



**Legal regulation of materials and articles, intended for contact with food  
in the legislation of Ukraine and the EU**

**Regulamentação legal de materiais e artigos destinados ao contacto com  
alimentos na legislação da Ucrânia e da UE**

Yurii Burylo<sup>1</sup>

Oleksandr Malyshev<sup>2</sup>

Olha Seleznova<sup>3</sup>

Nataliia Lepish<sup>4</sup>

Marta Samchenko<sup>5</sup>

**Abstract**

The aim of the article is to assess Ukraine's progress in the approximation of its administrative legislation on food contact materials and articles with the relevant EU law. The study has been carried out using the method of system analysis and synthesis, comparative legal method as well as historical legal method. It has been established that most of the legal requirements for food packaging materials in Ukraine have been brought in line with those of the EU. Similar to the EU Ukraine can now use such administrative regulatory instruments as the adoption of special requirements for certain groups of food packaging materials as well as the state

<sup>1</sup> Doctor in Law, Academician F.H. Burchak Scientific Research Institute of Private Law and Entrepreneurship, National Academy of Legal Sciences of Ukraine, Volodymyrska St, 60, Kyiv, Ukraine, 02000.

E-mail: [burylojunior@gmail.com](mailto:burylojunior@gmail.com) Orcid: <https://orcid.org/0000-0001-8743-7739>

<sup>2</sup> PhD in Law, Koretski Institute of State and Law of the National Academy of Sciences of Ukraine, Triokhsviatytska St, 4B, Kyiv, Ukraine, 02000. E-mail: [savurmog@ukr.net](mailto:savurmog@ukr.net)  
Orcid: <https://orcid.org/0000-0002-5796-7808>

<sup>3</sup> Doctor in Law, Bukovinian University, Teatral'na Square, 2, Chernivtsi, Chernivets'ka oblast, Ukraine, 58002.  
E-mail: [celezniov@gmail.com](mailto:celezniov@gmail.com) Orcid: <https://orcid.org/0000-0001-5095-277X>

<sup>4</sup> PhD in Law, Lviv State University of Internal Affairs, Horodotska St, 26, Lviv, Lviv Oblast, Ukraine, 79000.  
E-mail: [nataljaja@ukr.net](mailto:nataljaja@ukr.net) Orcid: <https://orcid.org/0000-0002-5754-3511>

<sup>5</sup> PhD in Law, Lviv State University of Internal Affairs, Horodotska St, 26, Lviv, Lviv Oblast, Ukraine, 79000.  
E-mail: [samchenkom@ukr.net](mailto:samchenkom@ukr.net) Orcid: <https://orcid.org/0009-0009-9797-9190>

registration (authorization) of substances that can be used in the manufacture of food packaging materials. At the same time, the conclusion is made that there are discrepancies between Ukraine's legislation and the EU law regarding the recycling of plastic. These discrepancies can be explained by the fact that the EU has recently adopted new legislation, which is more comprehensive and addresses the recycling of plastics at the level of industrial technology, recycling processes and recycling equipment, whereas Ukraine's national legislation is mainly focused on plastic recycling processes.

**Keywords:** Food Packaging Materials. Legislative Approximation. Administrative Legislation. Administrative Regulatory Instruments. Food Safety. Chemical Migration.

### **Resumo**

O objetivo do artigo é avaliar o progresso da Ucrânia na aproximação da sua legislação administrativa sobre materiais e artigos em contacto com alimentos com a legislação relevante da UE. O estudo foi realizado utilizando o método de análise e síntese de sistemas, método jurídico comparativo e também método jurídico histórico. Foi estabelecido que a maioria dos requisitos legais para materiais de embalagem de alimentos na Ucrânia foram alinhados com os da UE. À semelhança da UE, a Ucrânia pode agora utilizar instrumentos regulamentares administrativos, como a adoção de requisitos especiais para determinados grupos de materiais de embalagem de alimentos, bem como o registo estatal (autorização) de substâncias que podem ser utilizadas no fabrico de materiais de embalagem de alimentos. Ao mesmo tempo, conclui-se que existem discrepâncias entre a legislação da Ucrânia e a legislação da UE relativa à reciclagem de plástico. Estas discrepâncias podem ser explicadas pelo facto de a UE ter adoptado recentemente nova legislação, que é mais abrangente e aborda a reciclagem de plásticos ao nível da tecnologia industrial, dos processos de reciclagem e dos equipamentos de reciclagem, enquanto a legislação nacional da Ucrânia se centra principalmente na reciclagem de plásticos processos.

