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Romania

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

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Report Highlights:

The following report provides updated information on 2017 agricultural and food legislation in Romania. In 2017, new rules pertaining to milk and dairy-product labeling, and food-waste reduction were adopted. This report should be read in conjunction with the comprehensive <u>FAS USEU European</u> Food & Agricultural Import Regulations (FAIRS) Report.

DISCLAIMER: This report was prepared by U.S. Embassy Bucharest's Office of Agricultural Affairs for U.S. exporters of domestically-produced food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate due to policy changes since its preparation, or because clear and consistent information about these policies was not available. Post advises that U.S. exporters verify the full set of import requirements with their foreign customers (importers), who are normally best equipped to research such matters with local authorities, before any goods are shipped. Final approval of any product is subject to the importing country's rules and regulations as interpreted by border officials at the time of product entry.

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Section I. General Food Laws:

Romania's food laws and regulations are harmonized with European Union (EU) legislation. Romania, as an EU Member State, follows the EU regulations therefore this report is recommended to be read in conjunction with the <u>FAS USEU European Food & Agricultural Import Regulations (FAIRS) Report</u> produced by the U.S. Mission to the EU in Brussels, Belgium. Several Romanian governmental entities share responsibilities related to food and agricultural products, produced locally or imported, as outlined below:

Ministry of Agriculture and Rural Development (MARD) is responsible for drafting and implementing the national agricultural policy. MARD ensures the implementation of the EU regulations in the field of agriculture, food processing and industry, land reclamation, and agricultural research.

Ministry of Environment, Water and Forests is the institution in charge of national environment protection, water, and forestry management. It is the main regulatory body for conducting environmental risk assessment (including for genetically engineered products) and monitoring activities that may affect human health and the environment.

National Sanitary Veterinary and Food Safety Authority is the main body charged with sanitary, veterinary, and food-safety activities in Romania. It regulates animal health and food safety for animal and non-animal food products, either produced locally or imported. The National Sanitary Veterinary and Food Safety Authority publishes annual information on the surveillance, prevention, and control of animal diseases and for the surveillance and control of food safety.

Ministry of Health (MOH) is responsible for overseeing the production and registration of drugs, food additives, and medical equipment. It is also responsible for public health as it relates to contaminants and food supplements.

National Authority for Consumers Protection is the agency established to protect consumer rights and interests. The authority enforces legislation related to consumer protection, including food products. Regulating food labeling is one responsibility of this authority.

The major pieces of legislation which govern the production and import of food and agricultural products are listed below:

- Government Decision 106/2002 concerning food labeling with subsequent amendments;
- Government Ordinance 34/2000 concerning organic food along with Order 1253/2013 issued by MARD regarding the registration of producers, processors, and importers of organic products (with the subsequent amendments);
- Emergency Ordinance 43/2007 transposing <u>Directive 2001/18</u> regarding the deliberate release into the environment of genetically-modified organisms;
- Emergency Ordinance 44/2007 transposing <u>Directive 90/219</u> referring to contained use of genetically-modified micro-organisms;
- Order 438/2002 issued by the Ministry of Health defining and listing additives permitted for use in foodstuffs, with subsequent amendments;
- Order 112/2017 issued by the National Sanitary Veterinary and Food Safety Authority setting the technical regulation for monitoring and surveillance in livestock, animal and non-animal origin products;

- Government Decision 935/2011 on the promotion of the use of biofuels amended by Government decision 928/2012 and Government Decision 1121/2013 approving new biofuel mandates concerning the market conditions for introducing biofuels on the market;
- Law 321/2009 concerning food products trading, amended through Law 150/2016
- Government Decision 563/2007 on the protective measures against the introduction into Romania of organisms harmful to plants or plant products from other member states or third countries and against their spread amended in 2014.

Section II. Food Additives Regulations:

Romania follows EU legislation on the additives permitted for use in foodstuffs. Order 438/2002 regarding the <u>food additives</u> to be used in foodstuff for human consumption has been amended several times since its initial publication in order to reflect EU legal amendments. Information about the EU legislation regarding food additives may be found in the <u>FAS USEU European Food & Agricultural</u> <u>Import Regulations (FAIRS) Report</u>. An updated list of permitted additives, flavorings, processing aids, and enzymes provided by EU regulations may be found on the <u>European Commission website</u>.

