable legislation.

If the DVFA discovers issues of non-compliance during a control visit, different types of administrative sanctions can be issued. The sanctions range from informal guidance to injunction, mandatory injunction to stop a product’s marketing, recall of the product and/or administrative fines.

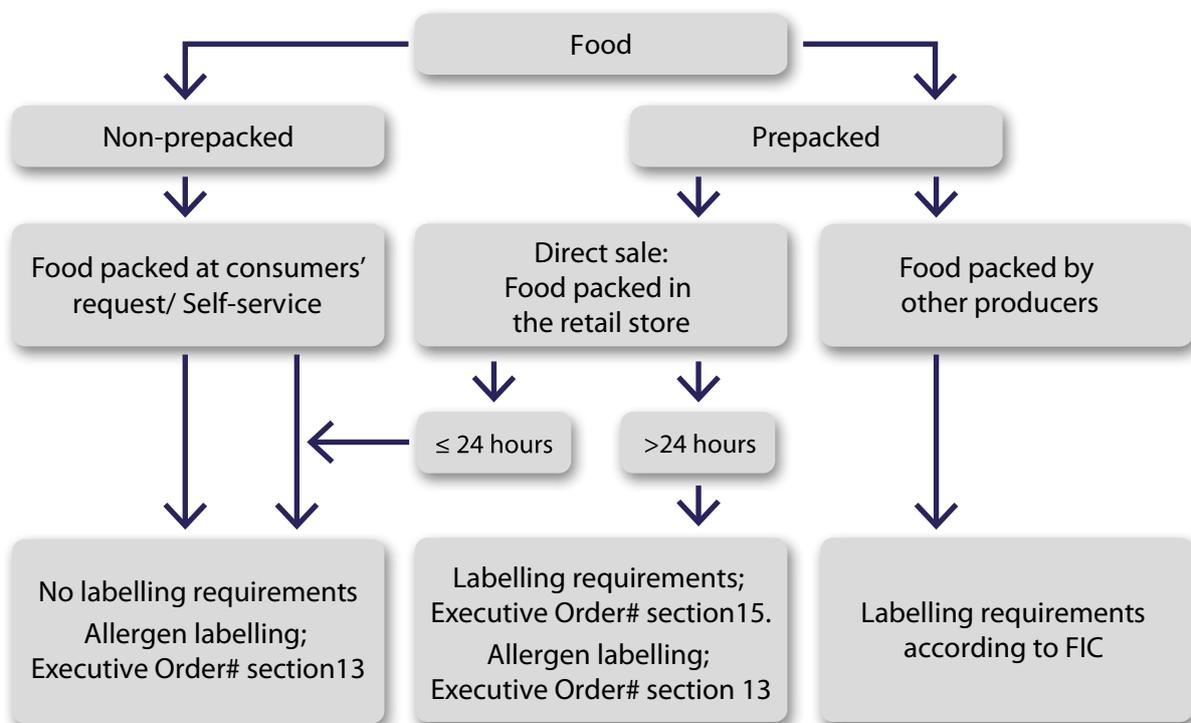
Under very rare circumstances, the responsible food business operator can be sanctioned with imprisonment. The maximum sentence is 2 years (Executive Order, section 25(5)).

Complaints regarding sanctions issued by the DVFA can be submitted to the Danish Appeals Boards Authority (Authority). The Authority is the high complaint board for all decisions made by the Ministry of Environment and Food of Denmark. Its decisions as well as decisions made by the DVFA can be appealed in the courts of Denmark. Administrative fines issued by the DVFA cannot be taken to the Authority, only challenged in court.

Inadequate, wrong or missing information about the presence of allergens in food products often leads to product recalls.

We also see that cases involving misleading labelling or no labelling of food products with information about possible allergens (i.e. “may contain traces”) most commonly leads to product recalls.

Figure 1: Decision tree for labelling of foodstuff in Denmark*



*Adapted from the Food labelling Guideline issued by the Danish Veterinary Food Administration, 2016.

Executive Order no. 1355 of 27 November 2015

FIC: EU Regulation (EC) No. 1169/2011

Martin Dræbye Gantzhorn is a highly specialised lawyer and partner in the Life Science Group at Bech-Bruun Law Firm. He has a Master of Laws and advises national and international clients on legal contentious and non-contentious matter in relation to marketing and distribution of

medicines, medical devices, food and cosmetics; and legal issues related to clinical research and intellectual property rights. Martin teaches at national and international conferences and is the author of a number of books and articles within the field of life science.



Gundula Maria Kjær is a Regulatory Affairs Manager in the Life Science Group at Bech-Bruun Law Firm. She holds a Master of Science in Business Administration and Commercial Law and has worked on food legislation and food policy for more than 10 years at the Ministry of Food and Environment, including in the Danish Veterinary and Food Administration. She has

also worked 2 years at the EU Commission, DG Sante, on food nutrition and legislation. Gundula advises national and international clients on issues related to EU and Danish food legislation and the marketing of food products. Gundula teaches at national and international conferences on food legislation and policy.



Lise Aagaard is a junior associate in the Life Science Group at Bech-Bruun Law Firm. She is trained as a pharmacist, holds a Master of Laws and a Ph.D. in social pharmacy. Lise advises national and international clients on issues

related to the regulation, marketing and market access of pharmaceutical products, medical devices and food products. Lise is the author of several articles within the field of life science, particularly on drug safety.



BECH-BRUUN

Langelinie Allé 35
2100 Copenhagen
Denmark
www.bech-bruun.com

Bech-Bruun Law Firm is an international full service law firm situated in Denmark and located in its two major cities, Copenhagen and Aarhus. The Company renders advice on all aspects of corporate

and commercial law and is highly specialised within the Life Science and Healthcare Sector. Bech-Bruun's clients are Danish and international enterprises, organisations and public authorities.

France

EU FOOD INFORMATION TO CONSUMERS REGULATION 1169/2011: IMPLEMENTING MEASURES BY FRANCE

Authors: Antoine de Brosse & Adrien Caillavet; Product Law Firm

I. OBJECTIVES PURSUED BY NATIONAL IMPLEMENTATION MEASURE

The previous EU labelling Directive No. 2000/13 was implemented in France mainly into the so-called "Code de la consommation" (Consumer Code).

The French authorities enacted several national measures to review and adapt the Consumer Code and incorporate the new Food Information to Consumers Regulation No.

1169/2011. These measures also incorporate into French law the provisions of EU Directive No. 2011/91 on indication or marks identifying the lot to which a foodstuff belongs.

As of this writing (23 February 2017), two orders have been issued to implement the FIC into French law. They address the general and specific provisions (e.g. allergens in non-prepacked foods) of the FIC and penalties for nonconformity:

- First, Order No. 2014-1489 of 11 December 2014 modifying the French Consumer Code with respect to Food Information to Consumers.
- Second, Order No. 2015-447 of 17 April 2015 regarding non-prepacked food and information about allergens in non-prepacked foods.

These orders have been incorporated into the Consumer Code, and as such, references in this article correspond with the relevant provisions of the Consumer Code rather than the orders.

II. NOTIFICATION PROCEDURE UNDER THE TECHNICAL REGULATION INFORMATION SYSTEM (TRIS)

There are currently no French legislative drafts pending under TRIS. Several drafts were notified by the French authorities in 2016 that are not relevant here because they were enacted into law after the respective three-month standstill periods expired.

III. LABELLING REQUIREMENTS FOR NON-PREPACKED FOOD

National measures on non-prepacked foods have entered into force in France.

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

French law states that 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, whether it has no packaging at all, was packed on the seller’s premises at the consumer’s request or was prepacked for direct sale.

At any place where meals are served (such as a restaurant or cafeteria), allergen information must be provided in writing, in a way that is legible and visible, in a place accessible to the public. If information about allergens present in foods is not on display, an alternative method indicating where such information is freely and directly available in writing to the public (e.g. on a fact sheet by the cashier) is permissible.

Due to an exemption, the provision of allergen information is not mandatory when the consumer has stated prior to consuming the food that he or she does not wish to eat specific ingredients listed as allergens in the FIC. This derogation is applicable only to so-called “contract catering organisations” such as restaurants or cafeterias serving meals to a regular group of consumers linked to the restaurants by agreement or contract (e.g. company dining halls or school cafeterias, etc.). The food business operator in such instances must keep a record of allergenic ingredients that the consumer refuses for three years.

Lastly, French law states that restaurant suppliers must provide a document including technical specifications and allergen information with any shipment of foods.

All of the above-discussed provisions can be found in Articles R 412-13 to R 412-16 of the Consumer Code.

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

In France, in addition to the list of allergens, the product name as well as any other mandatory particulars for non-prepacked products pursuant to EU or French law (i.e. origin of fresh fruit or vegetables) must be provided. 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 set forth in Article R 412-11 of the Consumer Code.

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

French law does not prescribe in detail the means of expression and presentation of information about non-prepacked foodstuffs. It only states that the information should be “on the foodstuff itself, or in close proximity to it, leaving no doubt concerning the foodstuff to which it refers”. It allows for various means of presentation depending on the product type, the type of business, the consumer relationship, etc., as long as the information is legible and the consumer can easily correlate it with the intended non-prepacked product.

