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Review article / Обзорная статья

Conformity assessment for organic products in the European Union

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Abstract. The adoption of organic agriculture has acquired particular significance as one of the effective means of high-quality and safe products recovery. A brief conformity assessment of requirements for organic products and their regulation in the European Union is provides. The EU legislative acts are confirmed to EU market features raised for organic products. EU regulatory legal acts for imports of organic products from third countries, food quality and labeling of organic production, organic aquaculture animal and seaweed production, organic wine are considered. All food manufacturers must comply with general EU foodstuff laws and regulations, which include labeling regulations. Regulation is complemented by several legislative acts on the production, distribution and marketing of organic products, which are the legal framework for determining rules for their implementation in the EU. The United States permits the sale of European products that produced and certified under the EU organic program as organic in the United States are considered. Legislative acts EU Regulation 1235/2008, EU Regulation 2020/25, EU Regulation 889/2008, EU Regulation 710/2009, EU Regulation 203/2012 are discussed.

Keywords: organic products, organic standards, food quality, standardization, EU legislative act

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Обзор оценки соответствия органической продукции в странах EC

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Аннотация. Ведение органического сельского хозяйства приобрело особое значение как одно из эффективных средств получения качественной и безопасной продукции. Приводится обзор оценки соответствия требованиям к органическим продуктам и их регулированию в Европейском союзе. Рассмотрены законодательные акты ЕС, предъявляемые к органическим продуктам, отражающие особенности местного рынка, а также нормативные акты ЕС, регулирующие импорт органической продукции из третьих стран, качество пищевых продуктов и маркировку органической продукции, органической аквакультуры, продукции животноводства и морских водорослей, органического вина. Все производители пищевых продуктов должны соблюдать общие нормативные акты ЕС в отношении пищевых продуктов, в том числе правила маркировки. Регулирование дополняется несколькими законодательными актами о производстве, распространении и маркетинге органических продуктов, которые являются правовой основой для определения правил их реализации в Европейском союзе. Соединенные Штаты на своем рынке разрешают продажу европейских продуктов, произведенных и сертифицированных в рамках органической программы ЕС, в качестве органических. Рассмотрены законодательные акты Европейского союза EU Regulation 1235/2008, EU Regulation 2020/25, EU Regulation 889/2008, EU Regulation 710/2009, EU Regulation 203/2012.

Ключевые слова: органическая продукция, стандарты органической продукции, качество продуктов питания, стандартизация, нормативные акты EC

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Introduction

Modern organic agriculture has long since ceased to be a "niche segment of the market." It has become one of the most dynamically developing sections of the European Union agricultural sector. Market value for organic products in the EU is estimated at 27 billion euros (an increase of 125% in ten years) [1; 2]. Moreover, the area of agricultural land cultivated using organic technologies increases annually by 400 thousand hectares.

In recognition of environmental situation in the world, consumers and governments (especially in EU countries) place greater focus on the safety of agricultural and food products. Therefore, in recent decades, the adoption of organic

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agriculture has acquired particular significance as one of the effective means of high-quality and safe products recovery [3; 4]. There is IFOAM definition: "Organic agriculture is a production system that sustains the health of soils, ecosystems, and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects."

Regulation of organic products in the European Union

In 2007, the Council of the European Union adopted Regulation EC 834/2007 on organic production and labeling of organic products, which sets out the principles, goals and general rules for organic production and defines labeling requirements for organic products [4]. This regulation is complemented by several legislative acts on the production, distribution and marketing of organic products, which are the legal framework for determining rules for their implementation in the EU, including the requirements for products imported from non-EU countries. There are also additional special rules regulating aquaculture and wine production.

Such legislative acts include:

- 1) EU Regulation 1235/2008 on rules for imports of organic products from third countries;¹
- 2) EU Regulation 2020/25 amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries;²
- 3) EU Regulation 889/2008 on organic production and labeling of organic products with regard to organic production, labeling and control;³
- 4) EU Regulation 710/2009 for the implementation of Council Regulation (EC) No 834/2007 on rules on organic aquaculture animal and seaweed production;⁴
- 5) EU Regulation 203/2012 s for the implementation of Council Regulation (EC) No 834/2007 on rules on organic wine.⁵

According to EU Regulation 834/2007,⁶ organic production is an overall system of farm management and food production that combines the best environ-

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¹ EUR-Lex. Commission Regulation (EU) No 1235/2008 of 8 December 2008. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1235 (accessed: 06.08.2020).

² EUR-Lex. Commission Implementing Regulation (EU) 2020/25 of 13 January 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0025 (accessed: 06.08.2020).

³ EUR-Lex. Commission Regulation (EC) No 889/2008 of 5 September 2008. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R0889 (accessed: 06.08.2020).

⁴ EUR-Lex. Commission Regulation (EC) No 710/2009 of 5 August 2009. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2009.204.01.0015.01.ENG (accessed: 06.08.2020).

⁵ EUR-Lex. Commission Implementing Regulation (EU) No 203/2012 of 8 March 2012. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0203 (accessed: 06.08.2020).

⁶ EUR-Lex. Commission Implementing Regulation (EU) 2020/25 of 13 January 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0025 (accessed: 06.08.2020).

mental practices, ensuring a high level of biodiversity, the preservation of natural resources, applying high standards of animal welfare and production standards in accordance with the certain consumer's preference of products produced using natural substances and processes.

EU Regulation 834/2007 defines general objectives and basic rules affected on EU Regulation $2020/25^7$:

- all stages of production, processing and marketing of ecological products, as well as their control;
 - data usage for labeling and advertising that refer to sustainable production.