Section III. Pesticides and Other Contaminants:

Three Competent Authorities oversee the National Monitoring Program for pesticide residues: National Sanitary Veterinary and Food Safety Authority (NSVFSA), MARD, and MOH. The first listed entity bears the responsibility to develop the Program for pesticides residues in cooperation with the other two authorities. The Program sets the samples of food of plant origin from Member States and third countries, the sampling location, and the active substances subject to analysis.

While the National Sanitary Veterinary and Food Safety Authority implements the National Program for Surveillance and Control for foods of plant and animal origin, MARD is responsible for national monitoring plan of pesticides residues in fruits, vegetables, cereals.

Romanian follows the maximum residues levels (MRLs) established by the EU under <u>EU Regulation</u> <u>396/2005</u> on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. Romania follows EU legislation on pesticide MRLs for food and feed of plant and animal origin. U.S. exporters are advised to check the European Commission's website for latest updates <u>here</u>.

Section IV. Packaging and Container

Requirements:

Packaging Waste Management

Member States are required to reduce packaging waste. Romanian legislation concerning packagedwaste management has been in place since 2005, when it harmonized with EU regulations through Government Decision 621/2005. Reporting requirements vis-à-vis quantities of recyclable waste were established under by Law 211/2011, which was amended in 2016 by Emergency Ordinance 68/2016 regarding waste management. According to these provisions, business operators whose products put packaging material into commerce must recover part of the packaging materials for recycling. The law also applies to food operators, producers, importers and traders, industries dealing with packaged products, such as the canning industry, dairy industry, soft drinks industry, mineral water, wine, etc. regardless the origin of the products, domestic or foreign.

Food Waste reduction

Romania approved Law 217/2016 which obliges companies to donate or sell at reduced prices the food products that are close to expiration dates. The provisions requested that companies active in the food sector need to take measures to prevent food waste, starting from the production, processing, storing, distribution, and sale of products. The law was set to be implemented six months after publication, however it was contested by various industry bodies, citing lack of clarity and difficulties if the law implementation. In response to these concerns, the Romanian Government decided in June 2017 to delay the enforcement until January 2018.

Section V. Labeling Requirements:

General Requirements

The principal law on food labeling remains Government of Romania Decision 106/2002, which outlines the methodology and requirements for food labeling, accompanied by its Enforcement Rules. Decision 106/2002 was amended several times since its publication, as Romania has gone through the process of transposing EU Directives.

As a general rule, the information on the labels cannot mislead consumers regarding the characteristics of the food product, especially regarding its nature, identity, features, composition, amount, durability or its origin, as well as the manufacturing or production methods.

The labels must contain the following compulsory specifications in Romanian language:

- Name of the product;
- Ingredient list (for processed products only). These ingredients must correspond to the ones specified in the technical description of the product. The vitamins and minerals must be also mentioned in the list, if added in the product;
- Net content (weight/capacity) for prepackaged products;
- Expiration date; in case the expiration date includes the day, the expression "*to be consumed*, *preferably, before*..." should be used, while in case only the month or month and year are printed, the expression "*to be consumed, preferably, until the end* ..." should be used
- Required storage conditions (temperature, humidity, etc.), when applicable;
- Usage instructions, in case the absence might result in improper usage;
- Place of origin or provenance if its absence would mislead consumers;
- Lot identification, which has to correspond with the number written in the export documents, with few exceptions;
- Name and address of the producer/packager/ distributor registered in European Union; in case of food products imported from third countries, the name and address of importer/distributor registered in Romania; and
- Date of manufacturing.

In addition, the provisions of the <u>Regulation 1169/2011</u>, also called "Food Information to Consumers", are applicable in Romania. The regulation entered into force on December 13, 2014, with the exception of the nutrition declaration which was applied starting with December 13, 2016.

In general, Romanian language labels are applied in Romania, but exporters and importers may agree on attaching labels at the port of origin, or an EU port-of-entry third-country. To avoid delays in placing the food products on the Romanian market, U.S. exporters are advised to check in advance about new or additional labeling requirements prior to shipping.