IV. LABELLING REQUIREMENTS FOR PREPACKED FOOD

There are many specific requirements in France for prepacked foods.

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

In France, there are numerous national measures creating additional mandatory particulars for certain prepacked foods. Many of these requirements were already in effect before the FIC was enacted, e.g., for yoghurts and fermented milks (Order No. 88-1203 of 30 December 1988), cheeses (Order No. 2007-628 of 27 April 2007), truffles (Order No. 2012-129 of 30 January 2012), etc.

2. Milk and milk products (Article 40 FIC)

There is no specific French measure applicable to milk and milk products sold in bottles intended for reuse because milk and milk products are not sold in reusable bottles in France.

3. Alcoholic beverages (Article 41 FIC)

There are several French rules requiring an ingredients list on certain alcoholic beverages, such as fruit-based spirits, pastis, ouzo, liquors, wine-based aperitifs, etc. These provisions are still in effect, and may continue pursuant to Article 41 FIC (pending the adoption of related EU provisions).

4. Expression of net quantity (Article 42 FIC)

There are three foods for which France has opted to maintain a specific requirement for the expression of net quantity that differs from the FIC: 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 412-7 of the Consumer Code).

This deviation is a result of France’s Order No. 2015-447 of 17 April 2015 on food information which was notified in TRIS before 13 December 2014 pursuant to article 42 FIC.

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

As of this writing (23 February 2017), there are no French reference intakes for specific population groups.

V. LABELLING REQUIREMENTS FOR PREPACKED AND NON-PREPACKED FOODS: USE OF LANGUAGE (ARTICLE 15(2) FIC)

France’s Order No. 2014-1489 of 11 December 2014 confirms that food products sold on the French market must be labelled in the French language (new Article R 412-6 of the Consumer Code).

VI. EXEMPTION FROM NUTRITION LABELLING: THE NOTION OF “DIRECT SUPPLY” (ANNEX V NO. 19)

There is no legal authority that explains the notion of “*direct supply*” referred to in Annex V FIC on foods exempted from the mandatory nutrition declaration.

However, French law already contains several provisions creating exceptions to food regulations for handcrafted foods supplied directly by the producer to the consumer in small quantities. The notion of “*direct supply*” refers to a situation in which the consumer buys the food directly from its producer without any intermediary (such as at farmers’ markets).

VII. APPLICATION AND ENFORCEMENT

Under French law, it is necessary to adopt a special legal act in order to make an EU law enforceable. For the FIC, the act was

Order No. 2014-1489 of 11 December 2014, published the day before TRIS became applicable.

The new Articles R 412-18 of the Consumer Code created by the December 2014 Order states that Articles 1, 2, 6 to 10, 12 to 28, 30 to 37, 44, and Annexes I to XV of the FIC are considered to be implementing measures of the French criminal offence of fraud/deception. This means that lack of compliance with the articles and annexes of the FIC referred to above can be sanctioned with criminal penalties for fraud and deception:

Antoine de Brosses is founding Partner at Product Law Firm. He is specialized in regulations and litigation. Pioneer in Food Law in France.



Adrien Caillavet is an associate at Product Law Firm Adrien Caillavet and holds a degree in Litigation, Arbitration and Alternative Dispute Resolutions.



When Antoine de Brosses and Gilles Boin founded Product Law Firm in 2014, they shared the same vision: to provide a full line of services regarding the legal framework of products. Thanks to many years of experience in renowned international Law firms, they offer global expertise, interfacing between law, regulation, science and technology. The law firm aims at accompanying clients in every step of their products lifecycle, while offering practical solutions for each issue

ProductLawFirm®

Antoine de Brosses, Partner
Adrien Caillavet, Associate
Product Law Firm
16, rue d'Athènes
75009 Paris - France
www.product-lawfirm.com

- A charge of fraud/deception can be brought against a food business operator if the non-compliance with the FIC was likely to mislead the consumer. In this case, the sanction may be two years in prison and a maximum fine of 300,000 EUR for an individual, and for companies, 1,500,000 EUR, which may be increased by up to 10 % of the average annual revenue of the three preceding years, in proportion to the profit from the fraud/deception.
- In the case of a labelling offence, the authorities may determine that the lack of compliance with the FIC was not likely to mislead the consumer (e.g. if missing information was minor or non-essential, information was given in a non-compliant way, etc.). In this case, the sanction is a maximum fine of 450 EUR for individuals (2,250 EUR for companies) per non-compliant item. In practice, this means that the amount of the fine (between 0 and 2,250 EUR, determined by the Judge) may be multiplied by the number of non-compliant items and can result in a significant total financial impact.

French inspectors always take a pragmatic approach when they enforce a new legislative act. For example, they did not begin to immediately enforce the FIC after its entry into force on 13 December 2014. They first observed the global level of compliance among food business operators, and then took into account any efforts made to ensure compliance with the

FIC. They also may consider that a relevant provision of the FIC remains incomplete because EU and national implementing measures are pending. Since the FIC now has been applicable for more than 6 months, the authorities enforce it more strictly.

VIII. MISCELLANEOUS / COMMENTS

Since January 1st, 2017, there is a French Order in effect that requires a statement of the origin of meat or milk when used as ingredients of a processed product. The text was adopted urgently during an agricultural crisis, mainly to calm relations between farmers and the government.

The legality of the Order is uncertain in that it appears to be contrary to the FIC. Specifically, Article 39(2) FIC states that Member States may require indication of the country of origin or place of provenance "only where there is a proven link between certain qualities of the food and its origin or provenance".

However, France does not provide any evidence of this proven link between the (French) origin of the meat or milk ingredient and "certain qualities" of the food.

According to the French *Conseil d'Etat*, this order is currently facing a legal challenge from a French company. However, as of today, no Court decision has been rendered on this topic yet.

Germany

GERMAN IMPLEMENTING REGULATION CONCERNING REG. 1169/2011

Author: [Bärbel Ines Hintermeier](#), [meyer.rechtsanwälte](#)

The first German provisional regulation concerning the adaption of national law in conformity with Regulation (EU) 1169/2011 on the provision of food information to consumers (*Vorläufige Lebensmittelinformations-ergänzungsverordnung*, abbr.: VorLMIEV) was published in the so called "*Bundesgesetzblatt*" (Federal Law Gazette) in 2014. The scope of this provisional regulation was limited to national regulation of allergens in non-prepackaged foodstuffs.

In the beginning of 2016, the German food regulatory authority (BMEL) published a draft of a new, comprehensive regulation (*Verordnung zur Anpassung nationaler Rechtsvorschriften an die Verordnung (EU) Nr. 1169/2011 betreffend die Information der Verbraucher über Lebensmittel*, abbr: LMIDV). This draft includes regulations on allergens as well as sanctions for violations of mandatory provisions in Regulation 1169/2011.

This article aims to provide a short summary of the content of this pending draft of the German implementing regulation (LMIDV).

SCOPE OF APPLICATION AND GENERAL RULES

The LMIDV addresses the sale of foodstuffs directly to consumers, to mass caterers (Article 2(2)(d) Reg. 1169/2011), and other provision of foodstuffs.

In general, food information in the German language must be provided per Section 2 LMIDV, whereas Article 7 LMIV only requires that food information be accurate, clear, and easy to understand. In application of the law, the stricter German regulation must be observed.

For foodstuffs introduced onto the German market by airplane, general food information may be in a language other than German, but information on ingredients and processing aids must be provided in German as well.

NON-PREPACKAGED FOOD AND INFORMATION ON ALLERGENS

Non-prepackaged foodstuffs must bear certain mandatory information indicated in Article 9(1)(c) Reg. 1169/2011.

Non-prepackaged food for sale must be accompanied by the required information on a sign on or near the food, on the menu of the restaurant, on a notice board, or in another written or electronic form which is directly and easily available to the consumer.

Furthermore, information on ingredients and processing aids may be provided orally by an employee who is informed adequately about these substances.

The German regulation also declares allergen information to be mandatory for non-prepackaged foods, and therefore it must be provided as described above as well.

BEER AND CHEESE

The regulation also includes special provisions, e.g., for beer and cheese. According to the German LMIDV, beer must be labelled with a list of ingredients under Article 9 Reg. 1169/2011. Moreover, cheese within the meaning of the German "Käseverordnung" (cheese regulation) must bear the indication "The plastic coating is unfit for human consumption".

SANCTION SYSTEM

Infringements of the provisions of Reg. 1169/2011 in Germany are not yet prosecutable because there is no regulation in place that would provide a legal basis for sanctions. More than two years after those provisions became effective, the draft of the LMIDV finally presents a proposed sanction system.

In the sections that constitute the sanction system, each and every prohibition of Reg. 1169/2011 is repeated. Though at first glance it may seem unnecessary, this regulatory framework is rooted in a German constitutional principle that prohibits sanctions without prior law. Thus Section 6 LMIDV echoes the prohibitions of Reg. 1169/2011 to anchor them in German law

and thereby provide a basis for the system of sanctions in Section 7 LMIDV.

Beyond these considerations, the German implementing regulation LMIDV only serves to adjust the wording of certain provisions in various relevant regulations.

Bärbel Hintermeier is an attorney and master of law (in intellectual property law) specializing in the law of food. She advises international and national clients on general matters, labeling and advertisement issues.



