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## Summary of legal regulation of additional mandatory particulars for specific types or categories of foods according to the regulation FIC

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### ABSTRACT

The paper presents a summary of the legal treatment of additional mandatory particulars for specific types or categories of foods under Regulation (EU) 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. The authors of the paper analyse and interpret the relevant legislation using traditional methods of legal analysis and legal-hermeneutical methods, with an emphasis on the linguistic and systematic interpretation of those provisions that are directly related to the indication of additional mandatory particulars for foods packaged in certain gases, foods containing sweeteners, foods containing glycyrrhizic acid or its ammonium salt, Beverages with high caffeine content or foods with added caffeine, Foods with added phytosterols, phytosterol esters, phytosterols or phytosterol esters, and frozen meat, frozen meat preparations and frozen unprocessed fishery products. The paper's authors aim to provide the reader with a comprehensive summary of the legislation on the indication of additional mandatory particulars for specific types or categories of food.

**Keywords:** food labeling, additional, mandatory, particular, sweetener, caffeine, date of freezing

### INTRODUCTION

Mandatory food information under Regulation (EU) 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 (from now on referred to as '*the FIC Regulation*') [1] may be divided into mandatory particulars as referred to in Article 9(1) of the FIC Regulation and additional mandatory particulars for specific types or categories of food. The legal basis for the existence of additional mandatory particulars is based on Article 4(2) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation, and advertising of foodstuffs for sale to the ultimate consumer [2]. This Article of that Directive did not yet contain a list of additional mandatory particulars. Still, it did allow legislation that applies to specific foods and not to foods, in general, to provide for the obligation to indicate on those foods further (additional) particulars in addition to the mandatory food particulars. Concerning the obligation to include additional mandatory particulars for specific foods, specific legislation has gradually been adopted, which has completed the legal basis for including additional mandatory particulars. These were as follows:

- Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC [3],
- Council Directive 96/21/EC of 29 March 1996 amending Commission Directive 94/54/EC concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 79/112/EEC [4],
- Commission Directive 2002/67/EC of 18 July 2002 on the labeling of foodstuffs containing quinine, and of foodstuffs containing caffeine [5],
- Commission Directive 2004/77/EC of 29 April 2004 amending Directive 94/54/EC as regards the labeling of certain foods containing glycyrrhizinic acid and its ammonium salt [6] and
- Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning labelling foods and food ingredients with added phytosterols, phytosterol esters, phytosterols, and/or phytostanol esters [7].

The current legislation on additional mandatory particulars for specific types and categories of food is contained in Annex III of the FIC Regulation, where additional mandatory particulars for specific types and categories of food are listed in an exhaustive (closed) list. The European Commission is empowered by Article 10(1) of the FIC Regulation to establish the additional mandatory particulars for specific types and categories of food, by Article 10(1) of the FIC Regulation. The European Commission has adopted only one delegated Regulation under this empowerment about modifying the additional mandatory particulars for foods with added phytosterols and phytosterols and their esters [8].

For the labelling of foods with additional mandatory particulars under Annex III of the FIC Regulation, the general requirements for the presentation of mandatory food information under the FIC Regulation (a form of presentation, availability, location, and presentation of mandatory particulars) apply. However, certain rules do not apply to the labeling of foods with additional mandatory particulars.

The first derogation concerns the form of the additional mandatory particulars. Mandatory food particulars under Article 9(1) of the FIC Regulation must be given in words and numbers. However, these particulars may additionally be expressed using pictograms and symbols. However, using pictograms and symbols instead of words or numbers is not allowed under Article 9(2) of the FIC Regulation. This requirement does not apply to the indication of additional mandatory particulars for specific food types and categories. The exact form of the additional mandatory particulars is set out in Annex III of the FIC Regulation. In addition, these particulars may not be expressed using pictograms and symbols. About the indication of additional mandatory particulars under Annex III of the FIC Regulation, neither can the European Commission adopt delegated and implementing acts allowing food business operators to express one or more additional mandatory particulars using pictograms or symbols instead of words or numbers.