**Palavras-chave:** Materiais para Embalagens de Alimentos. Aproximação Legislativa. Legislação Administrativa. Instrumentos Reguladores Administrativos. Segurança Alimentar. Migração Química.

## Introduction

Nowadays people routinely have to use materials and articles, intended for contact with food. Food contact materials include paper, glass, foil, metals, plastics, ceramics etc. Various types of food contact materials can be used in the production of food contact articles (Groh et al., 2021). Food contact articles comprise packaging materials, cooking and eating utensils as well as various equipment used in the manufacture, processing, storage and transport of foodstuffs (for ease of reference – food packaging materials). On the one hand, food packaging materials are indispensable when it comes to the manufacture, storage, transport, marketing and consumption of food. It is widely recognized that food packaging materials contribute to the safety and quality of food enhancing its shelf life. Overall, these materials facilitate the preservation and marketing of food making it more available and accessible for people. On the other hand, food packaging materials can pose a certain risk to human health as all of them transfer chemical compounds they are made of into the food they are supposed to hold (Claudio, 2012; Alamri et al., 2021).

Health concerns related to food packaging materials gave rise to the legislation governing their manufacture and use in many parts of the world, including the EU. The main focus of this legislation is to ensure a high level of public health protection as well as the protection of consumers' interests. This legislation includes a number of administrative legal mechanisms aimed at ensuring the safety of food packaging materials, consequently the safety of foodstuffs for consumers.

Ukraine, as a country having an association agreement with the EU and aspiring for membership in the EU, has been making consistent efforts to bring its own national legislation on food packaging materials in line with the relevant legislation of the EU. As part of legislative approximation efforts Ukraine's parliament adopted the Law of Ukraine "On the materials and articles, intended for contact with food" in November, 2022 (Law of Ukraine No. 2718-IX, 2022). This law is based on the provisions of the relevant EU legislation, including Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, which is often referred to as the FCM Framework Regulation (Regulation No. 1935/2004, 2004). Therefore, it is time to assess the progress made by Ukraine in terms of aligning its administrative legal mechanisms in the area of food packaging materials with those of the EU.

## Methodology

The methodological basis of this study comprises such methods of scientific research as system analysis and synthesis, comparative legal method as well as historical legal method. The method of system analysis and synthesis is used to examine the legal provisions concerning food contact materials and articles as a single integrated system of intertwined and interacting elements. The use of this method also made it possible to identify the existing problems of administrative legal regulation in this area and to elaborate some conclusions and solutions to these problems. The comparative legal method is used for identifying the similarities and differences between the national legislation of Ukraine and relevant EU law on food contact materials and articles. The application of the historical legal method provides the possibility to trace the development of certain provisions in the legislation on food contact materials both in Ukraine and the EU.

Food safety issues as well as some issues relating to food packaging materials have been examined by many scientists. In particular, L. Claudio, A. Almari A. Qasem, A. Mohamed, Sh. Hussain, M. Ibraheem and many others investigated the impact of food contact materials on food safety. Food contact chemicals as well as hazards associated with them were examined by K. Groh, B. Geueke, O. Martin, M. Maffini, J. Muncke. The issues of chemical migration from food packaging materials into the food were explored by K. A. Barnes, C. R. Sinclair, D.H. Watson and others. However, there is still a gap in the legal research of issues stemming from the approximation of Ukraine's national legislation on food contact materials with the relevant legislation of the EU. Considering the fact that the EU legislation on food contact materials and articles has been rapidly evolving in recent years, the purpose of this article is to highlight Ukraine's accomplishments and shortfalls in building an administrative legal framework for food packaging materials against the background of the evolving EU legislation. In order to achieve this goal, it is necessary to compare Ukraine's national legislation on food packaging with the relevant legislation of the EU, single out the pivotal regulatory mechanisms and point out the existing differences in the relevant legal framework of Ukraine and the EU.