She is also one of the experts at meyer.rechtsanwaelte for risk assessment and crisis management with specific experience in product recalls and warnings.

meyer

Bärbel Ines Hintermeier, LL.M.
(Dresden/Exeter)
Rechtsanwältin

meyer.rechtsanwaelte
Sophienstr. 5
D-80333 München - Deutschland
www.meyerlegal.de

Italy

ITALIAN IMPLEMENTING REGULATION ON REG. (EU) 1169/2011

Author: [Cesare Varallo](#)

NON-PREPACKED FOODS

Italy has not yet adopted implementing provisions for Regulation (EU) No. 1169/2011, nor notified any draft regulation to European Commission – at least through the TRIS procedure (Directive No. 98/34/EC).

However, the competent Ministries are reviewing the current national regulation on food labelling (Legislative Decree No. 109/1992 implementing Directive No. 2000/13/EC) with the goal of making it compatible with the FIC Regulation. In this

context, Italy will determine which mandatory information will be required on non-prepacked foods and the methods by which such information must be made available.

First of all, it must be emphasised that the draft of the new test (neither publicly available nor final) adopts a clear distinction between foods packed on the sales premises at the consumer's request and foods prepacked for direct sale.

For foods packed on the sales premises at the consumer's request, information should appear on a billboard or other similar means accessible to consumers that indicates to which

foods or display counters it relates. The notice should be in plain sight and freely available to customers. The following indications should appear on the billboard: name of the food, list of ingredients with allergens highlighted in accordance with Article 21 of the FIC Regulation, special storage conditions (when appropriate), and other specific information for particular types of food products (e.g. use-by date for fresh pasta, alcoholic strength, percentage of icing for frozen seafood products, "defrosted" if applicable, etc.).

In relation to foods prepacked for direct sale, considering that they have a label, it has been stated that information should be directly indicated on the package. In particular, the indications must include the name of the food, net quantity, date on which the product was prepacked, use-by date or date of minimum durability (if the packaging was conducted in a protective atmosphere) and allergens (in accordance with Article 21 of the FIC Regulation).

With respect to mass caterers, the Italian Health Ministry issued a note on 6th February 2015 entitled "*Indications on the presence of allergens in foods supplied at mass caterer (Reg. (EC) No. 1169/2011)*". In accordance with this note, every business which supplies ready-to-eat food in an establishment (e.g. restaurants, canteens, schools, etc.), also through a catering service, should provide information relating to allergens to final consumers. This information must be provided on the menu, on specific registers, on a billboard or other similar – including digital – media, which should be in plain sight, easily and freely accessible to the consumer.

Obligations arising under the FIC Regulation's will also be considered satisfied in the following circumstances:

- Food business operator writes in a visible place a clear statement such as "*information relating to the presence of substances or products causing allergies or intolerances can be obtained by addressing employees*";
- Food business operator writes on the menu, on the register or on a specific billboard a statement such as "*for information on substances and allergens, it is possible to consult the specific documentation provided upon request by employees on duty*".

In any case, it is necessary for information required by the FIC Regulation to be provided with adequate written documentation that has been seen and approved in advance by employees – easily accessible to both the competent authority and the final consumers.

The food business operator may choose from the above methods the best solution for its particular organization and dimensions.

SANCTIONS

For violations of Reg. (EU) No. 1169/2011 there are no specific sanctions yet in place. A long-awaited Legislative Decree draft is under review by the competent Ministries, but is uncertain when it will be published.

COUNTRY OF ORIGIN

On 19 January 2016, an Italian Decree of the Ministry of Agriculture and Forestry requiring the mandatory indication of the country of origin for milk and milk used as an ingredient was published in the Italian Official Journal.

The above-mentioned Decree would apply only to prepacked milk products (Article 2, para. 2, lit. e) Reg. (EU) No. 1169/2011). Consequently and in accordance with a circular of the Ministry of Economic Development from 2 February 2017, foods packed on the sales premises at the consumer's request and foods prepacked for direct sale are excluded from the scope of the Decree.

The measure intends to require food business operators to indicate information on the country of milking and conditioning or processing for milk and milk used in dairy products including cream, butter, cheese, curd and yoghurt. Entry into force is foreseen on 19 April 2017, and food business operators will have a six-month transition period to adapt to the new rules.

Discussions about the introduction of a mandatory obligation to declare the origin of grain on pasta are on-going.

Cesare Varallo is a food lawyer in Italy. His specialisation lies mainly on food safety, food labeling and food regulatory issues. He has his own independent consultancy firm for food business operators.



Cesare Varallo, attorney at law
Corso Vittorio Emanuele II, 27
10125 Turin
Italy

www.foodlawlatest.com

NETHERLANDS IMPLEMENTING REGULATION ON REG. (EC) 1169/2011

Authors: *Natasja Brusik and Victor van Ahee; Loyens & Loeff*

In the Netherlands, the national food legislation is incorporated in a clear framework. Specific food provisions are, however, scattered across different decrees and regulations. The aim of this contribution is to explain how to navigate this layered legislative structure.

A LAYERED LEGISLATIVE FRAMEWORK

The Dutch primary food act is the so-called Commodities Act (*Warenwet*), which lays down general rules on public health, product safety, fair trading and consumer information. Linked to (and based on) the Commodities Act are a large number of decrees (*Warenwetbesluiten*) and regulations (*Warenwetregelingen*). Commodities Act decrees cover topics addressing food products generally and related issues, such as dairy, labelling, hygiene and food supplements. The Commodities Act regulations deal with more specific food products, such as deep frozen food, dehydrated milk, preserved mushrooms or sauerkraut.

COMMODITIES ACT DECREE ON FOOD INFORMATION

The Dutch food labelling rules are predominantly laid down in the Commodities Act Decree on Food Information (*Warenwetbesluit Informatie Levensmiddelen*, hereinafter: the 'WIL'). In the WIL, violations of Regulation 1169/2011 on Food Information to Consumers (the 'FIC Regulation') are sanctioned (see below for more details) and certain deviations and exceptions have been included. The WIL also contains additional rules, such as the rule that labels on food must be in Dutch (based on Article 15(2) of the FIC Regulation) and the rule that only the particulars included in Article 9(1)(f) and (h) of the FIC Regulation are mandatory for reusable glass milk bottles (based on Article 40 FIC).

In addition to the above, the WIL also includes the (general) rules imposed by Directive 2011/91 on lot identification and Regulation 1924/2006 on nutrition and health claims made on foods.

FOOD-SPECIFIC PROVISIONS

If the WIL does not provide an answer, a closer look must be taken at other Commodities Act decrees, such as the decrees on dairy, and cocoa and chocolate, and at Commodities Act regulations, such as the regulations on dehydrated milk, deep-frozen foods and allergen information on non-prepacked foods.

Victor van Ahee, attorney at law, is a member of the Competition & Regulatory practice group and the Loyens & Loeff Benelux Food & Beverage sector team. He specialises in administrative and public law, with a (regulatory) focus on food law as well as environmental law. He advises on and litigates on behalf of food business operators, life sciences companies, supermarkets, property developers and –investors. Victor is also a member of the Loyens & Loeff Pharma Team.

victor.van.ahee@loyensloeff.com



in

Natasja Brusik, attorney at law, is a member of the Competition & Regulatory practice group. She specialises in European and Dutch competition and food law. Natasja has experience in proceedings before the European Commission, the Authority for Consumers & Markets, the Dutch Healthcare Authority and the judiciary; she also has experience in advising on the application of European and Dutch competition rules (ban on cartels, ban on the abuse of a dominant position and merger control). Furthermore, she advises companies in the food sector on the implementation of European and Dutch food law. She is also a member of the Benelux Food & Beverages Team and the Corporate Investigations Team.

natasja.brusik@loyensloeff.com



in

LOYENS & LOEFF

Victor van Ahee, attorney at law
Natasja Brusik, attorney at law
LOYENS & LOEFF Advocaten
Fred. Roeskestraat 100
1076 ED Amsterdam
The Netherlands
www.loyensloeff.com

The specific decrees and regulations contain further national measures concerning matters not specifically harmonised by the FIC Regulation, such as rules on (i) a particular food like honey (e.g. specific names for different types of honey) or chocolate (e.g. a specific ingredient declaration), and (ii) specific production stages (e.g. storage and transport) and preparation of food (e.g. use-by dates).

Furthermore, on some occasions the FIC Regulation is also applied outside of the Dutch 'Commodities Act framework', for example in agricultural / animal welfare legislation, where specific names for poultry meat are linked to the FIC Regulation (such as free-range chicken meat).

ENFORCEMENT AND SANCTIONING OF FIC PROVISIONS

In the Netherlands, the Food Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*, NVWA) is responsible for monitoring and enforcing compliance with food legislation in the Netherlands. If food legislation is violated, the NVWA may issue a warning or impose administrative measures. Such administrative measures include both sanctions such as fines, and corrective measures such as an order to end non-

compliant behaviour subject to a penalty payment. Whereas fines are quite easy to enforce, corrective measures are more complex due to the fact that an administrative procedure must be followed to remediate the violation.