The second derogation concerns the presentation of the additional mandatory particulars. Mandatory food particulars under Article 9(1) of the FIC Regulation shall be presented in such a way as to ensure their unambiguous legibility and in a font size such that the median font height (x-height) as defined in Annex IV of the FIC Regulation is greater than or equal to 1,2 mm. For foodstuffs with a wrapper or container whose largest surface area is less than 80 cm<sup>2</sup> (e.g. chewing gum, lollipops), the median font height shall be greater than or equal to 0,9 mm. These rules do not apply to the additional compulsory indications under Annex III of the FIC Regulation (e.g. the additional compulsory indication '*Packaged in a protective atmosphere.*' or the date of freezing or the date of first freezing). However, if an additional mandatory particular is made in the name of the food, for example, contains sweetener(s) - cola-flavored lemonade contains sweeteners, this additional mandatory claim must also comply with the minimum font size requirements of Article 13 of the FIC Regulation, as it is part of the mandatory claim under Article 9(1) of the FIC Regulation [9].

Finally, about the indication of additional mandatory particulars, it should be noted that where specific (other) requirements for the form of indication, availability, location, or presentation of such particulars are set out in Annex III of the FIC Regulation, the specific provisions contained in Annex III of the FIC Regulation (*lex specialis*) apply instead of the general requirements for mandatory food information (*lex generalis*). This is because the specific legislation takes precedence in application over the general legislation [10].

### MATERIAL AND METHODOLOGY

The subject of this paper is the identification of the legislation at a national and supranational level that contains the legal regulation of additional mandatory particulars for specific types or categories of food under the FIC Regulation. The individual legal standards are obtained from [www.eur-lex.eu](http://www.eur-lex.eu), the official website of the European Union, for searching European Union legal acts, other acts, and official information published in the Official Journal of the European Union, and from [www.slov-lex.sk](http://www.slov-lex.sk), the official website of the Ministry of Justice of the Slovak Republic, which contains the Collection of Laws of the Slovak Republic. We draw in particular on the

FIC Regulation, the derogated Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation, and advertising of foodstuffs [11] and Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, as amended [2] and related legal acts. The source of information at the national level (Slovak Republic) is also Food Law 152/1995 Col. SR, as amended [12], [13]. The subject matter of the uniform regulations is then analysed and interpreted using traditional methods of legal analysis and legal-hermeneutical methods, emphasising the linguistic and systematic interpretation of those provisions directly related to the indication of additional mandatory data. Domestic legislation is compared with supranational legislation to present it systematically within the logical structure of classical legal dogmatics as a systematic set of legal institutes, legal norms, and the consistent results of legal application and legal implementation practice. The findings of practice are subsumed under specific hypotheses of legal norms. At the same time, logical syllogism is used to deduce legally established dispositions and sanctions tied to the fulfilment of the hypotheses of legal norms. Given the interdisciplinary nature of the paper, the system of legal dogmatics of additional mandatory data is confronted and supplemented, where appropriate, with current legal and food doctrine.

## RESULTS AND DISCUSSION

Additional mandatory particulars are provided for the following types or categories of food:

- foods packaged in certain gases,
- foods containing sweeteners,
- foods containing glycyrrhizinic acid or its ammonium salt,
- beverages with high caffeine content or foods with added caffeine,
- foods with added phytosterols, phytosterol esters, phytostanols, or phytosterol esters and
- frozen meat, frozen meat preparations and frozen unprocessed fishery products.

### Foods packaged in certain gases

To extend the shelf life of food, the food industry uses modified atmosphere packaging. Packaging plays a crucial role by facilitating the containment, transportation, and logistics of fresh and processed commodities [14]. Modified atmosphere food packaging has a composition of gases surrounding the food that is different from that of air. Under reduced O<sub>2</sub> and high CO<sub>2</sub>, the metabolic processes of the horticultural product and microbial activity are slowed down, contributing to extended shelf life [14]. Packaging of food in a modified atmosphere can take the form of vacuum packaging or packaging in a protective atmosphere [15]. Packaging gases are a functional class of food additives according to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [16]. Food additives are divided according to the function they perform into so-called functional classes. The functional classes of food additives are listed in Annex I of Regulation (EC) No 1333/2008 [16]. One of these functional classes is packaging gases. Packaging gases are used to package food in a protective atmosphere. Packaging gases are gases other than air, introduced into a container before, during, or after placing a foodstuff in that container. Packaging gases are listed in Table 1.

