

# Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at [enrico.bonadio.1@city.ac.uk](mailto:enrico.bonadio.1@city.ac.uk)

## Food

*This section aims at updating readers on the latest developments of risk-related aspects of food law at the EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.*

### Ukraine Adopts New Food Safety Legislation in Order to Align its Legal Framework with that of the EU

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#### I. Introduction

As Ukraine's development and economy continue to grow, the Government of Ukraine has recognised that one important issue that it should prioritise is food safety. On 15 September 2014, Ukraine's President Petro Poroshenko signed *Law No. 1602 VII on Amendments to Certain Legislative Acts of Ukraine related to Food Products* (hereinafter, Law No. 1602 VII),<sup>1</sup> which had previously been adopted by the *Rada* (i.e., Ukraine's Parliament). Law No. 1602 VII intends to align Ukraine's food legislation with the food law of the European Union. In particular, Law No. 1602 VII establishes a completely new wording for the *Law of Ukraine on the Safety and Quality of Food* (hereinafter, Law on Food Safety), which, will apply as of 20 September 2015 and will be titled *Law on the Ba-*

*sic Principles and Requirements for Safety and Food Quality*. Several provisions of the Law on Food Safety will be enacted at a later stage (i.e., in 2 to 5 years). In addition, Law No. 1602 VII amends certain provisions of the following Ukrainian legislation related to food: the *Law on State Regulation of Agricultural Imports*; the *Law on the State Biosafety System for Developing, Testing, Transportation and Use of Genetically Modified Organisms*; the *Code on Administrative Offences*; the *Economic Code*; the *Law on Protection of Consumers' Rights*; the *Law on Sanitary and Epidemiological Welfare*; the *Law on the Withdrawal from Circulation, Processing, Disposal, Destruction, or Continued Use of Poor Quality and Unsafe Products*; the *Law on the List of Permits for Business Activity*; the *Decree of the Cabinet of Ministers of Ukraine on Standardisation and Certification*; and the *Law on Drinking Water and Water Supply*.

#### II. Background

The Law on Food Safety aims at harmonising the legislation on food safety and quality of food products of Ukraine with that of the EU, ensuring a high level of public health protection and consumers' interests, as well as maintaining transparent conditions

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<sup>1</sup> Law No. 1602 VII enters into force on 20 September 2015, Official Gazette of Ukraine of 26 September 2014.

for conducting business activities, raising competitiveness of domestic food products, and achieving price reductions.

Adopting a new general food law appears also to be relevant in the context of the Association Agreement between the EU and its Member States, of the one part, and Ukraine, of the other part (hereinafter, EU-Ukraine Association Agreement, or EUAA)<sup>2</sup> ratified by the European Parliament in September 2014, which began applying provisionally on 1 November 2014 but which requires ratification by each EU Member State.<sup>3</sup> The first sentence of Article 474 of the EUAA provides that, in line with the objectives of the EUAA, Ukraine will carry-out a gradual approximation of its legislation to EU law, as referred to in Annexes I to XLIV to the EUAA, based on commitments identified in Titles IV, V and VI of the EUAA, and according to the provisions of those Annexes. The general EU food law established in 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<sup>4</sup> (hereinafter, the EU General Food Law or GFL) is not explicitly listed in the various Annexes to the EUAA. However, the second sentence of Article 474 of the EUAA states that sentence 1 shall be without prejudice to any specific principles and obligations on regulatory approximation under Title IV (on Trade and Trade-related Matters) of the EUAA. Title IV refers in Chapter 3 to TBT measures (i.e., Technical Barriers to Trade), including “*marking and labelling*”, and in Chapter 4 to SPS measures (i.e., Sanitary and Phytosanitary Measures), including legislation on GMOs. A general food law addressing SPS issues like food safety and TBT issues like the labelling and traceability of food falls arguably under Title IV of the EUAA, where a gradual approximation of Ukraine’s legislation to that of the EU is required under the EUAA.