Other specific labeling requirements

a. COOL Labeling for meat and milk

In 2016 specific rules on COOL labelling for meat and milk were adopted. According to the provisions of law 150/2016 concerning food products trade the meat label should contain the following information: origin country of the animal, country where the animal was born in, raised, slaughtered, the health stamp/identification and name of the commercial operator, country of the cutting plant. In the case of meat products, the label must indicate the percentage of meat originating from Romania. The above provisions of the law have not been fully implemented though due to the concerns expressed by the European Commission regarding its content, so the law is under revision in the Romanian Parliament.

A similar Country of Origin Labelling (COOL) law was approved on dairy products in May 2016. The European Commission though found Law 88/2016 to be non-compliant with EU notification procedures because Romania passed and published the Law without receiving final approval from the EU. Consequently, Romania did not enforce the Law and coordinated with the European Commission regarding the necessary amendments to ensure compliance. As a result, the Romanian Parliament amended the law in 2017 bringing mandatory measures for fresh milk and dairy product labeling. The enforcement date for the new provisions is January 1 2018. For further details, please read the GAIN report <u>"Romania Amends COOL on Milk and Dairy"</u>.

b. Biotechnology labeling

In this area the legislation has not been amended. Agricultural Ministry Order No. 61/2012 transposing <u>Regulation (EC) No 1830/2003</u>, which provides labeling requirements of food stuff derived from genetically engineered (GE) products or containing ingredients which have been genetically engineered, remains valid. Animal feed, if produced from GE crops, is required to be labeled, according to Government Decision 256/2006, which has not been altered.

c. Organic labeling

Ordinance 34/2000 provides information on the organic product label specifications. No changes were made in 2017 in regard to labelling. The label attached to organic products should include information regarding the name and the address of the producer/processor, the name of the product and the ecological production method, the name and the mark of the inspecting and certifying institution, the storage conditions, the minimum term of validity, the interdiction to store the ecological products along with conventional products.

Section VI. Other Specific Standards:

a. Food Supplements

In Romania food supplements are regulated by Order 1228/2005 approved by the Ministry of Agriculture and Ministry of Health, which was amended by Order 972/2007. Two entities regulate food supplements: Ministry of Health and Ministry of Agriculture. Their responsibilities are separated based on the composition of the food supplements.

In case of <u>food supplements containing permitted vitamins and minerals only</u>, the provisions of <u>Directive 46/2002</u> and <u>Regulation 1170/2009</u>, transposed through Order 1069/2007 are applicable. According to the above rules, the business operators must submit a notification dossier to the Ministry of Health, both electronically and by mail, along with the product label. The notification procedure is

not fee-based.

In case of <u>food supplements containing permitted vitamins and minerals mixed with other substances</u>, a notification dossier has to be submitted to either the Institute for Food Bio-resources, part of the Ministry of Agriculture, or the National Institute of Public Health, part of the Ministry of Health. The notification dossiers for imported food supplements must be submitted in two copies and include the following documents:

- Notification request
- Registration certificate for the importer
- Self-Declaration (Self-commitment) per the model published on the website
- Certificate of conformity and the country of origin
- Product technical sheet, which should include information regarding the nature of the product, active substances and their effect on the human body, information regarding the toxicity, relevant literature
- Full list of ingredients (quantitative of in percentages)
- Proof of the quality of ingredients, such as Bulletins of analysis for physical-chemical composition and microbiology for each ingredient or excipient
- Bulletins of physical-chemical and microbiology analysis for final product to be placed on the market
- Bulletin of analysis or quality certificate for packaging material
- Product label in Romanian language (details regarding the information to be included on the label are posted on the website)
- Product Prospect (optional, but mandatory in case the prospect is mentioned on the label)
- Sample mandatory (the same form the product will be placed on the market).

Additional information for placing food supplements on the Romanian market is available on <u>http://www.bioresurse.ro/notifications</u> (English language).

b. Alcoholic beverages from fruits

Order 1219/2014 establishes rules on production, labelling and marketing of alcoholic fermented beverages, other than beer and wine. It also sets the process used for flavoring and sweetening of the beverages and the name under which such beverages may be marketed - "fermented alcoholic beverages". When a single fruit was used for fermentation, the label may indicate "fermented alcoholic beverage from" followed by the name of the fruit and fruits, in case more than one fruit was used in fermentation.