## Results and Discussion

Adopting its national legislation on food contact materials and articles Ukraine used the same differentiated approach as the EU in its FCM Framework Regulation. There are two

types of requirements applying to food packaging materials. First of all, there are general requirements, which are common for all kinds of food packaging materials. These legal requirements are set out in article 3 of the FCM Framework Regulation and article 6 of the relevant Law of Ukraine. According to these articles manufacturers are supposed to ensure that food packaging materials are produced in conformity with GMP (good manufacturing practice) and under normal foreseeable conditions of use these materials and articles do not transfer their constituents to food in quantities which could jeopardize human health or cause significant changes in the composition of food or adversely affect the organoleptic properties of food. Besides, the labelling, advertising and presentation of such materials and articles must not mislead consumers.

In addition to the general requirements there are special requirements (specific measures according to the FCM Framework Regulation) applying only to certain kinds of food packaging materials, such as active and intelligent materials and articles, adhesives, ceramics, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, varnishes, waxes, etc. The full list of food packaging materials subject to special requirements (specific measures) is set out in Annex I to the FCM Framework Regulation and article 8 of the relevant Law of Ukraine. It should be pointed out that only some of these food packaging materials, namely active and intelligent materials, regenerated cellulose films, ceramic materials and plastics, including recycled plastics, are currently covered by specific measures in the EU. At the same time there are no harmonized requirements for other materials at the EU level. As a result, manufacturers of food packaging materials have to comply with the national legislation of EU member-states regarding such materials (Leo, 2021). As for Ukraine, which is not yet part of the EU, it will have to implement the existing EU requirements for these materials and supplements its national legislation with the requirements for other packaging contact materials, which are not covered by the EU regulations.

These special requirements may include the adoption of purity requirements and special conditions of use for substances which are components in food contact materials and articles; specific migration limits (SML) for certain constituents or total specific migration limit (SML(T) for groups of constituents of food contact materials; an overall migration limit (OML) for constituents of food contact materials; requirements for the collection of samples and the methods of analysis; special rules on the traceability of food contact materials and articles, etc. In Ukraine special requirements for food packaging materials are regarded as specific administrative instruments that can be adopted by the Ministry of Health and the

Ministry of Agrarian Policy and Food in case they are needed, whereas in the EU these specific measures are adopted by the Commission.

The analysis of the general requirements as well as special requirements (specific measures) for food contact materials and articles shows that much, if not the most, of the current legal regulation in this area is aimed at preventing the migration of various chemicals and chemical compounds from food contact materials and articles into or onto foodstuffs. The objective of preventing chemical migration stems from the need to ensure the safety of food for consumers. It is well-known from scientific sources that none of the existing food packaging materials is completely inert and therefore it is always possible for chemical substances to get from food packaging materials into the packaged food. If chemical migration is not properly controlled it can be dangerous for human health. The exception is 'active materials' releasing chemical substances (antioxidants, preservatives, etc.) into the food with beneficial effects (Barnes et al., 2007, pp. 1, 8). This is why the existing legal framework for food packaging materials both in the EU and Ukraine is designed in such a way as to prevent the migration of hazardous chemical substances into the food.

The above-mentioned administrative instruments (measures) play a crucial role in the functioning of the whole legal framework for food packaging materials, as they are designed to provide a practical mechanism for the enforcement of the general requirement aimed at preventing the transfer of food packaging materials' constituents into food (chemical migration) in quantities presenting a risk to human health or significantly affecting the composition and organoleptic properties of food. Setting overall migration limits or specific migration limits for certain chemical substances as well as other special requirements, the Ministry of Health of Ukraine or the Commission in the case of the EU can limit the exposure of consumers to hazardous chemicals thus protecting public health. Without such administrative instruments the general requirements for food packaging materials would be only an empty declaration of good intentions and there would be no practical way to implement these requirements.