**Table 1** Packaging gases.

E number	Name of the packaging gas
E 290	Carbon dioxide
E 938	Argon
E 939	Helium
E 941	Nitrogen
E 948	Oxygen
E 949	Hydrogen

Packaging gases used in the packaging of certain foods (e.g. packaged cut meat, meat products, or cheese) are not considered food ingredients within the meaning of the FIC Regulation and, therefore, do not appear in the list of food ingredients. However, consumers should be informed about the use of packaging gases in the packaging of foodstuffs, as foodstuffs packaged in this way have a longer shelf life than similar foodstuffs packaged in other ways. Legislation on the indication of additional mandatory particulars on foods whose shelf-life has been extended by the use of packaging gases has been adopted at the European Union level by Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of

particulars other than those provided for in Council Directive 79/112/EEC [3]. This legislation is now contained in Annex III of the FIC Regulation.

In the case of foodstuffs whose shelf life has been prolonged by the use of packaging gases, an additional mandatory particular 'Packaged in a protective atmosphere' must appear on the packaging or the label attached thereto. This additional mandatory particular is mandatory on the packaging or the label attached to the food and does not need to appear in the name of the food or in close proximity to the name of the food.

## Foods containing sweeteners

Foods containing sweeteners must also contain additional mandatory particulars. This obligation was first established at the European Union level by Council Directive 96/21/EC of 29 March 1996, amending Commission Directive 94/54/EC concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 79/112/EEC [4]. Today, the legislation is contained in Annex III of the FIC Regulation. Sweeteners are a functional class of food additives under Annex I of Regulation (EC) No 1333/2008. Sweeteners are substances used to impart a sweet taste to foods or as table-top sweeteners. Artificial sweeteners are significantly sweeter than conventional sugar (sucrose) but have no calories. Thus, the popularity of artificial sweeteners in the global food market as substitutes for sugar has increased in recent years [17]. The use of artificial sweeteners is controversial due to concerns about carcinogenicity [18] and the potential for promoting obesity and type II diabetes [19]. Only substances listed in Annex II, Part B, point 2 may be used as sweeteners. The list of sweeteners is given in Table 2. The Scientific Committee on Food issued its first opinion on 14 September 1984 to review the safety of the use of certain sweeteners [20].

**Table 2** Sweeteners.

E number	Name of the sweetener
E 420	Sorbitol
E 421	Mannitol
E 950	Acesulfame K
E 951	Aspartame
E 952	Cyclamate
E 953	Isomalt
E 954	Saccharin
E 955	Sucralose
E 957	Thaumatococin
E 959	Neohesperidin DC
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides
E 961	Neotame
E 962	Aspartame-acesulfame salt
E 964	Polyglycitol syrup
E 965	Maltitol
E 966	Lactitol
E 967	Xylitol
E 968	Erythritol
E 969	Advantame

A food containing sweetener(s) shall bear the additional mandatory particular '*contains sweetener(s)*' in the name of the food. For example, cola-flavoured lemonade contains sweeteners. If a food contains added sugar(s) and sweetener(s), the name of the food must include the additional mandatory particular '*contains sugar(s) and sweetener(s)*'. For example, '*sterilized cucumbers in spicy sweet and sour brine, contains sugar and sweeteners*'.

Foods containing the sweeteners aspartame (E 951) or aspartame-acesulfame salts (E 962) shall bear the additional mandatory particular '*Contains aspartame (source of phenylalanine)*' on the packaging of the food or on the label attached to the food if aspartame or aspartame-acesulfame salts are listed in the list of ingredients of the food only as a reference to the E number. For example, if the ingredient '*E 951*' is listed in the composition of chewing gum (without the specific name of the sweetener), an additional mandatory particular '*Contains aspartame (source of phenylalanine)*' shall be indicated on the packaging of the chewing gum. Where aspartame

or aspartame-acesulfame salts are listed in the list of ingredients of the food under their specific name, the additional mandatory particular '*Contains phenylalanine source*' shall be indicated on the food packaging or the label attached thereto. For example, if the ingredient '*aspartame*' is listed in the composition of a lemonade, the packaging of that lemonade shall bear the additional mandatory particular '*Contains a source of phenylalanine*'. These additional mandatory particulars shall appear on the packaging or the label attached to the food and need not appear in or adjacent to the name of the food. A warning about the source of phenylalanine in foods is very important for phenylketonuria sufferers, as they cannot metabolise this amino acid [21].