### III. Comment

The Law on Food Safety provides for legislative improvements in terminology, specifies types of offences and the adequateness of legal penalties, distinguishes a system of competent authorities on food safety, abolishes certain pre-market approval proce-

dures, and implements a number of EU provisions on GMOs, in particular on the registration of GMO sources. The Law on Food Safety lays down and specifies the competences and obligations of state inspectors and the rules and detailed procedures for conducting state controls. It also clarifies the requirements of the documents to be issued upon an inspection.

The Law on Food Safety sets forth central executive bodies responsible for food safety (and certain indexes of quality of food products) which are as follows: (i) the Cabinet of Ministers of Ukraine; (ii) the central executive body that ensures and implements the state policy in protection of public health (i.e., the Ministry of Health Protection); (iii) the central executive body that ensures and implements state policy in food safety and certain indexes of quality of food products (i.e., the Ministry of Agricultural Policy and Food of Ukraine); the central executive body that implements state policy in food safety and certain indexes of quality of food products (i.e., the competent authority – the State Veterinary and Phytosanitary Service of Ukraine); and (v) the central executive body that implements state policy in sanitary and epidemiological welfare (i.e., the State Sanitary and Epidemiological Service of Ukraine).

Other executive authorities and agencies are not eligible to establish or in any other way regulate and/or perform state control, including information about food, except as provided by the Law on Food Safety.

The State Veterinary and Phytosanitary Service of Ukraine (hereinafter, SVPSU) is a central executive authority directed by the Cabinet of Ministers of Ukraine through the Minister of Agricultural Policy and Food of Ukraine. The SVPSU is a part of the system of executive bodies and ensures implementation of the state policy on veterinary medicines, food safety, quarantine policy and plant varieties protection, and state surveillance in livestock breeding.

Article 1(92) of the Law on Food Safety defines “*food*” as a substance or product (unprocessed, partially processed or processed) intended for human consumption. Food products include beverages (in-

2 OJ 2014 L 161/3-2137.

3 The text of the initialled Agreement is available on the Internet at: [http://eeas.europa.eu/ukraine/assoagreement/assoagreement-2013\\_en.htm](http://eeas.europa.eu/ukraine/assoagreement/assoagreement-2013_en.htm) (last visited on 1 March 2012).

4 OJ 2002 L 31/1.

cluding drinking water), chewing gum and any other substances that are specifically incorporated into the food during manufacture, preparation or treatment. It further provides that the term “*food*” does not include: feed; live animals, unless they are designed for placing on the market for human consumption; plants (before harvest); drugs; cosmetic products; tobacco and tobacco products; narcotic drugs and psychotropic substances (within the definition of the UN Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971); and residues and contaminants. Thus, the scope of the definition of “*food*” in Article 2 of the EU GFL is wider than the one in Ukraine’s Law on Food Safety, as it does not only cover substances or products “*intended for human consumption*”, but also those “*intended to be, or reasonably expected to be ingested by humans*”. A second difference is that the EU GFL’s definition of “*food*” excludes in letter d) of Article 2 “*medicinal products*” from its scope, while Ukraine’s “*food*” definition does not.

The Law on Food Safety establishes provisions on, *inter alia*: the safety of food; traceability; and risk analysis (defined as a process consisting of three interconnected components: risk assessment, risk management and risk communication), which can be considered equivalent to the rules set out in the EU GFL.

The Law on Food Safety defines “*food business operator*” as a business entity conducting either a profit-oriented or non-profit activity, which operates facilities primarily for processing and marketing food. Natural persons conducting similar activities as business entities fall within the scope of the “*food business operator*” definition. Under Article 20(1) of the Law on Food Safety, food business operators are responsible for compliance with safety law and specific indicators of food quality within the activities they carry out, equivalent to Article 1(1)(a) of Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs,<sup>5</sup> which establishes that the primary responsibility for food safety rests with the food business operator. According to Article 20(2) of the Law on Food Safety, food business operators must develop, enact and implement permanent procedures based on the principles

of the system of hazard analysis and critical control points (hereinafter, HACCP). Similar to the system in the EU, set out in Regulation (EC) No. 852/2004 under which the application of HACCP principles to primary production is not yet generally feasible, Article 21(2) of the Law on Food Safety establishes that the requirements for application of permanent procedures based on the principles of the HACCP system do not apply to operators engaged in primary production.