The Commodities Act Decree on Administrative Fines (*Warenwetbesluit Bestuurlijke Boeten*) provides for a system where each prohibitive provision in the 'Commodities Act framework' is sanctioned with a set amount. With regard to violations of the WIL (and several other food regulations), the maximum fine per violation is EUR 525 for companies with up to and including 50 employees and EUR 1,050 for companies with more than 50 employees. The set amount can, however, be increased if the party that violated the provision has already violated such provision in the two years preceding the 'new' offence.

In addition to the above, as of July 2016 a revenue-based fine has been introduced for food business operators with annual turnover of more than EUR 10 million. Such revenue-based fines can be imposed on food business operators that have intentionally or with gross negligence violated certain Dutch food legislation, including the WIL. The revenue-based fine can reach up to 1 percent of annual turnover in the previous calendar year with a maximum of EUR 820,000(!).

Norway

NORWEGIAN IMPLEMENTING REGULATION ON REG. (EC) 1169/2011

Author: *Marie Vaale-Hallberg, Kvale*

INTRODUCTORY NOTE

Before describing how Norway has incorporated Regulation (EU) 1169/2011 on food information to consumers (FIC) into its national legal system, a brief note on the relationship between Norway and the EU is appropriate. Although Norway is not a member of the EU, it is a party to the European Economic Area Agreement of 1992 (the EEA Agreement) between EFTA and the EU. The EEA Agreement implies that Norway, Iceland and Lichtenstein (EEA/EFTA Member States) join the internal market for all goods and services designated under the EEA Agreement, and consequently, rules such as the FIC that are relevant to the internal market are often EEA-relevant as well.

Whilst EU Member States have transferred some of their legislative powers to EU bodies, the legislative powers of the EEA/EFTA Member States remains vested in their respective national legislatures. The EEA Agreement sets forth how EU law is determined to be EEA-relevant, and the procedures for incorporation. The FIC was incorporated into Norwegian law in the form of Regulation on food information of 28 November 2014 No. 1497.

When incorporating FIC, the authorities chose not to adopt additional national rules, although the FIC grants the right

to do so¹. Nevertheless, certain observations may be made, particularly with regard to allergen labelling.

ALLERGEN INFORMATION

The Norwegian Food Safety Authority (NFSA) first suggested that allergen information could be provided orally. The reason for this may have been that the preceding Norwegian regulation allowed satisfaction of mandatory information requirements orally upon request³. Section 6 of the first draft regulation stated that, when selling non-prepacked food over the counter at restaurants or similar, mandatory information could be provided on the menu or orally. Unlike the preceding regulation, the "upon request" requirement was not included,

¹ We have informally been made aware that it is unlikely that additional requirements will be made in accordance with Article 39-43. As to Article 39 (measures on additional mandatory particulars), the NFSA has expressed that it is unlikely that it will create any such rules because of the difficulty of proving necessity as required. Measures in accordance with to Article 43 (voluntary indication of reference intakes for specific population groups) are, according to NFSA, unlikely due to of the amount of work required to establish a specific reference group. Furthermore, as of today, it is not considered to be necessary to create further provisions as to any such specific reference groups.

thus the food business operator had to ensure that the information was provided always, rather than only upon request.

The NFSA later chose to remove the alternative to provide the allergen information orally after an overall assessment, citing for example its intention to strengthen consumer rights, and also referring to the Commission's Health and Consumer Directorate General in a Q&A-document⁴.

The NFSA has provided a guidance document on how to provide information about allergens for non-prepacked foods⁵. For example, it states that the information shall be available directly to the consumer in a written format. The requirement of "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 unambiguous. According to the view of the NFSA, the relevant allergen must be named – simply referring to "nuts" is unacceptable, for instance.

OTHER COMMENTS

The Norwegian Regulation on food information 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 requirement, but a case-by-case determination is necessary. Aligned with the wording in the FIC, the mandatory information may be provided by using another language to the extent that the phrases used are substantially similar to Norwegian and therefore may be understood easily by Norwegian consumers.

It is also worth mentioning that the Norwegian regulation additionally includes further criteria for food groups which do not have EEA relevance (specific labelling requirements for fresh fruit, berries, vegetables and potatoes)⁶, and genetically modified food.⁷ Labelling requirements in various national regulations for specific foods still apply, and the implementation of the FIC did result in some further amendments in relation to regulations for specific food groups.⁸

² See NFSA's first hearing statement, p. 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). http://www.mattilsynet.no/om_mattilsynet/regelverksutvikling/aktive_prosesser/horingsbrev.4712/binary/Horingsbrev (Norwegian).

³ The Norwegian regulation on labelling of 21 December 1993 no 1385 (repealed) section 7.

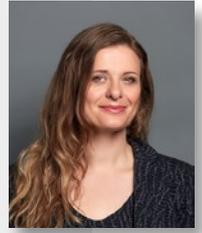
⁴ See NFSA's second and final hearing statement, p. 6-8. The hearing statement is found at http://www.mattilsynet.no/mat_og_vann/merking_av_mat/generelle_krav_til_merking_av_mat/oppsummering_og_vurdering_av_horingsuttalelsene.8714/binary/Oppsummering%20og%20vurdering%20av%20horingsuttalelsene (in Norwegian).

⁵ https://www.mattilsynet.no/om_mattilsynet/gjeldende_regelverk/veiledere/veileder_informasjon_om_allergener_for_ikke_ferdigpakket_mat.19459/binary/Veileder%20Informasjon%20om%20allergener%20for%20ikke%20ferdigpakket%20mat

⁶ Agriculture products fall outside the scope of the EEA Agreement (cf. EEA Agreement Article 8), but intra-EU/EEA trade is encouraged according to

Marie Vaale-Hallberg is specialized in intellectual property law, in addition to having solid experience with contracts and contract negotiations. She has broad IP judicial practice, involving research and development agreements, protection and enforcement of trademarks, patents and designs, IP strategies and marketing law.

Marie has extensive knowledge of the food industry, especially regarding regulatory issues related to foodstuffs.



Marie Vaale-Hallberg, Partner
Haakon VII's gate 10
0161 Oslo
Norway
www.kvale.no

VIOLATION AND SANCTIONS

A violation of the Norwegian regulation may result in the imposition of a fine or imprisonment for up to 1 year (2 years for aggravated offences). However, imprisonment is very rare in practice, and reserved for severe violations such as animal welfare-related offences. The NFSA is authorized to make any decision required in order to ensure compliance with the Food Act and related regulations. Thus, depending on the severity

EEA Agreement Article 19. Section 3 of the Norwegian Regulation on food information states that fresh fruits, berries, vegetables and potatoes that are not prepacked shall be labelled with/accompanied by a trade description. Both prepacked and non-prepacked foods shall be labelled with/accompanied by information on country of origin. Apples, pears, plums, cherries and strawberries which are not prepacked shall be accompanied by information on the species.

⁷ Both packed and non-prepacked genetically modified foods shall, as a general 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 25 February 2017, no such approval has been given for foodstuffs sold to consumers.

⁸ For example, the previous Norwegian regulation on labelling also included labelling requirements for foodstuffs treated with ionising radiation (Directive 1999/2/EC) and for quick-frozen foodstuffs for human consumption (Directive 89/108/EEC). The FIC does not amend or annul these provisions, but NFSA has decided to move these provisions to the regulations regarding the related specific food groups.

of the violation, the NFSA will determine the appropriate sanction in each case.

The most common form of sanctioning is an injunction requiring revision of the labelling/advertisement, or an injunction requiring changes to the content of the food product such that it corresponds with its labelling. The NFSA may also impose fines for each day that the company remains noncompliant despite an injunction, but these occur rarely, and are typically small amounts (approx. 2,000 – 20,000 NOK).

Furthermore, the NFSA is empowered to impose administrative

fines, but this is uncommon. Of practical interest is the fact that the NFSA may prohibit the sales, or require the withdrawal of the foodstuffs in question from the market. The Food Act also gives a legal basis for criminal prosecution, which may result in criminal fines and imprisonment. However, such actions are reserved for serious cases, such as those involving the abuse of animals. An entity subject to sanction by the Norwegian authorities is normally entitled to comment on the circumstances, and there is a formal complaint system in place for when a sanction is actually imposed. Thereafter, the case may be disputed in court.

Portugal

PORTUGUESE IMPLEMENTING REGULATION ON REG. (EU) 1169/2011

Author: *Francesco Montanari / Arcadia International*

BACKGROUND

Portugal adopted implementing legislation for Regulation (EU) No 1169/2011 on food information to consumers (FIC Regulation) in June 2016 in the form of Decree-Law No. 26/2016. The decree laid down national requirements for the provision of food and allergen information for non-prepacked foods by food business operators in accordance with Article 44 FIC Regulation. Specific requirements for distance selling of such goods have been published as well, with a specific sanction regime for the violation of EU and national requirements governing food information to consumers.

Decree-Law No. 26/2016 entered into force on 7 December 2016, repealing Decree-Law No. 560/99, which served to implement the provisions of Directive 2000/13/EC on labelling, presentation, and advertising of foodstuffs for over a decade.