The order sets clear provisions regarding the names that should not appear on the label or to be used in advertising or display of the products. Storage location should be separated from the ones where wines or distilled spirits are produced, stored or packaged, unless facilities are used during different timeframes.

c. Organic food

In 2013 the Ministry of Agriculture issued Order 1253 instructing organic products traders to inform the Agricultural Office at county level quarterly or whenever requested to do so, regarding the status of their import/export situation by product, quantity, origin country. The order was amended few times since its publication bringing additional clarification concerning organic operators' registration. The order set a 5-year prohibition new registration requests, in case an inspection and certification body cancelled its previous certification as a result of a major fraud. These provisions have not been amended over the course of 2017.

d. Infant and follow-on formulas

In accordance to the provisions of law 207/2016 it is prohibited that producers or distributors conduct any advertising at any step along the supply chain for a comprehensive list of products targeting infants up to two years. The list of products includes: infant formula and follow-on formula (for babies up to 2 years), any liquid food or solid food for babies up to six months. No special offers, lottery, prizes or discounts, sample distributions. The law was scheduled to be enforced in May 2017, but the concerns raised by these provisions at the EU member states level determined the Romanian Government to approve the Emergency ordinance 35/2017 which delays the implementation of this law with three years.

e. Frozen food

In 2016 the Consumer Protection Authority published Order 183/2016 concerning the information that has to be provided to consumers by the suppliers of certain foods obtained from frozen foods. The list of products to which this order applies is the following: bread, baked goods and other pastry goods obtained from frozen products. The order applies also to hotels, restaurants and institutions which use frozen goods in order to prepare the meals. "Frozen food products" concept applies to the following categories: bread and baked goods, pastry products, meat/products of animal origin, vegetables, fruits.

All suppliers of products listed above as well as the foodservice companies have to mandatorily inform consumers by placing the information in a visible way, readable, easy to understand on the package label or in the restaurant menu the wording *"defrosted product or from defrosted product"*.

f. Samples

Implementation of legislation governing sample imports varies by product. In case of some food

products the Romanian importer has to provide the Food Safety Border inspectors at the entry point a self-statement assuring that the samples will not be sold and that will be used for marketing purposes in Romania. In other cases, samples are treated as regular commercial shipments subject to import requirements. Therefore it is recommended that U.S. exporters interested in shipping samples to a Romanian partner contact the competent authorities listed below or FAS Bucharest.

Section VII. Other Certification and Testing Requirements

a. Seeds and seedling material

Ministry of Agriculture issued Order 34 concerning quality and phytosanitary control regarding import and export of seeds and seedling material in 2011. In order to enter the Romanian market with seeds/seedling material, the importer must apply for an import approval, after submitting the set of documents listed below to the Ministry of Agriculture:

- Official request per the model published in the above order, submitted with minimum 10 days before goods arrival at the border, in which the importer should specify the purpose of utilization and types of seeds: "seeds from non-genetically modified varieties", "organic seeds", "seeds from genetically modified varieties";

- Authorization for producing, processing or marketing the seeds and seedling material;

- Import contract or a similar document which shows the species, variety, seeds category, total amount, compliance with the EU and OECD rules, multiplication rights, and seeds type;

- Multiplication contract;

- The consent of the author or variety owner, in case the seeds are under the framework of property rights on the Romanian territory;

- Self-declaration regarding the seeds (genetically engineered or non-genetically engineered); and

- Other documents which may be required by the Ministry of Agriculture.

The import approval issued in case the shipment complies with the current legislation is valid six months from the moment of its issuance.

b. Products Derived from Biotechnology

Order 61/2012 ensures full traceability of biotech products as provided in <u>Regulation (EC) No 1830/2003</u>. According to this order, all operators involved in this area along the commercial chain must transmit and retain information about products that contain or are produced from genetically engineered (GE) products at each stage of placing them on the market. The regulation covers all products, including feed, containing of or derived from GE ingredients that received a national authorization. GE animal feed and GE foods are

regulated through Government Decision 256/2006, which transposes Regulation (EC) No 1829/2003.