Article 1(22) of the Law on Food Safety provides for a definition of “*operational permit*” as a permit issued by the competent authority to the food business operator based on the results of on-site inspection of its facilities. Article 23 further clarifies the conditions for obtaining operational permits as well as relevant exemptions. It should be noted that operational permits are issued to the facility (with detailed description of the production line) located at one address to a particular food business operator. The operational permit has an unlimited term of duration.

Pre-market approval and/or registration is required under the Law on Food Safety only for novel foods, food supplements, flavours, enzymes, materials in contact with food, and natural mineral water. It appears that other permits and licensing procedures absent in the EU have been abolished in Ukraine.

Operational permits enable food business operators to engage in business activities related to the production and/or storage of food of animal origin. Food business operators conducting activities related to primary production, transportation, storage and/or sales of food, that does not require conservation at a particular temperature regime, that can be stored at above 10°C and that is available for human consumption, do not require an operational permit. Such obligation does not apply to public catering, companies producing food of vegetable origin or processed products of animal origin and retail stores with volumes of sales that do not exceed thresholds set by the Cabinet of Ministers with due regard to the best international and European practices, as well as documents of the relevant international organisations. In absence of the aforementioned resolution of the Cabinet of Ministers of Ukraine, such provisions apply to all retail stores.

Food business operators holding an operational permit are subject to public record in the register

5 OJ 2004 L 139/1.

maintained by the competent authority (i.e., the SVPSU). This register is publicly available in electronic format on the website of the SVPSU.

The grounds for refusal of issuing an operational permit are substantially revised by the Law on Food Safety. For instance, the previous edition of the Law on Food Safety denied the issue of the permit if the food business operator was responsible for food intoxication and/or outworn products within six preceding months at its facilities. The amended law provides general reasons for rejection of issuing of an operational permit, such as failure to submit required documents; inaccuracy of the submitted data; inconsistency of the declared capacities to those provided by the Law; and if the food business operator on the agrifood market failed to ensure necessary conditions for the due operation.

Besides such general provisions, the Law on Food Safety regulates some specific areas. With regard to the advertising of food supplements (defined as food consumed in small quantities for addition to the usual diet, which is a concentrated source of nutrients, including protein, fat, carbohydrates, vitamins, minerals, and made in the form of tablets, capsules, pills, powders, liquids or other forms), Article 39(8) of the Law on Food Safety prohibits using: (i) statements on potential health benefits or the relief of pain; (ii) reference, recognition letters, advice if related to the facilitation of medical condition; and (iii) statements or expressions that might cause or contribute to the occurrence of a negative psychological state or feeling. Such specific requirements are regulated in the EU in secondary legislation such as Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.<sup>6</sup>

Article 39 of the Law on Food Safety sets out some general requirements for the labelling of foods. In particular, food labelling must provide consumers with information that allows them to make informed choices. All foods that are in circulation in Ukraine must be labelled in the official language (operators may choose to place a product on the market in other languages next to the text in the official language).