Another important administrative legal mechanism of ensuring the safety of food packaging materials is the authorization (the state registration in the wording of the Ukrainian law) of substances used in the manufacturing of food contact materials and articles as well as the authorization of recycling processes for plastic waste. The authorization procedure is set out in the Law of Ukraine "On the materials and articles, intended for contact with food" and is largely based on the relevant provisions of the FCM Framework Regulation as well as some provisions of the Commission Regulation (EC) No. 282/2008 of 27 March 2008 on recycled

plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006 (Regulation No. 282/2008, 2008).

It should be pointed out that prior to the adoption the Law of Ukraine “On the materials and articles, intended for contact with food” there was a legal requirement for the authorization (state registration) of food packaging materials in the Law of Ukraine “On the Main Principles and Requirements for the Safety and Quality of Food” (Law of Ukraine No. 1602-VII, 2014). However, that requirement has never been applied due to the absence of an administrative legal mechanism for its implementation. This gap in the legislation was addressed when the Law of Ukraine “On the materials and articles, intended for contact with food” was adopted. So, hopefully the authorization procedure will start working as soon as this law comes into force.

The main goal of applying the authorization procedure is to ascertain that a particular chemical substance (chemical compound) is safe for human health when used as a constituent in food packaging materials as well as to establish the conditions for its safe use. For this reason, the crucial part of the whole authorization procedure is the safety assessment of a substance. The findings of the safety assessment are of paramount importance for the outcome of the authorization procedure. The safety assessment of a substance involves its technical dossier evaluation, including chemical risk assessment. Normally such risk assessment implies the examination of toxicity associated with migrating food contact chemicals (Beneventi et al., 2020; Muncke et al., 2017). Since safety assessment is a complex scientific process, it takes a long time (up to six months or even longer). As a result, the safety assessment is the lengthiest part of the whole authorization procedure. In addition, the compilation of the technical dossier for a substance undergoing the authorization procedure is also time-consuming and costly. So, overall from the perspective of business operators interested in the production and marketing of food contact chemicals the authorization procedure is the most burdensome administrative legal instrument at the disposal of the authorities.

The administrative mechanism of authorization (state registration) can be potentially applied to chemical substances used in the manufacture of all food packaging materials, covered by special requirements (specific measures). However, at the moment under the Ukrainian law this administrative instrument is supposed to be applied only to substances used in the production of active and intelligent materials, ceramic materials, regenerated cellulose and plastics, since the EU currently applies the same approach. The most plausible explanation for the limited application of the authorization as an administrative regulatory instrument is

the administrative and financial burden on business operators wishing to introduce new innovative substances into their food packaging. Moreover, there is also an additional burden on the public authorities responsible for the implementation of regulatory policies with regards to food packaging materials, because the processing of relevant authorization applications as well as the safety assessment of food contact chemicals also require appropriately qualified staff and financial resources.

At the same time from the perspective of ensuring food safety, which obviously depends on the safety of food packaging materials, the authorization of food contact chemicals is a powerful administrative legal mechanism enabling the public authorities to obtain a comprehensive safety assessment of food contact chemicals before making decisions on their possible use in the manufacturing of food packaging materials. Hence, if food safety and the protection of public health are recognized as the topmost priorities both in Ukraine and the EU, the broadening of the application of this administrative regulatory instrument should be viewed as desirable way forward.

The authorization procedure also applies to plastic recycling processes. The need for the application of this procedure stems from the fact that the recycled plastic, which is used in food packaging materials, is usually produced from plastic waste that can be contaminated with various chemical substances deriving from the previous use of plastic items or other waste contacting such items (Ibrahim et al., 2022). Unsurprisingly, recycled plastics contain higher levels of known hazardous chemicals, in particular oligomers, which can migrate into food, as well as more unknown chemicals in comparison with virgin plastic (Muncke, 2022; Matthews et al., 2021, p. 4).