Food containing more than 10% added alcoholic sugars (polyols) must be labelled with the additional mandatory particular "Excessive consumption may have laxative effects" (e.g. some chewing gum). This additional mandatory particular shall appear on the packaging or the label attached to the food. Alcoholic sugars (polyols) are alcohols containing more than two hydroxyl groups. A list of polyols is given in Table 3 [22].

**Table 3** Polyols.

<b>E number</b>	<b>Name of the polyol</b>
E 420	Sorbitol
E 421	Mannitol
E 953	Isomalt
E 965	Maltitol
E 966	Lactitol
E 967	Xylitol
E 968	Erythritol

### **Foods containing glycyrrhizinic acid or its ammonium salt**

Foods containing glycyrrhizinic acid or its ammonium salt shall also contain additional mandatory particulars. Glycyrrhizinic acid is found naturally in the plant *Glycyrrhiza glabra*, and its ammonium salt is produced from aqueous extracts from this plant. Glycyrrhizic acid has been known in China, Egypt, and Japan [23]. Licorice has a wide use in traditional Chinese and Japanese medicine. Over the past 50 years, the biological and therapeutic activity of glycyrrhizinic acid has been intensively studied in Asia and Europe [24]. There are numerous studies on the antiviral activity of glycyrrhizinic acid against various viruses [25]. Glycyrrhizic acid also has anti-inflammatory effects, as proven through many scientific studies [26]. Relevant scientific studies also point to the specificity of glycyrrhizinic acid for liver diseases. In particular, glycyrrhizinic acid has been found to exhibit a hepatoprotective effect, conditioned by the antioxidant activity of glycyrrhizinic acid [27]. Glycyrrhizinic acid also shows significant anti-cancer effects as it can induce apoptosis in tumour cells of different types of cancer [28].

Exposure to glycyrrhizinic acid and its ammonium salt generally occurs through the consumption of liquorice confectionery, chewing gum, herbal teas, and other beverages. Mandatory labelling of certain foods (confectionery and beverages) with additional mandatory particulars was introduced at the European Union level by Commission Directive 2004/77/EC [6] based on the Opinion of the Scientific Committee on Food of 4 April 2003 on glycyrrhizinic acid and its ammonium salt of 4 April 2003 [29]. The legislation for this Directive is now contained in Annex III of the FIC Regulation.

Glycyrrhizic acid (FL 16.012) and its ammonium salt (FL 16.060) are food flavourings according to Regulation (EC) No 1334/2008 [30]. Glycyrrhizinic acid and its ammonium salt were added to the list of flavouring substances by Commission Implementing Regulation (EU) No 872/2012 [31] based on the Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials of the European Food Safety Authority of 22 May 2008 (EFSA-Q-2003-172B) [32].

Confectionery or beverages containing glycyrrhizinic acid or its ammonium salt as a result of the addition of these substances or licorice, at a concentration of 100 mg/kg or 100 mg/l or more, shall contain, immediately after the list of ingredients, the additional mandatory particular '*Contains licorice*'. If the food does not bear a list of ingredients, the additional mandatory particular '*Contains licorice*' shall be added and shall appear next to the name of the food. The obligation to include this additional mandatory indication shall only apply if the term '*licorice*' is not already included in the list of ingredients. For example, the ingredient '*licorice extract*' is mentioned in the composition of the confectionery or the name of the food, e.g. licorice confectionery.

Confectionery containing glycyrrhizinic acid or its ammonium salt as a result of the addition of these substances or licorice, at a concentration of 4 g/kg or more, must include an additional mandatory particular immediately after the list of ingredients '*Contains licorice - people with high blood pressure should avoid*

*excessive consumption*'. For example, some pellets. In this case, it is irrelevant whether or not the term '*licorice*' appears in the list of ingredients or the name of the food. If the above conditions are fulfilled, the confectionery must contain this indication immediately after the list of ingredients. If the food does not bear a list of ingredients, an additional mandatory particular shall be given close to the name of the food.

