

Legal aspects of labelling gluten-free products

1. The subject of these considerations is the legal issue of the safety of food of particular type on the example of gluten-free food. It has been known for years that the diet has a direct impact on human health. Some food ingredients can be harmful to people who, because of illness, allergies, or food intolerances, cannot eat them. Therefore, alongside the usual food generally available and addressed to all consumers there are also various food categories dedicated to specific groups of consumers developed precisely according to their specific needs.

Directive 2009/39/EC¹ has introduced measures for particular nutritional uses, that is food, which, thanks to its special composition or manufacturing process, is clearly distinguishable from foodstuffs for normal consumption. Moreover it corresponds with the nutritional purposes claimed on the label and is sold in a manner indicating its properties. It also meets the specific nutritional requirements of certain categories of persons who suffer from digestive or metabolism disorders, or certain categories of persons who are in a special physiological condition and are therefore able to derive special benefit from controlled consumption of certain substances in foodstuffs, as well as healthy infants or small children.²

The directive has been replaced by EU Regulation No 609/2013³ which entered into force on 16 July 2016 and which distinguishes food intended for

¹ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ EU L 124/21 of 20.5.2009 (hereinafter referred to as: Directive 2009/39/EC).

² Article 1 para. 3 of Directive 2009/39/EC.

³ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and

infants and young children and food for special medical purposes as well as foodstuffs constituting daily diet replacement for weight control.

In addition, on 20 July 2016 a new Regulation (No 828/2014⁴) entered into force, governing the way in which information on the absence or reduced amount of gluten in food is provided to consumers. According to this piece of legislation, information on the absence or reduced amount of gluten in foods should help people who are intolerant to gluten in finding and choosing a varied diet including nutrition at home and outside the home.⁵ Gluten-free food is a separate category of food, subject to special legal regulation on labelling. The latter is the subject of the analysis in these considerations.

Owing to the framework of this paper the observations presented in it refer to the issue concerning exemplary gluten-free food designed for people with celiac disease and suffering from sensitivity to gluten. The celiac disease is a lifelong auto-immune disease of genetic nature, characterised by a permanent intolerance to gluten, which is protein in cereals such as wheat, barley, rye, and whose only treatment is a lifelong gluten-free diet.⁶ Regulation No 41/2009⁷ which regulated the requirements of information for consumers on the absence or reduced amount of gluten in foods has now been replaced with the above-mentioned legislative acts.

The legal aspects of labelling of gluten-free foods have not yet been reported in relevant literature, which is the argument for the elaboration of the subject specified in the title of the paper. The above issues are also of interest of medical sciences⁸ and have been subject of numerous publications on health and human nutrition.⁹

(EC) No 953/2009, OJ EU L 181/35 of 29.6.2013, hereinafter referred to as Regulation No 609/2013, see Article 22.

⁴ Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food, OJ EU L 228/5 of 31.7.2014 (hereinafter referred to as: Regulation No 828/2014). L.G. Vaque, *Information to Consumers on the absence or reduced presence of gluten in food*, „European Food & Law Review” 9(6), 2014, pp. 258ff.

⁵ Point 2 of preamble to Regulation No 828/2014,

⁶ See closer: G. Konińska, A. Marczevska, M. Żródlak (eds.), *Celiakia i dieta bezglutenowa – praktyczny poradnik* [Celiac disease and gluten-free diet – a practical guide], Warsaw 2015, p. 11.

⁷ Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten, OJ EU L 16/3 of 21.1.2009 (hereinafter referred to as: Regulation No 41/2009).

⁸ B. Wedro, Celiac disease, http://www.medicinenet.com/celiac_disease_gluten_enteropathy/article.htm [accessed: 20 September 2016].