NON-PREPACKED FOODS: MANDATORY FOOD INFORMATION

Decree-Law No. 26/2016 indicates the mandatory particulars that business operators selling non-prepacked foods must provide to consumers as well as the permissible methods for making this information available. For instance, foods pre-packed on the retailer's premises for direct sale must bear labels providing the legal name of the food, name of the business operator responsible for food information, allergen information, net quantity, packing date, storage instructions, instructions for use, and country of origin information if applicable. For foods sold by mass-caterers, only the legal name and allergen information must be provided to consumers, but the presence of allergens must be flagged by any means that allows consumers to easily take notice of it.

Francesco Montanari is a lawyer specializing in food law. He holds a Ph.D. in EU law from the University of Bologna, and has fifteen years of experience in the food sector. He has worked in the British retail sector and for the European Commission (DG SANCO). Based in Lisbon, he currently works for Arcadia International E.E.I.G., providing business and non-business clients with a wide range of services in Portugal and throughout the EU. He offers policy evaluations, SPS-related technical assistance, regulatory compliance advice, and training. Francesco is a regular contributor to peer-reviewed food law journals and professional magazines. He is fluent in English, French, Italian and Portuguese.



Francesco Montanari, attorney at law
ARCADIA International
Chaussée de Louvain, 1220 A 4/3
B-1200 Woluwe Saint Lambert -
Brussels, Belgium

www.arcadia-international.net

NON-PREPACKED FOODS: DISTANCE SELLING

As online sales of food products steadily rise in Portugal, Decree-Law No. 26/2016 has been implemented to regulate the provision of consumer information for non-prepacked foods purchased from distance-sellers in addition to the provisions for prepacked foods in Article 14 FIC Regulation.

Under national rules, the product's legal name, allergen information, storage instructions, conditions for use, and country of origin if applicable are to be made available to consumers before the purchase is concluded through the distance selling medium, or by indicating in a prominent place in that medium how such information may be obtained. Information on allergens and country of origin must also appear on the accompanying documents or on the product label at the moment of its delivery.

SANCTIONS

Based on Decree-Law No. 26/2016, the violation of national food information requirements for non-prepacked foods may

result in the imposition of sanctions ranging from 100 to 3,740 EUR for natural persons and from 250 to 44,890 EUR for legal persons. The competent national authorities may impose sanctions of the same amount for violations of certain other requirements set by the FIC Regulation as well.

COUNTRY OF ORIGIN FOR MILK

Like several other EU Member States, Portugal is considering at present whether to create an obligation to provide information to consumers and mass-caterers on the country of origin of milk. A draft national measure was notified to the European Commission on 27 July 2016 under Article 45 FIC Regulation. The measure aims to require food business operators to include information on the country of milking and processing for milk and milk used in dairy products including cream, butter, cheese, curd and yoghurt, on food labels. The adoption of the final text will most likely occur in the first half of 2017. The decree should apply for a couple of years, after which the national competent authorities are expected to draw up an evaluation of its application.

Poland

IMPLEMENTATION OF EU REGULATION NO. 1169/2011 IN POLAND

Authors: *Grażyna Osęka & Jowita Prokop*

Polish labelling provisions are set out primarily in the Act on Safety of Food and Nutrition and the Act on Marketing Quality of Agricultural and Food Products, adopted on 25 August 2006 and 21 December 2000, respectively. Following the entry into force of Regulation No. 1169/2011, related Polish laws were appropriately adapted to implement EU law.

BASIC NATIONAL REGULATIONS

Product labelling must be in Polish (Article 6 of the Act on Marketing Quality of Agricultural and Food Products and Article 48 of the Act on Safety of Food and Nutrition) and include the manufacturer's code identifying a certain batch of the product (Article 7a of the Act on Marketing Quality of Agricultural and Food Products).

When labelling products destined for the Polish market, one should also consider interpretations contained in the official guidance document on Regulation No. 1169/2011 issued by the Agricultural and Food Quality Inspectorate in cooperation with the Ministry of Agriculture and Rural Development and the Office of Competition and Consumer Protection. The document is frequently updated, most recently in August 2016, and it provides guidelines for, inter alia, the use of terms such as "country style", "grandma's", etc. on the product label.

LABELLING OF INDIVIDUAL TYPES OF FOODS

Provisions implementing the Act on Marketing Quality of Agricultural and Food Products (Regulations of the Minister of Agriculture and Rural Development) also regulate the labelling of individual types of foods, such as foods sold to the final consumer or to mass caterers without prepackaging, or packed on the sales premises at the final consumer's request¹. Wherever these products are offered for sale, the name of the food, name of the manufacturer and list of ingredients must be provided. This information is given on the sales premises in the form of a notice concerning a particular food, or in a different manner at a place directly accessible to the final consumer.

Other specific regulations set out rules for the labelling of vegan and vegetarian products or fermented wine beverages. The latter are subject to the Regulation on Types of Fermented Wine Beverages and Specific Organoleptic, Physical and Chemical Requirements for These Beverages, notified to the European Commission as technical provisions.² The Regulation

¹ Regulation of the Minister of Agriculture and Rural Development of 23 December 2014 on the Labelling of Individual Types of Foods

² Regulation of the Minister of Agriculture and Rural Development of 22 May 2013 on Types of Fermented Wine Beverages and Specific Organoleptic, Physical and Chemical Requirements for These Beverages (Journal of Laws, it. 633)



Figure 1:
Polish strawberry wine

on the Labelling of Individual Types of Foods (§ 6) specifies that on the label of fermented wine beverages³ obtained from musts referred to in the Wine Act and containing at least 75% of a particular fruit or juice of a fruit, the term “fruit” may be replaced with the name of the fruit used to make the must. In such instances it would also be permissible to use a graphic of the fruit named.

It should be emphasized that the Regulation on the Labelling of Individual Types of Foods is subject to frequent changes. An amendment currently being developed would create conditions for use of the term “fresh” with regard to dairy products.

Sanctions for non-compliance with Regulation No. 1169/2011 or national regulations implementing the above-mentioned provisions are set out in both the Act on Marketing Quality of Agricultural and Food Products and the Act on Safety of Food and Nutrition. They are of a general nature and relate to infringements in food advertising, presentation and labelling.

“POLISH PRODUCT” AND “TRY FINE FOOD” LOGOS

Poland, alongside other EU countries such as Italy and France, has adopted national provisions on the indication of the country of origin of a food. The latest amendment to the Act on Marketing Quality of Agricultural and Food Products sets forth requirements for labelling with the “Polish product” (“produkt polski”) term (Article 7b). The label and logo, following the model set out in the Regulation of the Minister of Agriculture, may be used for both unprocessed and processed products. Unprocessed products may bear this information if production primarily took place in Poland. A processed food may carry the “Polish product” label when:



Figure 2: Regulation of the Minister of Agriculture and Rural Development of 16.12.2016 on the model for logo containing the “Polish product” term

³ As referred to in Article 3 (1) (c)-(e), (i), (m) and (o) of the Act on the Production and Bottling of Wine Products, Trade in these Products and Organization of the Wine Market

Grażyna Osęka specializes in issues connected with borderline products, health claims and also novel food. She is an external expert of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. In her capacity of a consultant, she collaborates with the food industry and the pharmaceutical industry, implementing numerous projects, connected, among others, with the qualification of products, introducing them in the market, and also with marking, presenting and advertising. She has participated in the works of a working group for novel food of the European Commission in Brussels.

For little fewer than 5 years, **Jowita Prokop** has been dealing with the issues of food labelling and food quality. She is the co-author of publications in the field of food law. She delivers lectures at training events concerning food labelling and official controls. Her professional experience has been gained in Warsaw law firms and at the Main Inspectorate of Agricultural and Food Quality, where she was responsible for works of the Food Fraud Contact Point. She was participating in works of European Commission. She graduated as a lawyer from the Faculty of Law and Administration at the Warsaw University.



Grażyna Osęka, food technologist
Jowita Prokop, attorney at law
Foodie sp. z o.o. sp. k.
39 Hoża Street, flat number 8
00-681 Warsaw - Poland
www.foodie.pl

1. It was produced on the territory of the Republic of Poland and all its ingredients are from Poland
2. Conditionally, it does not exceed the allowed use of up to 25% of its ingredients from outside Poland.

Foods may also bear the "Try fine food" logo certifying their high quality, which is granted by the Minister responsible for agricultural markets (Article 13).

ACT ON PREPACKAGED GOODS

Matters related to the labelling of prepackaged foods are regulated in the Act on Prepackaged Goods. Supervision of compliance with its provisions is a responsibility of the Central

Office of Measures. Provisions of the Act and guidelines are very specific, and thus must be discussed separately. According to the official position of the Office, for example, it is incorrect to indicate weight in grams with the capital letter "G" instead of the small letter "g". Proper indications, including use of the correct type and size of fonts, are necessary in order to avoid costs related to changing the labelling of prepackaged goods already on the market.



Figure 3: Regulation of the Minister of Agriculture and Rural Development of 21.07.2004 on the model for logo of quality of agricultural and food products

Romania

ROMANIAN DRAFT LAW ON IMPLEMENTATION OF REGULATION (EU) 1169/2011

Authors: *Oana Constantinescu & Toma Barbarasa*

The Romanian consumer protection authority (ANPC) recently published a draft law that would integrate the requirements of Regulation (EU) 1169/2011 on the provision of food information to consumers (FIC) into Romanian national law. The draft law aims to ensure the proper application of the FIC. National food labelling provisions have been applicable since the 2002 entry into force of Directive 2000/13/EC (which was repealed by the FIC), but there is currently no authority expressly tasked with ensuring compliance with the FIC.