Beverages containing glycyrrhizinic acid or its ammonium salt as a result of the addition of these substances or liquorice, at a concentration of 50 mg/l or more and, in the case of beverages containing more than 1,2 % alcohol by volume, at a concentration of 300 mg/l or more, shall contain the additional mandatory particular '*Contains licorice - people with high blood pressure should avoid excessive consumption*' immediately after the list of ingredients. This level applies to products prepared for direct consumption or after preparation according to the manufacturer's instructions. In this case, it is irrelevant whether or not the term '*licorice*' appears in the list of ingredients or the name of the food. If the above conditions are fulfilled, the confectionery must contain this indication immediately after the list of ingredients. If the food does not bear a list of ingredients, an additional mandatory particular shall be given close to the name of the food.

### Beverages with high caffeine content or foods with added caffeine

Caffeine is a naturally occurring central nervous system (CNS) stimulant belonging to the methylxanthine class and is widely recognised as the most utilised psychoactive stimulant worldwide. Although this drug is most commonly sourced from coffee beans, it can also naturally occur in certain types of tea and cacao beans [33]. Additional mandatory particulars shall also be provided on caffeinated beverages and caffeinated foods. The original legislation was contained in Commission Directive 2002/67/EC [5], the wording of which has been taken over in Annex III of the FIC Regulation. This legislation was adopted following the conclusions of the opinion of the Scientific Committee on Food on 21 January 1999 concerning caffeine, taurine, and D-glucuronolactone as ingredients in so-called energy drinks [34]. This legislation was based on the belief that consumers should be given information on the presence of caffeine, as well as a warning notice and information on the amount of caffeine in drinks, which are usually caffeine-free and where caffeine is more abundant.

Caffeine (FL 16.016) is a food flavouring according to Regulation (EC) No 1334/2008 [30]. It was added to the list of flavouring substances by Commission Implementing Regulation (EU) No 872/2012 [31]. Caffeine is a central nervous system and cardiovascular stimulant. It increases respiratory, heart, and blood pressure [21]. Caffeine is popular among athletes mainly due to its ergogenic effects on enhancing performance [35]. A scientific study examining caffeine's effects on muscles shows that caffeine affects muscles through an increase in intracellular calcium. Therefore, consuming caffeine improves muscle strength and endurance [36]. The Scientific Committee on Food issued the first opinion regarding caffeinated foods on 7 July 1983 [37]. Caffeine is a flavouring that is restricted to selected foods. Caffeine may be added to dairy products and ice cream in quantities not exceeding 70 mg/kg, to confectionery in quantities not exceeding 100 mg/kg, and to non-alcoholic beverages in quantities not exceeding 150 mg/kg, for example, energy drinks.

Beverages that are intended to be consumed unaltered and contain caffeine from any source above 150 mg/l (e.g. energy drinks) or are in concentrated or dried form and, when reconstituted, contain caffeine from any source over 150 mg/l shall contain the additional mandatory *claim* '*Caffeinated. Not recommended for children or pregnant or lactating women*', followed by the caffeine content expressed in mg/100 ml in brackets. The obligation to indicate the additional mandatory particulars on the food does not apply to coffee, tea, or coffee or tea extract-based beverages if the name of the food contains the term '*coffee*' or '*tea*'.

Foods other than beverages that have been added to for physiological purposes must bear the additional mandatory particular '*Contains caffeine. Not recommended for children or pregnant women*'. This additional mandatory particular shall be followed by a parenthetical indication of the caffeine content expressed in mg per 100 g/ml. For example, '*Contains caffeine. Not recommended for children or pregnant women (1596 mg/100 ml)*'. Regarding food supplements, the caffeine content shall be expressed per dose as recommended according to the daily consumption on the label.

The above additional mandatory particulars shall appear on the food in the same field of vision as the name of the food. The field of vision is all surfaces of the food packaging that can be read from a single point of view. At the same time, the legislator stresses that these additional mandatory particulars must be displayed in a prominent position so that they are easily visible and legible. They must not be hidden, obscured, distracted, or interfered with in any way by other text pictures, or other distracting material. However, these requirements apply to all mandatory food information under the FIC Regulation.