However, in comparison with the general rule in Article 16 of the EU GFL, which states that “*without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they*

*are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers*”, the Ukrainian text does not refer to the main concept expressed in Article 16 of the EU GFL: that the labelling, advertising and presentation of food or feed must not mislead consumers. Also Article 7 of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (hereinafter, the FIR) specifies that the use of information that would mislead the consumer is prohibited, in particular as to the characteristics of the food, food effects or properties, or attribute medicinal properties to foods.<sup>7</sup>

On the other hand, Article 39 of the Law on Food Safety sets out some specific requirements on GM foods: if the content of GMOs in food exceeds 0.9% in any food ingredient containing, consisting of or produced from GMOs, food must be labelled as “*GMO*”. This provision roughly mirrors Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.<sup>8</sup> However, it does not provide, *inter alia*, that the 0.9% threshold does only apply where these traces are adventitious or technically unavoidable. Interestingly, Article 39 of the Law on Food Safety establishes that market operators may optionally label their products as “*GMO-free*”. EU legislation does not establish requirements for, nor does it forbid the use of, “*GM-free*” labels to indicate that foodstuffs do not contain GM crops, or were produced without using GMOs. However, such labels are regulated in individual EU Member States.<sup>9</sup>

In addition to the new wording of the Law on Food Safety, Law No. 1602-VII amends a number of legisla-

6 OJ 2002 L 183/51.

7 Article 7 of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council 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 2011 L 304/18–63.

8 OJ 2003 L 268/24–28.

9 Ignacio Carreño and Paolo Vergano, “Uses and potential abuses of ‘negative claims’ in the EU: the urgent need for better regulation”, 5(4) *EJRR* (2014), pp. 469–490.

tive acts. In particular sanitary, epidemiological and veterinary controls of agricultural products imported into Ukraine (*inter alia*, food intended for human consumption, products of animal origin, vegetables, cereal crops, oil seeds, oleaginous fruits, vegetable plaiting materials, animal or vegetable fats and animal feed) are abolished and only radiological and State control remain under the *Law on State Regulation of Agricultural Imports*.

Law No. 1602-VII clarifies that the *Decree of the Cabinet of Ministers of Ukraine on Standardisation and Certification* no longer applies to food products. More importantly, this Decree envisaged veterinary certification of food of animal origin, which is now abolished. Interestingly, in order to include a product in the Unified Register of Certified Products, a company has to submit a compliance certificate and a certificate of compliance recognition, while under the previous procedure a compliance declaration issued by the producer on each supply of the food or supporting materials had to be submitted.

The requirements as to the packaging and State registration of the documents on drinking water were simplified by Law No. 1602-VII (modifying the *Law on Drinking Water and Water Supply*). In particular, requirements as to including the date of production, term of use and storage, name and address of the producer, and indication of the legislative act concerning the quality of water on the labelling, were excluded. Additionally, a provision on State registration of regulatory documents (i.e., a regulation stipulating that producers had to provide manufacturing instructions with detailed descriptions of the production process, indicating the list of substances used in this production and a positive conclusion of the State Veterinary Service) was excluded.

## IV. Conclusion

Improving the regulatory framework on food safety is one of the crucial pre-requisites for EU market access. Notably, the precise regulation of the relations between competent authorities, food business operators and consumers, together with a clarification of the legal framework for imports of food products and for their introduction to the market, will promote transparency and predictability. This, in turn, will facilitate and expand trade. Food operators and traders interested in setting-up compliance mechanisms to make full use of the new EU-Ukraine trade opportunities should make the necessary investments.

With Law No. 1602 VII, including a completely new wording for Ukraine's Law on Food Safety (which applies as of 20 September 2015), Ukraine's food legislation is gradually approximating its legislative framework in this field to the one of the EU. There are some inconsistencies with EU law, such as the fact that medicinal products are not explicitly excluded from the definition of "food", and it will take time until the full EU *acquis* in the field of food law is "transposed" into Ukrainian law. The current situation appears similar to the one experienced in the past with Central and Eastern EU accession candidate countries, where the EU Commission analysed whether the requirements of EU food law were met in their legislation and concentrated in particular in the abolishment of pre-market approvals. Food business operators present in Ukraine and those who want to access Ukraine's market should monitor the development of new food legislation and seek expert advice when it comes to the approval and/or registration procedures for certain products or questions regarding the labelling of products.