The draft law designates the ANPC as the authority responsible for enforcing the FIC; it is already the main authority for food labelling issues as well as food safety inspections and sanctions.

This article provides a short summary of the Romanian draft law, which must be approved by the Romanian Government and published in the Official Gazette in order to enter into force.

SCOPE OF NEW RULES

The draft law contains regulations pertaining to non-prepacked foods and batch indication. The latter are already applicable in Romania following the entry into force of Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs.

Also, the draft law states that food information shall be in the Romanian language and introduces a definition of non-prepacked foods based on Article 44 FIC.

The indication of allergens is also addressed, as well as control measures and sanctions that may be imposed by ANPC representatives for violations of mandatory FIC provisions.

NON-PREPACKED FOODS AND INFORMATION ON ALLERGENS

Non-prepacked foods must bear the name of the product, date of minimum durability or the "use by" date, allergens, and in the case of glazed frozen foods, ice glaze proportion. Such information must be provided to consumers on a sign, notice, or in any other form that does not risk confusion.

Allergen information must be indicated either where the foods are offered to consumers or by a notice which invites the consumer to request such information from the personnel. Also, in case the non-prepacked foods are offered in multiple locations within the same unit, the allergen information must be presented in each location.

Allergen information may also be verbally communicated by the personnel or by an adequate device, provided that all of the following conditions are met: (i) there is a notice/sign that invites consumers to discuss allergens with personnel, (ii) the allergen information is available in printed or electronic form so as to be easily accessed by consumers, and (iii) the allergen information is always provided before the sale of the foods and only at the marketplace, without any costs incurred by the consumer.

SIGNIFICANT FINES IMPOSED FOR BREACHES

The draft law foresees that food business operators may incur significant fines for breaches of most of the FIC provisions.

For instance, if consumers are misled by food information, a fine of up to 50,000 RON (approx. 11,000 EUR) may be levied. This may relate to the legitimacy of the product, country of

origin, or to attributing effects or properties to a food which it does not have.

Breaches of FIC provisions concerning the responsibilities of the food business operator marketing/importing the product may be sanctioned with fines ranging from 3,000 to 30,000 RON (approx. 666 to 6,666 EUR). Such situations may include for instance when food operators do not ensure the presence and accuracy of food information in accordance with applicable legislation, or in cases where they know or could presume foods for sale to be non-compliant on the basis of information in their possession.

Lack of mandatory information (e.g. net weight, storage conditions, allergen information, etc.) on the label may be sanctioned with a fine of up to 10,000 RON (approx. 2,222 EUR). Also, non-observance of the FIC provisions for prepacked foods offered for sale by means of distance selling may be sanctioned with fines ranging from 2,000 to 5,000 RON (approx. 444 to 1,111 EUR).

Furthermore, the draft law foresees fines ranging from 1,000 to 10,000 RON (approx. 222 to 2,222 EUR) for non-indication of the batch number or violations of the language obligation or mandatory information requirements for non-prepacked foods.

Last but not least, additional sanctions such as a temporary injunction on marketing a food may also be imposed. In cases where the mandatory indication of allergens has not been made and a risk to consumers' health results, the authorities may also halt further marketing of the affected product and compel the recall of products already placed on the market.

Oana Constantinescu is partner at schoenherr attorneys in Bucharest. Her focus lies within the legal service concerning real estate, food & beverage as well as consumer protection law.



Toma Barbarasă, attorney at schoenherr, provides legal service to international clients with regard to real estate, construction & infrastructure, food & beverage, consumer protection law as well as regarding corporate/M&A.



schoenherr

Oana Constantinescu, partner
Toma Barbarasa, attorney at law
Schoenherr si asociatii sca/schoenherr
attorneys at law
30 Dacia Blvd, sector 1
RO-010413 Bucharest
Romania
www.schoenherr.eu

Slovakia

SLOVAK NATIONAL IMPLEMENTING REGULATION CONCERNING REG. 1169/2011

Author: *David Štros, Štros Kusák Attorneys at law & Patent attorneys*

The Slovak regulation that adapts national law in conformity with Regulation (EU) 1169/2011 on the provision of food information to consumers is Act No. 152/1992 Coll. on foodstuffs (*Zákon o potravinách*, abbr. ZOP). ZOP provides general rules for the labelling of foodstuffs as well as sanctions for violations of mandatory provisions of Regulation 1169/2011 and national food labelling law.

The regulation of allergen labelling for non-prepacked foodstuffs is set forth in national Decree No. 243/2015 Coll. on food labelling requirements, which was issued by the Ministry of Agriculture and Rural Development of the Slovak Republic (*Vyhláška o požiadavkách na označovanie potravín*, abbr. VPOP) and has been in effect since 1 November 2015.

In July 2016, the Ministry of Agriculture and Rural Development of the Slovak Republic published a draft amendment to the VPOP that includes slight changes regarding labelling of non-prepacked foodstuffs.

This article provides a short summary of the Slovak national regulations of allergen labelling and labelling of non-prepacked foods, as well as an overview of the sanction system and changes to national law concerning Regulation 1169/2011. It also provides a short summary of the pending draft amendment to the VPOP.

SCOPE OF APPLICATION AND GENERAL RULES

The ZOP and the VPOP address the sale of foodstuffs directly to consumers and to mass caterers (Article 2(2)(d) Reg. 1169/2011).

According to Section 9 para. 1 ZOP, food information must be provided in the Slovak language.

NON-PREPACKED FOOD AND INFORMATION ON ALLERGENS

Non-prepacked foodstuffs must be labelled with certain mandatory information as prescribed in Article 9(1)(c) Regulation 1169/2011.

According to the pending draft amendment to the VPOP, non-prepacked foodstuffs must be accompanied by required allergen information nearby. Such information must be provided in the immediate vicinity of the item – on the price label, near the price label, or in such a way that it clearly indicates only the intended non-prepacked food.

The pending draft amendment to the VPOP further states that in the case of a non-prepacked foodstuff, dish, or food placed marketed by means of over-the-counter sale or self-service, the list of allergens must be located in an easily visible place on the counter from which this non-prepacked foodstuff, dish, or food is sold, or in its accessible vicinity.

In the case of food offered to the final consumer through a separate menu, allergens must be indicated for each food.

MILK

The VPOP also includes special provisions with regard to milk and milk products presented in glass bottles intended for reuse. These products must be labelled only on the bottle cap with at least the name of the foodstuff, fat content as a percentage of weight, net amount, and the best-before or expiration date.

SANCTION SYSTEM

The sanctions for a violation of the labelling requirements set forth in Regulation 1169/2011 and national law are regulated in ZOK.

In the event that a foodstuff is not labelled properly in accordance with European or national law or is not labelled at all, a fine ranging from 100 to 100,000 EUR may be imposed. For an infringement repeated within one year from the imposition of a fine, the fine may be doubled.

Dr. David Štros is attorney-at-law and patent attorney. His work focuses on intellectual property rights, industrial rights, competition law, and civil law. He assists with all aspects of Czech law issues and offers essential and specialized advice on Slovak law.



ŠTROS & KUSÁK

Dr. David Štros
Národní 32
CZ-110 00 Praha 1
Czech Republic
www.stroskusak.cz

Slovenia

SLOVENIAN IMPLEMENTING REGULATION CONCERNING REGULATION 1169/2011 (“FIC REGULATION”) AND NATIONAL RULES ON ALLERGENS

Author: [Petra Smolnikova](#)

In 2014, the government of the Republic of Slovenia adopted the Decree on the implementation of Regulation 1169/2011 (“Decree”), which designates competent authorities for oversight of information provided to consumers, states the acceptable practices for labelling allergens, and provides for penalties in the event of noncompliance. The authority for supervision and control is vested in the Administration of

the Republic of Slovenia for Food Safety, Veterinary and Plant Protection, and in certain instances, the Health Inspectorate of the Republic of Slovenia. Under the Decree and in accordance with Art. 44 para. 1(b) and 2 FIC Regulation, all information on allergens should be designated on the foodstuff, in its direct vicinity, or in a catalogue or other area where the non-prepacked foodstuffs are presented. The designation must

be clearly visible, unambiguous, legible, and fully uncovered. Furthermore, in public food venues, allergens must be indicated next to the foods to which they pertain (e.g. on menus, boards, displays).

In late 2015, the Slovenian Chamber of Commerce and the Institute for Nutrition published the document "Guidelines for the labelling of allergens in non-prepacked foodstuffs" ("Guidelines"), which includes permissible methods for providing allergen information, but does not vary significantly from the rules stated in the Decree. Despite the Guidelines' approval from the Ministry of Agriculture, Forestry and Food in its Resolution U0070-24/2015, they are intended for use on a voluntary basis for orientation purposes, and do not hold any formal legal status.