⁹ G. Konińska, A. Marczevska, M. Żródlak (eds.), op. cit.; „The Guardian”, *More Americans are eating gluten-free despite not having celiac disease*, <https://www.theguardian.com/>

Starting a reflection on the issue specified in the title of this paper seems justified especially because of the importance of consumers' health. The objective of food law is, as is known, to ensure a high level of consumer health protection.¹⁰ For people with a celiac disease the non-gluten-free diet or unconscious consumption of products containing gluten is associated with serious health consequences, among others, risk of cancer, for example throat cancer, small bowel, intestinal lymphoma.¹¹ Therefore, the need to ensure the safety of any food category because of its specific use is based directly on grounds of a threat to health and life for particular groups of consumers. In particular, these consumers should be confident that food intended for them by the producers is devoid of harmful substance – gluten, and the labelling of food products should enable search for those that are allowable in a gluten-free diet.

Based on practical observations of labelling food products determined by the gluten content, it can be noted that there are at least several different ways of providing information on the presence or absence of gluten in food. Producers may indicate the ingredients of the product on its label but usually fail to inform on the same label whether the product contains gluten – in these cases, the consumer is forced to verify the composition of the product himself. There are also products on the market that are 'inherently' gluten-free, or products whose labelling (package) clearly indicates that the product may contain gluten, as well as other products, that are labelled gluten-free, solely in words or in words and graphically. Although each year the food product range gets wider, when it comes to gluten-free products, it still is not as rich as in the field of regular food and requires increased attention of people concerned.

The aim of the discussion presented here is an attempt to determine and assess whether and, if so, to which extent the legislator ensures the safety of food products referred to as gluten-free. The framework of considerations has been so designed as to serve this purpose.

2. Regulation No 178/2002 laid down the general principles and requirements of food law. According to Article 5(1) of this law, food law shall pur-

society/2016/sep/06/gluten-free-eating-celiac-disease-marketing-trend-diet [accessed: 20 September 2016].

¹⁰ Article 1(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ EC L 31/1 of 1.2.2002 (hereinafter referred to as: Regulation No 178/2002).

¹¹ See: G. Konińska, A. Marczevska, M. Źródak (eds.), *op. cit.*, p. 19.

sue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking into account, where appropriate, health and conditions of animal life, plant health and the environment. Moreover, food law aims to protect the interests of consumers and should provide a basis for consumers to make informed choices in relation to the foods they consume. It aims to prevent fraudulent or deceptive practices, adulteration of food and any other practices which may mislead the consumer.¹² Especially labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, used packaging, how it is exposed and displayed, and the information made available about them in any way, cannot mislead consumers.¹³

It is also important that the information formulated in a way that does not introduce a voluntary consumer confusion, is not ambiguous or confusing and must be, as appropriate, based on the relevant scientific data.¹⁴ Among voluntary information about food the legislator mentions:

- information on the possible and unintentional presence in food of substances or products causing allergies or intolerances,
- information related to the suitability of food for vegetarians or vegans; the indication of reference intakes for specific population groups in addition to the reference intakes set out in Annex XIII of Regulation No 1169/2011,
- information on the absence or reduced presence of gluten in food.¹⁵

In the light of this regulation any suggestions of manufacturers concerning the characteristics of the product to encourage the purchase, which, in fact, the product does not have, materially prejudice the interests of the consumer, who has the right to reliable information about the product and a guarantee of its characteristics.¹⁶ As long as it is merely an excessive and inaccurate transmission in the presentation of products characteristics which they do not have, the issue ends up with the operator liability for misleading of consumers. However, in the case of foods intended for particular nutritional uses, the consequences of such actions of manufacturers can directly be seen in the

¹² Article 8(1) 1 of Regulation No 178/2002.

¹³ Article 16 of Regulation No 178/2002,

¹⁴ Article 36(2) 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, OJ EU L 304/18 of 22.11.2011 (hereinafter referred to as: Regulation No 1169/2011).