Finally, concerning caffeine as a food flavoring, it may be added that it must be mentioned by its name in the list of ingredients immediately after the term '*flavoring*' or '*flavorings*' when used for the manufacture or preparation of food. For example, in the list of ingredients of an energy drink, caffeine shall be listed alone as '*caffeine flavoring*' or together with other flavorings as '*flavorings (caffeine,...)*'.

### **Foods with added phytosterols, phytosterol esters, phytostanols or phytostanol esters**

The obligation to provide additional particulars shall also apply to foods or food ingredients with added phytosterols and phytostanols and their esters. The term phytosterols (plant sterols) includes both phytosterols and phytostanols. These compounds are the most studied group of nutraceuticals whose health benefits have been known for more than seven decades [38]. Phytosterols and phytostanols, structurally and functionally related to cholesterol, are present in relatively high amounts in vegetable oils, nuts, and seeds, with total phytosterol content in some vegetable oils reaching values as high as 19 g/kg [39]. Phytosterols and phytostanols in plants have similar functions to cholesterol in humans. Phytosterols differ from cholesterol in that they have a different side-chain structure, whereas phytostanols are 5 $\alpha$ -saturated derivatives of phytosterols [40]. SITO is the most common phytosterol found in foods, and as scientific conclusions suggest, it is SITO that is strongly associated with inhibition of several hallmarks of cancer, including suppression of cell death, maintenance of proliferative signalling, induction of angiogenesis and metastasis, [41]. Foods or food ingredients in which phytosterols or phytostanols are naturally present (e.g. vegetable oils, legumes) are not subject to additional mandatory disclosures. This obligation was established at the European Union level by Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labeling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters [7], which was adopted based on the conclusions of the opinion of the Scientific Committee on Food of 26 September 2002 entitled '*Overall view on the long-term effects of the intake of increased amounts of phytosterols from multiple food sources, with particular emphasis on the effects of  $\beta$ -carotene*' [42]. This legislation has been incorporated into Annex III of the FIC Regulation.

Foods with added phytosterols and phytostanols and their esters must be labeled with the additional mandatory particular '*with added plant sterols*' or '*with added plant stanols*'. These additional mandatory particulars must appear on the food in the same field of vision as the name of the food. The field of vision is all the surfaces of the food packaging that can be read from a single point of view. However, there is no obligation to indicate them directly in the name of the food, although this practice may be encountered in food practice. For example, '*vegetable fat spread, with added plant sterols*'. In addition to the above additional mandatory particulars, the amount of added phytosterols, phytosterol esters, phytostanols, or phytostanol esters must be indicated in the list of ingredients of the food. The amount shall be expressed in % or grams of free plant sterols or stanols per 100 g or 100 ml of the food. For example, in the list of ingredients of a food supplement, the ingredient '*plant sterols (27,7 g per 100 g of product)*' shall be indicated.

Foods with added phytosterols and phytostanols and their esters shall also include the following additional mandatory particulars:

- a statement that the food is intended exclusively for people who want to lower their blood cholesterol level. For example, '*The product is not intended for people who do not need to check their blood cholesterol levels*'.

- A patient taking cholesterol-lowering medications should consume the product only under the supervision of a physician. For example, '*If you are taking a cholesterol-lowering medication, consult your physician about consuming the product*'.

- A claim that the food is nutritionally unsuitable for pregnant or lactating women and children under 5 years of age. For example, '*Products intended to lower cholesterol are not suitable for pregnant and lactating women and children under 5 years of age*'. This particular must be easily visible.

- Advice is that the food should be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables, which helps to maintain carotenoid levels. For example, '*The product is suitable for use as part of a balanced and varied diet, including regular consumption of fruit and vegetables, which helps to maintain carotenoid levels*'.

- The claim that consumption of more than 3 g of added plant sterols/stanols per day should be avoided. For example, '*Consumption of more than 3 g of added plant sterols per day is not recommended*'. This claim must be made in the same field of vision as claim (a). The field of vision is all surfaces of the food packaging that can be read from a single point of view.