It has to be emphasized that there are significant differences between Ukraine's national legislation and the relevant EU law when it comes to the regulation of the use of recycled plastic in food packaging materials. The provisions of the Law of Ukraine "On the materials and articles, intended for contact with food" applying to recycled plastic are based on the outdated Commission Regulation (EC) No. 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006. This EU regulation is no longer in force as it was repealed and replaced by Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No. 282/2008 (Regulation 2022/1616, 2022).

Although the authorization of recycling processes is provided for both in the old and in the new EU regulations, the new EU regulation is much more comprehensive. Along with



recycling processes Commission Regulation (EU) 2022/1616 also covers recycling technologies and recycling installations paying particular attention to decontamination issues (packaginglaw.com, September 26, 2022a). In other words, in respect of recycled plastic materials and articles Ukraine's national legislation is only partially aligned with the relevant legislation of the EU. Thus, it is necessary to take a closer look at the similarities and differences of the relevant legislation in Ukraine and the EU.

Similar to Commission Regulation (EC) No. 282/2008 the Law of Ukraine "On the materials and articles, intended for contact with food" stipulates that food packaging materials made of recycled plastic may be placed on the market only if recycled plastic is obtained from an authorized (registered) recycling process. However, according to Commission Regulation (EU) 2022/1616 a valid authorization of a recycling process is only one of many requirements that have to be met when using recycled plastic in the production of food packaging materials. Moreover, this legal requirement is mandatory only for individual recycling processes based on post-consumer mechanical PET recycling technology. At the same time recycling processes based on the technology of recycling from product loops which are in a closed and controlled chain (closed loop recycling) do not require any authorization.

Besides, there is no need for an authorization if food packaging materials are made of recycled plastic using novel technologies (HDPE mechanical recycling technology, chemical depolymerization technology, etc.) (packaginglaw.com, January 21, 2022b). In this case, instead of obtaining an authorization of a recycling process it is necessary to meet a number of additional legal requirements concerning the development of a novel technology, the operation of recycling installations applying novel technologies, the monitoring and reporting of contamination levels as well as supplementary information requirements on recycling installations. The replacement of the authorization mechanism, which can be a significant administrative hurdle for business operators, with a bunch of legislative requirements in relation to novel recycling technologies testifies that the EU authorities realize that there needs to be a new set of measures striking a balance between the protection of public health and the promotion of innovation.

Thus, it is clear that the new EU legislation employs a more selective approach to the use of authorization as an administrative regulatory instrument than the Commission Regulation (EC) No. 282/2008 and the Law of Ukraine "On the materials and articles, intended for contact with food". This can be explained by the fact that the new EU regulation on recycled plastic materials and articles has become much more technology-specific and uses a much broader array of legal instruments.

Along with a limited application of recycling processes' authorizations the new regulatory approach of the EU also implies the introduction of a number of additional requirements regarding recycling technologies and recycling installations. Thus, overall the EU currently has a multi-pronged approach to legal regulation regarding recycled plastic materials and articles addressing the safety of recycled plastic at the levels of recycling technologies, recycling processes and recycling installations.

Most notably, the legal regulation of recycled food contact materials and articles deals with the technology used for the recycling of plastics. Commission Regulation (EU) No. 2022/1616 divides all existing and future plastic recycling technologies into two categories: suitable recycling technologies and novel technologies. Each of these categories has its own distinct legal regime.

According to article 3 of Commission Regulation (EU) No. 2022/1616 a recycling technology is considered suitable if it can recycle plastic waste into recycled plastic materials and articles that are microbiologically safe and meet the general requirements for food contact materials and articles enshrined in the FCM Framework Regulation. All suitable recycling technologies are currently listed in Annex I of Commission Regulation (EU) No. 2022/1616 and comprise post-consumer mechanical PET recycling and recycling from product loops which are in a closed and controlled chain (closed loop recycling). Obviously, there are many more plastic recycling technologies available nowadays. However, the list of suitable recycling technologies in this EU regulation is quite short, because it includes only well-established and well-tested technologies with sufficient amount of scientific data on the safety of the recycled plastics they produce.