Also in 2014, the formerly applicable Rules on prepacked foodstuffs were repealed by the Rules on special conditions regarding labelling and presenting of prepacked foodstuffs (which, however, do not apply to foodstuffs on the market that are non-prepacked, packed in the place of sale based on the request of the end consumer, or for foodstuffs prepacked for direct sale whose labelling is regulated under special legislation).

THE NATIONAL SANCTION SYSTEM

Additionally, legal entities as well as persons responsible for compliance may be sanctioned under the Decree with penalties ranging between 6,000 – 30,000 EUR (respectively 1,500 – 3,000 EUR for individuals), inter alia, for placing foodstuffs on the market that are not in compliance with Art. 9 (para. 1, points a, b, c, f, h and i) or Art. 21 (para. 1) of the Regulation. The latter breaches are deemed as serious violations. Other breaches, inter alia, invoke penalties ranging between EUR 3,000 and 15,000 (respectively EUR 1,000 – 3,000 for responsible persons), when labelling, marketing or the presenting of foodstuffs is done in an incompliant manner based on Art. 9 (para. 1, points d, e, g, j, k and l) or Art. 36 (para 1 and 2) of the FIC Regulation. The same sanctions apply in the event that a supplier provides foods that, based on information in the supplier's possession and his or her specialized knowledge, the supplier should know or presume not to be in compliance with the Regulation, or if the supplier alters information accompanying the foodstuff

and these changes may mislead the end consumer or hinder the end consumer's ability to make an informed decision in any other manner.

BEER AND CHEESE

No further changes to national law are contemplated at this time, in particular with regard to regulations on beer and cheese. For beer, the Rules concerning the quality of beer from 2003 and 2008 still apply, and milk products should be labelled in accordance with the general rules on the labelling of prepacked foodstuffs, the rules on the designation of nutritional values, and other applicable regulations and standards.

Petra Smolnikar left

Schoenherr attorneys (Slovenia) in 2017 and founded her own law firm "Petra Smolnikar Law". Previously, as a partner at Schoenherr (Slovenia) she steered the Regulatory and Employment teams and also engaged in Corporate/M&A and Compliance. Within the regulatory field, Petra has been advising high-profile clients on various aspects of environmental and energy law as well as in food law, cosmetics and pharmaceuticals.



Petra Smolnikar - Attorney-at-law
Dunajska 51
1000 Ljubljana
Slovenia
info@petrasmolnikarlaw.eu
www.petrasmolnikarlaw.eu

Spain

SPANISH REGULATION IMPLEMENTING REG. 1169/2011

Author: *Mónica Weimann, Gomez-Acebo & Pombo*

Spain implemented EU Regulation 1169/2011 of 25 October on Food Information to Consumers (hereinafter, "**FIC**") with Royal Decree 126/2015 of 27 February (hereinafter "**RD**") which entered into force on 27 February 2015.

This paper briefly summarises key new elements introduced by the RD, but does not intend to provide a comprehensive legal analysis.

Additionally, it should be noted that AECOSAN (Spanish Agency of Food Security and Nutrition) has published guidance that aims to facilitate interpretation of the RD's provisions.

A. SCOPE OF APPLICATION (ARTICLE 2 RD)

The RD is applicable to:

- Food business operators at all stages of the food chain, in case their activities affect food information provided to consumers; and
- Food information of all foods destined to the final consumer:
 - i. That are non-prepacked and offered for sale to the final consumer and mass caterers;
 - ii. That are packed at the point of sale at the buyer's request;
 - iii. That are packed by retail traders for immediate sale at their own establishments;
 - iv. That are offered for sale via distance communication, with respect to all of the above-mentioned food types.

B. MANDATORY FOOD INFORMATION (ARTICLES 4 AND 5 RD)

The RD specifies what mandatory food information must be provided for each food category above. In particular, among such information, the presence of substances that cause allergies or intolerances (hereinafter jointly referred to as "Information on Allergens") must be indicated. The following scheme provides a brief overview:

Non-prepacked food offered for sale to final consumers and mass caterers

Name of the food; Information on Allergens; QID; and alcoholic strength by volume.

Foods packed at the point of sale at buyer's request

Name of the food; Information on Allergens; QID; and alcoholic strength by volume.

Foods packed by retail traders

Name of the food; list of ingredients; Information on Allergens; QID; net quantity; date of minimum durability; special storage instructions; name and address of food business operator; country of origin; and instructions for use.

Non-prepacked foods sold by mass caterers

Information on Allergens.

Fruits, vegetables, tubers and dried fruit

Name of the food; net quantity; and name and address of food business operator.

C. AVAILABILITY, PLACEMENT AND PRESENTATION OF MANDATORY FOOD INFORMATION

I. General provisions (Articles 6 and 7 RD)

Under the general principles of FIC, mandatory particulars always must be available and easily accessible. Article 44.2 FIC empowers Member States with discretion to determine on a national basis the means by which mandatory food information must be provided to consumers. The Spanish legislature exercised this power with the following results:

a) *Non-prepacked food offered for sale to final consumers and mass caterers, as well as foods packed at the point of sale at buyer's request.*

Mandatory food information shall be provided in writing, either on labels attached to the food or on signs placed (i) where the food is presented for sale, (ii) directly on top of the food, or (iii) nearby.

When the mandatory food information is provided directly on top of the food or on a label attached thereto, the characters shall be printed in such manner as to ensure clear legibility, using at least the same font size as the one defined in Annex IV of FIC.

b) *Foods packed by retail traders for immediate sale at their own establishments.*

Mandatory food information shall be provided on the packaging itself or on a label attached thereto. In the event the food is sold directly by a vendor, all mandatory food information save for the date of minimum durability or the 'use by' date may be provided on signs placed where the food is presented for sale.

The same font size specifications as in point a) apply when the mandatory food information is provided directly on top of the food or on a label attached thereto.

c) *Fruits, vegetables, tubers and dried fruit.*

Whenever these foods are sold in a self-service manner, the name of the food can be provided on signs placed where the food is presented for sale or nearby.

II. Specific provisions regarding Information on Allergens (Article 6.5 RD)

The RD offers the possibility of providing Information on Allergens by other appropriate means, i.e. different than those specified under section C. I.) above. Generally such other means must ensure that the information is accessible to consumers before purchase and does not entail any additional cost for them.

1) Information on Allergens can be provided in an oral manner, as long as:

- i. Such information can be given easily by the establishment's staff or by alternative means before the purchase has been concluded and does not entail any additional cost to the consumer.

- ii. The information is recorded in written or electronic form in the establishment where the food is offered for sale and is easily accessible to the establishment's staff, control authorities and consumers who request it.
- 2) In the areas of the establishment where foods subject to the RD are offered for sale, the following indications shall be made in such a way as to be easily visible, clearly legible and accessible to consumers:
- i. The location within the establishment where Information on Allergens is available; or alternatively
 - ii. That consumers may consult the establishment's staff to obtain Information on Allergens.

However, these indications are not necessary:

- When the Information on Allergens is provided on labels attached to the food or on signs placed near to it in a way that is easily readable by the consumer before the purchase has been completed.
- In places where foods specifically adapted to the needs of consumers affected by food allergies or intolerances are supplied. Nevertheless, information on substances and products that may cause allergies and intolerances must be available in such establishments and shall be provided at the request of consumers or control authorities.

D. NON-PREPACKED FOODS OFFERED FOR SALE VIA DISTANCE COMMUNICATION

(Article 9 RD)

Under Article 9 RD, when selling foods by means of distance communication, mandatory food information must be available in accordance with the provisions set forth in Article 14.5 FIC.

However, Article 9 RD provides an exception with regard to the indication of the country of origin or place of provenance as per Article 9.1.i) FIC, as well as to indications that are mandatory but not listed in Article 9.1 FIC. These indications do not necessarily have to be available before the act of purchase has ended, but in any case must be available at the time of delivery alongside all mandatory particulars as set forth in Articles 4 and 5 RD.

E. MANDATORY FOOD INFORMATION LANGUAGE (Article 10 RD)

The mandatory food information referred to in Articles 4 and 5 RD must read at least in the official language of Spain, which is Spanish. However, this requirement does not apply to traditional products produced and distributed exclusively within the scope of an Autonomous Community with its own co-official language, except for the Information on Allergens, which always must be provided in Spanish.

F. LIABILITY OF FOOD OPERATORS (Articles 11 and 12 RD)

Without prejudice to the liability scheme provided in FIC, the RD sets forth special obligations for food operators in relation

to the food categories subject to the scope of its application.

Food business operators are obliged to communicate mandatory food information to other food business operators (those that receive the food), including the Information on Allergens, in order to enable the latter to provide the information to final consumers.

In addition, food business operators must keep such information and make it available to any consumer or supervisory authorities upon request in order to guarantee accurate identification of the food. Food business operators must comply with this obligation at least until it can be reasonably assumed that the food has been consumed.

Mónica Weimann Gómez is resident partner in the London office of Gómez-Acebo & Pombo. She divides her time between the firm's London and Madrid offices. She has a strong focus on advising German clients on cross-border corporate transactions involving Spain, particularly in the transport and pharmaceutical sectors.