 This regulation is valid for the following agricultural products, including

This regulation is valid for the following agricultural products, including aquaculture, if it is marketed or intended to be marketed:

- fresh or unprocessed agricultural produce;
- processed agricultural produce intended for use as foodstuff;
- feed, including feed yeast;
- plant raw materials and crop seeds.

Hunting and fish-breeding wild-life animal products are not considered as organic products.

According to regulation of organic products,⁸ each country in the European Union appoints a competent authority (institution), which is ultimately held responsible for complying with EU regulations for organic products [1]. It is a general practice there is the Department of Agriculture or the Department of Public Health. The competent authority can delegate its function to:

- one or several private (inspection) authorities;
- one or more public control authorities;
- a mixed system with private control agencies and public oversight authorities.

Whether there is preferred system, the competent authority is responsible for carrying out the monitoring within its responsibilities.

Annually EU countries report to the European Commission on the results of control carried out relative to organic operators (farmers, processing organizations, sellers, etc.), and on the measures taken in case of non-compliance with the imposed requirements. Organic operators must be audited by a controlling authority (independent third party) that verifies operators and certifies organic production according to regulations before selling their products as organic. After verifying and matching, organic operators receive certificate confirming that their production complies with EU requirements [3–5].

An additional point is that regardless of whether products are organic or not, farmers (agricultural producers) must comply with a series of laws and regulations that protect human health, animals and plants as well as the environment. All food manufacturers must comply with general EU foodstuff laws and regulations, which include labeling regulations. There may be additional rules for certain products,

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⁷ EUR-Lex. Commission Implementing Regulation (EU) 2020/25 of 13 January 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0025 (accessed: 06.08.2020).

⁸ EUR-Lex. Commission Regulation (EC) No 1235/2008 of 8 December 2008. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1235 (accessed: 06.08.2020); EUR-Lex. Commission Implementing Regulation (EU) 2020/25 of 13 January 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0025 (accessed: 06.08.2020).

such as specific labeling requirements [3]. These rules are also binding on organic producers.

In accordance with Council Regulation (EC) No 834/2007⁹, a product imported from a third country may be placed on the EU market as organic, provided that:

- the product complies with the provisions established by the Regulation;
- all entrepreneurs, including exporters, are controlled by a recognized control agency or body;
- all entrepreneurs at any time can present to importers or national authorities a document issued by the supervisory authority confirming the identity of the entrepreneur who carried out the last work process and making it possible to check the compliance of the entrepreneur with the provisions of the regulation.

In accordance with the established procedure, the European Commission recognizes supervisory agencies and bodies responsible in third countries for the control and issuance of conformity assessment documents and maintains a list of these supervisory agencies and bodies. Supervisory bodies must be accredited according to the European standard EN 45011 or ISO 17065 ("Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services"). The activities of the supervisory bodies are regularly checked, monitored and evaluated over the years by the accreditation body.

On February 15, 2012, the European Union and the United States of America signed the Organic Equivalence Agreement, which entered into force on June 1, 2012. This agreement applies to organic products manufactured in the USA or the EU, as well as to products containing imported organic ingredients certified in accordance with US or EU organic standards, and which are finished or packaged in the USA or EU. Aquatic animals (e.g. fish and molluscs) are not included in the scope of the agreement.¹⁰

From June 1, 2012, certified organic products can move freely between the US and EU borders if they meet the terms of the agreement. Under the agreement, the EU recognizes the US national organic program as the equivalent of the EU organic program and permits the sale of products manufactured and certified to meet US standards as environmentally friendly in the EU [4]. Likewise, the United States permits the sale of European products produced and certified under the EU organic program as organic in the United States.

An organic import certificate must contain:

- an information about the place of production,
- an information about the organization that certified the organic product,
- an information about verification of using of prohibited substances and methods, about compliance with the terms of the agreement, and about permission of tracking of tradable products.

⁹ EUR-Lex. Commission Implementing Regulation (EU) 2020/25 of 13 January 2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0025 (accessed: 06.08.2020).

¹⁰ Hautman B. Eight in ten U.S. parents report they purchase organic products, Organic Trade Association's (OTA's) newly released 2013 U.S. Families' Organic Attitudes and 58 Beliefs Study, conducted Jan. 18–24. Available from: http://www.organicnewsroom.com/2013/04/eight in ten us parents report.html (accessed: 26.08.2020).

The agreement sets forth the following requirements for organic products. US organic products can be placed on the EU market as organic using the EU organic label if two conditions are met:

- tetracycline and streptomycin were not used for the treatment of bacterial burns of apples and pears;
- products are accompanied by an electronic or paper import certificate issued by an organization for certification of organic products accredited in the prescribed manner.

EU products can be marketed in the US as organic using the US organic label under two conditions:

- the animals were not administered antibiotics;
- the products are accompanied by an electronic or paper import certificate issued by an EU notified body.

Conclusion

To facilitate trade, the EU and the US have agreed to work together to promote an electronic certificate system for imports, as well as eliminate import certificates in the future. The United States and the European Union regularly review each other's organic programs to ensure that the terms of the agreement are being met.

Thus, organic agriculture is governed by numerous statutory regulations and exclusionary provisions, which makes the regulatory framework generally confusing and opaque, therefore, from the European Commission's point of view, the development of a standardized and unified EU regulation is an important step to ensure compliance with the rule of law and a stable planning horizon for organic sector. The dynamic development of the industry also requires updating the existing regulations, many of which were adopted more than 20 years ago.

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