¹⁵ Article 36(3) and (4) of Regulation No 1169/2011,

¹⁶ Cf. Judgment of the Provincial Administrative Court in Warsaw on 16 November 2011, VI SA/Wa 1912/11, Lex No 1155688, and the Judgment of the Provincial Administrative Court in Wrocław of 15 October 2008, III SA/Wr 434/08, Lex No 522691.

area of the health. Consequently, the sanctions in this case should be more harsh than in the case of ordinary food.¹⁷

The case law of administrative courts shows that the provisions regarding the prohibition to mislead consumers in relation to food products are interpreted in a strict manner. The Supreme Administrative Court in Warsaw held that the labelling on the packaging should reflect the composition of the food-stuff fairly declared by the manufacturer and leave no doubt as to its properties.¹⁸ Moreover, referring to the repealed Article 46 of the Law on Food Safety and Nutrition,¹⁹ the Supreme Administrative Court in Warsaw pointed out that the breach of the requirements for the labelling of foodstuffs is an administrative delict and ordered a ban the labelling of any food in a manner that may mislead the consumer by suggesting that the food has particular properties, when all similar foods possess such characteristics.²⁰

3. The use of the statements ‘gluten-free’ or ‘very low gluten’ is currently subject to Regulation No 828/2014, which was issued on the basis of Article 36(6)(d) of Regulation No 1169/2011. The Regulation indicates that the transmission of information on the absence or a reduced amount of gluten in food, as required by Article (36)(2) of Regulation (EU) No 1169/2011 was still based on the relevant scientific data and was not transferred on different bases, which could mislead or confuse consumers. It is therefore necessary to maintain the European Union’s uniform conditions of application of these requirements to the information on the absence or reduced amount of gluten in food transmitted by food business operators, and to base those conditions on Regulation (EC) No 41/2009.²¹

On the other hand, in the field of products for particular nutritional uses, new Regulation No 609/2013 clearly emphasises the need to meet the nutritional requirements of some clearly identified vulnerable groups of the population,²² although it establishes a list of substances that can be added to one or more categories of food and determine the rules applicable in the case of up-

¹⁷ Cf. Article 96(2) of the Law on Food Safety and Nutrition, Consolidated Text, Official Journal of 2015 item 594 as amended (hereinafter referred to as: the Law on Food Safety).

¹⁸ See for example the Judgment of the Supreme Administrative Court in Warsaw on 14 December 2014, II GSK 2033/13, Lex No 1643722.

¹⁹ The Act of 25 August 2006 on Food Safety.

²⁰ The Judgment of the Supreme Administrative Court in Warsaw delivered on 12 March 2015, II GSK 2369/13, Lex No 1746432.

²¹ Point 4 of the preamble to Regulation No 828/2014.

²² Point 15 of the preamble to Regulation No 609/2013.

dating the list, it is the EU legislator who dictates that food covered by Regulation No 609/2013 is placed on the market only if it complies with the provisions of this Regulation, while the retail sale can be introduced only in a packaged form.²³ These are analogous solutions to the ones previously in effect. The legislation also shows that in order to ensure a high level of health protection in respect of persons for whom the food is intended, the precautionary principle referred to in Article 7 of Regulation No 178/2002 shall apply.²⁴

Naturally, food must comply with any requirement of European Union law applicable to food, however, in the event of a conflict with other provisions of the control regulation, Regulation No 609/2013 will prevail, thus will be specific in relation to other provisions.²⁵

The legislator indicates that it is important that ingredients used in the manufacture of food covered by this Regulation are appropriate for satisfying the nutritional requirements of, and are suitable for, the persons for whom such food is intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.²⁶

The composition of food, as referred to in Regulation No 609/2013, shall be such so that it is appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended, in accordance with generally accepted scientific data.²⁷

Additionally the legislator introduces a requirement that on the basis of generally accepted scientific data, substances added to food for the purposes of satisfaction of the requirements of suitable satisfaction of each persons' nutritional needs as well as for the persons for whom the food is intended. It shall be bio-available for use by humans and have a nutritional or physiological effect.²⁸

4. In practice, there are attempts to eliminate gluten from gluten-containing cereals, which requires complicated operations due to technical difficulties and economical constraints. For this reason, the production of completely gluten-free foods from such cereal is difficult. Since the market

²³ Article 4(1) and (2) of Regulation No 609/2013.

²⁴ Article 5 of Regulation No 609/2013.

²⁵ Article 6(2) of Regulation No 609/2013.