As it stems from the provisions of article 3 of Commission Regulation (EU) No. 2022/1616, a recycling technology that has not been subject to a decision on its suitability is regarded as a novel technology. This means that such a technology can also be used subject to a number of additional legal requirements and administrative procedures, which are necessary for the collection of supplementary data on the use of a particular technology and the safety of recycled plastics produced by means of this technology.

The first administrative procedure to be followed with regards to a novel technology is to notify the relevant government agency of an EU member-state, where the developer of the technology is located, and the Commission of the novel technology. The notification is supposed to take place no later than six months before the beginning of the operation of relevant decontamination facility. After the notification the information about the novel technology is entered into the EU list of novel technologies, recyclers, recycling processes,

recycling schemes and decontamination equipment. The recyclers also have an obligation to notify the relevant government agency and the Commission of the decontamination installation at least thirty working days before starting the manufacture of recycled plastic using the installation. The information about the decontamination installation and the recycler is also recorded in the EU list of novel technologies, recyclers, recycling processes, recycling schemes and decontamination equipment.

Recyclers operating decontamination facilities have an obligation to monitor average contamination levels based on the sampling of plastic input batches and corresponding output batches of decontaminated plastic. The relevant information is passed on by recyclers to the developer of the novel technology on a regular basis. After analyzing the relevant data from all recyclers using the novel technology, the developer compiles a report and publishes it on its web-site. Besides, under Commission Regulation (EU) No. 2022/1616 recyclers have a lot of other responsibilities, including an obligation to have documented supplementary information on recycling installations using the novel technology and an obligation to fill out a compliance monitoring sheet. The relevant information and documentation must be provided at the request of the developer of the novel technology and the government agency.

All these responsibilities on the part of the developer of a novel technology and recyclers using relevant recycling equipment are supposed to facilitate the collection, exchange and analysis of information about this technology and the safety of the recycled plastic that is obtained as a result of its application. This information is essential for the assessment of such a technology by the European Food Safety Authority and making a decision on its suitability by the Commission. If the Commission decides that the novel technology is a suitable technology it also has to decide whether recycling processes applying that technology have to be subject to authorization.

Overall, the authorization procedure for individual recycling processes under Commission Regulation (EU) No. 2022/1616 has not changed much in comparison with the provisions of Commission Regulation (EC) No. 282/2008 with safety assessment remaining the pivotal part of the whole procedure. Therefore, with regards to the authorization of recycling processes the provisions of the Law of Ukraine “On the materials and articles, intended for contact with food” remain relevant, despite the fact that they were elaborated based on Commission Regulation (EC) No. 282/2008. At the same time this Law of Ukraine needs to be amended in order to take account of many other provisions of Regulation (EU) No. 2022/1616 concerning the legal regimes of suitable recycling technologies and novel technologies, in particular the administrative procedures used during the development and

application of novel technologies, such as notification and registration procedures for novel technologies, recyclers, recycling processes, recycling schemes and decontamination facilities.

### Conclusion

Based on the above, it is possible to conclude that the current administrative legal framework for food packaging materials in Ukraine is mostly aligned with the relevant EU law. Most of the existing administrative procedures applying to food packaging materials in Ukraine, such as the adoption of special requirements (specific measures) and the registration (authorization) mechanism for food contact chemicals, correspond to the same administrative instruments employed by the EU in order to control chemical migration for the sake of protecting human health.

However, due to the fact that the EU law on food contact materials and articles has been constantly evolving in recent years some parts of Ukraine's national legislation still are lagging behind. In particular, there is a significant gap between the new EU legislation on recycled plastic packaging materials and the relevant Ukrainian law. In light of the new developments in the relevant EU law Ukraine needs to update its national legislation with legal requirements for plastic recycling technologies, recycling processes and recycling installations, in particular introducing new administrative procedures for the notification and registration of novel technologies, recyclers, recycling processes, recycling schemes and decontamination installations.

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