### **Frozen meat, frozen meat preparations, and frozen unprocessed fishery products**

Meat and meat products play a crucial role in human diets due to their rich nutrients, such as protein, iron, zinc, selenium, vitamins, cholesterol, niacin, fats, etc. [43]. These nutrients supply large daily energy intakes for humans [44]. Meanwhile, these nutrients can also provide good growth conditions for various microorganisms, making meats prone to spoilage [45]. Preserving food to extend its shelf-life has been practised for several millennia. At its roots, food preservation involves altering the product's inherent properties, mainly pH and water activity (Aw), to inhibit the growth of pathogenic microorganisms, moulds, and spores [46]. According to Annex III of the FIC Regulation, the date of freezing and the date of first freezing are additional compulsory particulars. The date of first freezing must be provided as an additional mandatory indication in cases where the food has been

frozen more than once. The date of freezing and the date of first freezing shall be provided as an additional mandatory particular according to Annex III of the FIC Regulation at:

- frozen meat,
- frozen meat preparations, and
- frozen unprocessed fishery products [47].

The definitions of meat, meat preparations, and fishery products are based on Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific hygiene rules for food of animal origin [48]. Meat is the edible parts of domestic ungulates, poultry, lagomorphs, wild game, farmed game, and small and large wild game, including blood (e.g. sliced boneless pork loin or minced beef). Meat preparations mean fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings, or additives added to it, or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus eliminate the characteristics of fresh meat. (for example, slices of pork curry in a marinade for grilling or minced beef with salt and spices for making a hamburger). Fishery products mean all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles, and frogs) whether wild or farmed and including all edible forms, parts, and products of such animals. The obligation to indicate the freezing date or first freezing shall apply only to unprocessed fishery products. The definitions of processing, unprocessed products, and processed products are based on Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [49].

Frozen food is not defined for food labelling by European Union law. The definition of frozen food is to be found in the legislation of the individual Member States of the European Union. The Slovak Republic has a definition of frozen food contained in the Decree of the Ministry of Agriculture and Rural Development of the Slovak Republic No 82/2018 Coll. on frozen food and frozen products [50]. According to the law of the Slovak Republic, frozen food is frozen by a process in which the phase of maximum formation of ice crystals is carried out as quickly as possible and is appropriate to the type of food being frozen. After reaching the final temperature, after its equilibration and stabilisation, a temperature of -12 °C or lower is permanently maintained at each point of the food. During transport, the temperature of the frozen food may be briefly raised by no more than 3 °C. The name of the frozen food must include or be accompanied by an indication of the physical state of the food - 'frozen'. The obligation to include such an accompanying indication of the name of the frozen food shall apply only if its omission is likely to mislead the purchaser.

The date of freezing and the date of first freezing shall be indicated following Annex X of the FIC Regulation. The date of freezing and the date of first freezing shall consist of the day, month, and year. The sequence must be maintained, and the date must be given in uncodified form. This obligation shall not apply to deep-frozen meat preparations and unprocessed fishery products.

The date of freezing or the date of first freezing shall be indicated on the foodstuff by the word 'frozen'. This word shall be followed by the date itself or a reference to where this date appears on the food. The obligation to indicate the date of freezing or first freezing shall apply only to pre-packaged frozen meat, meat preparations, and unprocessed fishery products. For non-packaged frozen meat, frozen meat preparations, and frozen unprocessed fishery products, there is no obligation to indicate their freezing date or first freezing. However, this obligation may be laid down for non-prepacked foodstuffs by individual Member States of the European Union using so-called national measures, according to the Communication from the Commission on questions relating to the application of Regulation (EU) No 1169/2011 on the provision of food information to consumers [51] individual member states of the European Union through so-called national measures.

### CONCLUSION

Suppose the food is labelled with something other than additional mandatory particulars according to Annex III of the FIC Regulation. In that case, the food business operator commits an administrative offence under the provisions of Section 28(2)(f) of Act No. 152/1995 Coll. on Foodstuffs, as amended. For that administrative offence, the official food control authority shall impose a fine between EUR 100 and EUR 100 000.

The obligation to indicate additional mandatory particulars under Annex III of the FIC Regulation applies only to prepacked food. Non-prepacked foods do not have to bear the additional mandatory particulars under the FIC Regulation. The Slovak Republic has not adopted any national measures concerning the additional mandatory particulars contained in Annex III of the FIC Regulation, which would impose an obligation to indicate them for non-prepacked foodstuffs.



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