²⁶ Recital 19 of the Preamble to Regulation No 609/2013.

²⁷ Article 9(1) and (2) of Regulation No 609/2013.

²⁸ Article 9(3) of Regulation No 609/2013.

contains different types of food specially processed to reduce the gluten content, there is a risk that such food may contain a small residual amount of gluten.²⁹ Such a risk also applies to products containing oats which can be contaminated with wheat, rye or barley.³⁰

In terms of standards, the legislature refers to the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.³¹ According to the standards of the Code, producers may not label products as 'gluten-free' if the products are naturally gluten-free. Such products can therefore contain the phrase 'this food is by its nature gluten-free.'³²

The subject of legal regulation focuses on only two issues: the transmission of information to consumers on the absence or a reduced amount of gluten in food in accordance with Regulation No 828/2014. If the manufacturer decides to launch a food product dedicated for people suffering from a celiac disease or who are gluten intolerant, it is then required by law that information about the food is provided only in the form of wording in the Annex to the Regulation and under the conditions specified therein.³³

In addition, such products can be identified by phrases such as 'suitable for people intolerant to gluten' or 'suitable for people suffering from a celiac disease', 'designed specifically for people intolerant to gluten' or 'developed specifically for people suffering from a celiac disease' if the food that was produced, prepared or processed specifically in such a way as to reduce the gluten content of one or more gluten-containing ingredients; or replace gluten containing ingredients with other components naturally gluten-free.³⁴

In the light of the above legislation the statement 'gluten-free' may only be made where the food as sold to the final consumer contains no more than 20 mg/kg of gluten. Whereas the statement 'very low gluten' may only be made where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, contains no more than 100 mg/kg of gluten in the food as sold to the final consumer.

²⁹ Recital 6 of the Preamble to Regulation No 828/2014.

³⁰ Cf. Recital 7 of the Preamble to Regulation No 828/2014.

³¹ Standard for foods for special dietary use for persons intolerant to gluten, CODEX STAN 118-1979 Adopted in 1979, amended: 1983 and 2015, revised: 2008 [accessed: 5 June 2016].

³² *Ibidem*, point 4.3.

³³ Article 3(1) of Regulation No 828/2014.

³⁴ Article 3(2) and (3) of Regulation No 828/2014.

Also oats contained in a food product presented as gluten-free or very low gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg/kg. Undoubtedly, the word ‘gluten-free’, from the linguistic point of view can be understood as not containing gluten at all. Therefore a quantitative standard adopted by the legislator does not literally mean what really results from the permissible labeling of product.

It is worth noting that in practice for the purpose of packaging products designated as ‘gluten-free’ manufacturers also apply the logos, it is usually the logo of the crossed ear. However, one should bear in mind that the owner of that mark is a private entity – the Association of European Coeliac Societies which has registered the mark in the European Union Intellectual Property Office.³⁵ Manufacturers use the mark under license.

The legislator did not require producers to regularly examine products designated as gluten-free in terms of safety, understood as the conformity of the product properties declared by the manufacturer. Analyses of products performed under the specified terms are conducted by private operators, partially on the consumer’s own initiative. Naturally gluten-free products can be tested in the framework of official food control, like all others, including the tests for the presence of gluten if, for example they declare its absence.³⁶ There is no requirement though for the official attesting the conformity of gluten-free products with the requirements of the law, despite the fact that as it seems, this could be one of the possible solutions to safeguard the interests of consumers.

When it comes to the effects of infringements of the regulations on products intended for specific nutritional purposes, it must be noted that they differ slightly with regards to the sanctions for the breach of the rules on ordinary food.³⁷ According to Article 96(2) of the Law on Food Safety, the penalties are similar – a fine, restriction of liberty or imprisonment up to 3 years (in the case of the usual food 2 years) – for producing or marketing foodstuff for particular nutritional uses harmful to health or human life. Pursuant to Article 97(1) of the Law on Food Safety, he who produces or markets a spoilt or falsified foodstuff shall be subject to a fine, restriction of liberty or imprisonment for a year. Next, pursuant to Article 97(2) of the said act, if the

³⁵ Application number 004941324.