GÓMEZ-ACEBO & POMBO

Mónica Weimann Gómez, Resident Partner - London
 Five Kings House
 1 Queen Street Place - London
 EC4R 1QS - United Kingdom
www.gomezacebo-pombo.com

SWEDISH NATIONAL IMPLEMENTATION MEASURES WITH REGARD TO REGULATION 1169/2011 ON THE PROVISION OF FOOD INFORMATION TO CONSUMERS

Author: Magnus Friedberg; Gulliksson

The Swedish National Food Agency ("NFA") has implemented one national regulation relating to Regulation 1169/2011 on the provision of food information to consumers ("FIC"), the NFA Regulation (LIVSFS 2014:4) on food information. The Regulation was submitted under the TRIS notification procedure and subsequently implemented in 2014.

Additionally – and as a result of the FIC – consequential changes to other national regulations have been made as well, and a number of regulations have been repealed.

NFA REGULATION (LIVSFS 2014:4) ON FOOD INFORMATION

The Regulation relates to the following issues:

- Information on non-prepacked foods
- Language requirement
- Information concerning net weight
- Non-prepacked veal
- Certain information for prepacked and non-prepacked potatoes.

INFORMATION REQUIREMENTS FOR NON-PREPACKED FOODS

The provision of information on allergens in food or a declaration of where this information can be obtained is mandatory, regardless of whether or not the consumer inquires about it. The exception is where the consumer's allergy has been assessed and documented beforehand and the food product is provided to him or her based on this information. Otherwise, allergen information can be communicated to the consumer by any of the following methods:

1. Written notices or the like in the immediate vicinity of the food,
2. Written material that presents or accompanies the food;
3. Verbal communication,
4. The name of the food itself, provided that it makes clear that the allergen-related substance or product is an ingredient or processing aid, or
5. Other methods, given that the information, if necessary, also may be provided orally.

If the food business operator decides to provide the information only upon request by the consumer, the operator must ensure that it is clear to the consumer how he or she may gain access to those details. Separate information to this effect may be provided in writing (such as a notice or on a menu) or orally.

The name of the food – legal, customary, or descriptive name – must be provided upon request from the consumer for any non-prepacked food.

For foods packed at the point of sale at the consumer's request or prepacked for direct sale, mandatory food information required by Article 9(1)(b) and (e-k) FIC – for instance, a list of ingredients, net quantity, and "use by date" – must also be provided upon the consumer's request. Thus, this information requirement is limited to these particular categories of foods.

LANGUAGE

Mandatory food information and the food information provided in accordance with the National Food Agency's regulations must be provided in Swedish. Other languages may be used if the language is only slightly different from Swedish, such as if the words are sufficiently similar – that is, where the spelling is only slightly different such as "te" for "tea" or "tomater" for "tomatoes". Danish and Norwegian are often considered to be sufficiently similar; however, it should be noted that there are considerable differences both in spelling and wording, and the operator therefore cannot use these languages in many individual cases. The food information may be provided in several languages at the same time.

NET QUANTITY

When supplying liquid foods, the net quantity may be stated in decilitres rather than in terms as required by Article 23 of the FIC.

For packs of tablets, capsules or similar portions of table-top sweeteners, dietary supplements and food for special medicinal purposes, the net quantity may be provided by stating the number of tablets, capsules or similar portions rather than in terms as required by Article 23 of the FIC.

UNPACKED VEAL

Mandatory information regarding unpacked veal as required by Part I, Annex VII to Regulation (EC) No 1308/2013 of the

European Parliament and of the Council may be provided through the same methods as in points 1, 2, 3 or 5 of § 10.

POTATOES

Prepacked potatoes must be labelled with:

1. the name of the potato variety next to the name,
2. a statement that the potatoes are to be kept in a cool, dark place, and
3. the packing date.

This does not apply to products that are lawfully produced in another Member State of the European Union or in another state party to the European Economic Area Agreement (EEA Agreement) or Turkey.

Potatoes sold unpacked must be on display with the variety name next to the name by means of a sign or similar notice in the vicinity of the potatoes.

CONSEQUENTIAL CHANGES

The FIC has also required consequential changes to the following regulations due to their references to the FIC and other regulation above.

- SLVFS 1997:27 (grain-based foods and food for infants and small children)
- SLVFS 1997:30 (certain foods 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)

REPEALED REGULATIONS

The following regulations are repealed:

- The National Food Agency's regulations (1993:21) on nutritional declarations,
- The National Food Agency's regulations (2002:47) on the labelling of certain foods, and
- The National Food Agency's regulations (2004:27) on the labelling and presentation of food

Magnus Friberg is advocate and partner at Gulliksson Advocates, Sweden. Gulliksson Advocates is a full services business law firm with its base in intellectual property and the life sciences.



GULLIKSSON

Magnus Fridberg, Partner
Gulliksson Law Firm
Scheelevägen 27
223 63 Lund - Sweden
www.gulliksson.se

UK

UK IMPLEMENTATION OF FOOD INFORMATION FOR CONSUMERS (EC) REGULATION 1169 OF 2011 [EU FIC]

Author: David Hetherington, Higgs & Sons

GENERALLY

"The EU FIC sets common definitions, general principles, requirements and responsibilities to provide a clear framework and a common basis for EU and national measures governing food information, and in particular food labelling."

[*Explanatory Memo*. para 2.1]

The EU FIC was implemented into the law of England by The

Food Information Regulations 2014 SI [Statutory Instrument] No 1855. The UK regulation was made on 14 July 2014, but its main provisions became effective on 13 December 2014 when the EU FIC came into force.

Similar, but separate regulations, were made in Wales, Northern Ireland and Scotland, to implement the EU FIC into their respective devolved legal systems, as follows:

The Food Information (Wales) Regulations 2014
The Food Information Regulations (Northern Ireland) 2014
The Food Information (Scotland) Regulations 2014

POLICY

The implementation of EU FIC in the UK was stated to “meet our domestic policy aims by including a proportionate, effective and risk-based approach to the enforcement of the directly applicable EU FIC.” [Explanatory Memo. para 7.4]

Before 13 December 2014, food information and labelling breaches were immediate criminal offences under the UK Food Labelling Regulations 1996, which implemented the consolidated EU Food Labelling Directive 13 of 2000.

The main change in UK policy and law is to restrict the primary means of enforcement, where there are breaches of EU FIC, to Improvement Notices.

In the UK the main food authorities are local authorities or port health authorities. Local authorities employ environmental health officers and trading standards officers to investigate and enforce the law relating to food safety, labelling, and descriptions.

IMPROVEMENT NOTICES

Generally (unless the breaches involve consumer safety) the UK food authorities must first issue an Improvement Notice under S.10 Food Safety Act 1990, for breaches of EU FIC. This gives the food business operator the opportunity to correct the breach within the period stated in the Improvement Notice.

If the food business operator disagrees with the requirements of the Improvement Notice, it can appeal to the Magistrates Court under Sections 37 – 38 Food Safety Act 1990, within one month of the service of the Improvement Notice, or such earlier time before the notice is stated to take effect.

FOODS CONTAINING PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

The first area, where the UK still retains the discretionary power for food authorities to go straight to criminal prosecution, is in relation to foods containing products causing allergies or intolerances. The requirements are set out within three provisions of the EU FIC:

- Article 9 (1)(c) provides for mandatory particulars of ingredients or processing aids causing allergies or intolerances.
- Article 21 provides that these shall be emphasized with a clear reference to the product causing allergies or intolerances.
- Annex II lists 14 products causing allergies or intolerances.

FOODS WITH EXPIRED USE BY DATES

The second area, where the UK retains the discretionary power for food authorities to go straight to criminal prosecution, is for breaches of EU FIC Article 24, where the Use By Date on the

food has expired, and the food is deemed to be unsafe. This is subject to prosecution under the UK General Food Regulations 2004, Regulation 4, which implements the enforcement of EC Regulation 178 of 2002, of which Article 14 sets out food safety requirements.

BREACH OF IMPROVEMENT NOTICE

If the food business operator fails to comply with the Improvement Notice requiring compliance with a provision of the EU FIC within the time stated in the Improvement Notice, the food authority can then prosecute for non-compliance.

PENALTIES

If prosecuted, the Magistrates Courts, can impose as a financial penalty, an un-limited fine for an offence committed since 12 March 2015, plus costs. Moreover, financial penalties for offences involving food safety were effectively increased by Sentencing Council Guidelines which came into force for offences sentenced after 1 February 2016.

CONCLUSION

The UK Food Information Regulations 2014 implements a “more proportionate, effective and risk-based approach” by extending the use of Improvement Notices to enforce breaches of the EU Food Information to Consumers Regulation 1169 of 2011.

David Hetherington joined Higgs & sons, as a consultant, in 2011 with 30 years' experience of Local Authority and Government Regulatory enforcement, including Trading Standards, Environmental Health, Fire, HSE, DEFRA, Food Standards, and OFT. He has been independently recommended for 10 years as a Leader in the Field of Food Law in Chambers & Partners' UK legal guide and graded in Band 1.



**HIGGS
& SONS**
S O L I C I T O R S

David Hetherington,
Consultant Regulatory
Higgs & sons Solicitors
Waterfront
3 Waterfront Business Park
Brierley Hill, West Midlands DY5 1LX
United Kingdom
www.higgsandsons.co.uk

meyer. 

food. news 
legal and regulatory news

meyerlegal.de