³⁶ G. Konińska, A. Marczevska, M. Źródłak (eds.), op. cit., pp. 70 ff.

³⁷ See more: P. Wojciechowski, *Model odpowiedzialności administracyjnej w prawie żywnościowym* [Model of Administrative Responsibility in Food Law], Warsaw 2015.

perpetrator commits the crime penalised in paragraph 1 in relation to foodstuffs of significant value, he shall be punished by imprisonment from 6 months to 3 years. It is worth noting that the importance of the impact of infringements in the light of these provisions is not determined by the degree of harmfulness to the health of foodstuffs placed on the market, but their value (large value). For example, if the foodstuff is of insignificant value, but would present a high degree of hazard to the health, the consequences arising from the provisions referred to would be smaller since in such an event Article 97(1), not Article 97(2) would apply.

5. To sum up the above considerations, the following conclusions can be drawn. An analysis of the provisions of the new Regulations, particularly Regulation No 828/2014 leads to the conclusion that its provisions do not change the essential legal requirements regarding the possibility of the use of indications such as gluten-free or a product with a reduced presence of gluten. The new Regulation will, however, apply to non-packaged product, for example food served in restaurants in accordance with the existing regulations.

The new regulations also allow to explain to gluten intolerant consumers the differences between naturally gluten-free products and products intended for this group of people as gluten-free.

However, the negative aspects of the new regulations should be seen as well. First of all, despite the opportunity for the settlement of this matter the legislature failed to require confirmation of verification designated as gluten-free products in order to ensure consumer's safety. Still, as we know, the studies of these products are carried out on the private initiative of consumers.

Naturally, these products may be subject to official controls of food for the presence of gluten on a general basis. However, worthy of consideration is the issue of additional possible compliance of the product with the manufacturer's declaration in the form of, for example, certification. This however has been left out unregulated in the Regulation since it could affect the selling price of gluten-free products which already stands out from the price of others foodstuffs.

LEGAL ASPECTS OF LABELLING GLUTEN-FREE PRODUCTS

Summary

On 20 July 2016 a new Regulation (EU) No 828/2014 entered into force, regulating the provision to consumers of information on the absence or reduced presence of gluten in

food. In this paper an attempt is made to assess the extent to which the safety of gluten-free foodstuffs has been ensured under the new regulation.

It is proposed that the basic legal requirements governing the possibility of indicating products as gluten-free or containing a reduced amount of gluten have not changed much. The new provisions will apply mainly to unpacked products that are served in restaurants, for example, and will provide for the way of explaining to consumers who are intolerant to gluten the differences between products that are naturally free of gluten and products that are specially designated as gluten-free. It is also noted that a certificate verifying the absence of gluten in products designated as gluten-free is not required.

L'ETICHETTATURA DEI PRODOTTI SENZA GLUTINE: ASPETTI GIURIDICI

Riassunto

Il 20 luglio 2016 è entrato in vigore il regolamento n. 828/2014 che disciplina il modo in cui i consumatori vengono informati sull'assenza di glutine o sulla sua presenza in misura ridotta negli alimenti. L'obiettivo delle considerazioni è di valutare in quale misura il legislatore garantisce la sicurezza dei prodotti alimentari definiti senza glutine.

Secondo l'autrice il regolamento menzionato non modifica requisiti giuridici essenziali relativi alla possibilità di applicare un'etichettatura che identifichi prodotti senza glutine oppure prodotti con contenuto di glutine molto basso. Il nuovo regolamento troverà applicazione per prodotti senza confezione, p.es. quelli serviti nei ristoranti, finora in base alla normativa in vigore. Le nuove regolazioni consentiranno di spiegare ai consumatori intolleranti al glutine la differenza tra prodotti che sono naturalmente privi di glutine e quelli a loro destinati in quanto privi di glutine. L'autrice inoltre rileva che il legislatore ha omesso di richiedere che dai prodotti indicati come senza glutine venga confermata la verifica, al fine di garantire la sicurezza ai consumatori.