In 2014 the Ministry of Agriculture published Order 1573/2014 regarding the official control of seeds quality through tests of non-GE varieties for the inadvertent presence of GE varieties, which was enforced starting June 1, 2015. According to the order provisions, seed testing is conducted through methods approved by the Reference EU Laboratory for GE food and feed. The maximum percentage of inadvertent presence of GE seeds in batches of corn intended for cultivation is 0.1 percent, with zero tolerance for other crops, such as soybeans. According to the above order all batches with a higher presence percentage than maximum allowed or containing the presence of GE seeds not authorized for cultivation in any degree or not authorized for any purpose, will not be placed on the market in Romania. Batches refused for planting on the Romanian territory will be either destroyed or their destination will be changed to load the shipment elsewhere.

Section VIII. Import Procedures

As a member of the EU-28, Romania applies the same regime for importing animal and non-animal products originating from third countries as does the European Union. Depending on the type of agricultural or food product subject to import, specific authorities have responsibilities for clearing the shipments, namely National Sanitary Veterinary and Food Safety Authority, MARD, and Ministry of Finance through its Customs Directorate.

Each border inspection point is authorized to perform a certain set of checks depending on the type of commodity, thus U.S. exporters should verify prior to shipping if the border point they intend to use for commodities entrance in Romania is authorized by the competent authority to perform checks on the respective category of products (frozen, live etc.). The same border point should be indicated on the documents accompanying the goods. Please contact the Romanian Customs Authority (contact information below) or FAS Bucharest for a list of designated points for inspection of imported products.

The principles regulating the veterinary controls on animal products entering the European Union from third countries are set up by Order 206/2006 issued by the National Sanitary Veterinary and Food Safety Authority. The order was amended in 2014 by the same authority through Order 166/2014, with the purpose to transpose provisions from various EU directives. Order 145/2007 issued by MARD regulates the import requirements for products of non-animal origin.

According to these orders, the importer has to provide the border entry point through which the goods will pass detailed information about the shipment with 24 hours before arrival. In this regard, the importer will submit the "Document of entry of food products of non-animal origin", part A. Each shipment has to be accompanied by this notification in original. The importer has to submit to the entry point all documents accompanying the shipments in original, such as health certificate, bulletin of analysis, certificate of origin and the document attesting the product quality/product conformity.

Import procedures and types of control for categories of products (beef, poultry, seafood, dairy products, egg products, etc.) may be obtained from the <u>National Sanitary Veterinary and Food Safety</u>

Authority (available only in Romanian language).

The protective measures against the introduction into the European Union of organisms harmful to plants or plant products and against their spread within the EU are provided by the Government Decision 563/2007, which transposed the <u>EU Directive 29/2000</u>. The above decision established the protective measures against the introduction into Romania of organisms harmful to plants or plant products from other member states or third countries and against their spread as well as the phytosanitary -veterinary certificates models.

In regards to Customs duties level, Romania applies the Customs regime adopted at EU level through <u>EU Regulation 952/2013</u> of the EU Parliament. Import duties are determined by the tariff classification of goods and by the customs value. As all the EU Member States apply the same tariff on goods, if one product is cleared in one Member State, it may move freely to another EU member state. The link to the EU tariff database is <u>here</u>.

Appendix I. Government Regulatory Agency Contacts:

Ministry of Agriculture and Rural Development

24, Bd. Carol I, sector 2				
020921 Bucharest, Romania				
Phone: (+40) 21 307 2446/8682/8553	Fax:	(+40) 21 307 8554		
E-mail: comunicare@madr.ro	Website:	http://www.madr.ro		
Agency for Payments and Intervention in Agriculture – in case of imports of products subject of tariff quotas (for instance beef) 17, Bd. Carol I, sector 3 Bucharest, Romania				
Phone: (+40) 21 305 4801	Fax:	(+40) 21 305 4900		
E-mail: secretariat@apia.org.ro	Website:	http://www.apia.org.ro		
Ministry of Health 1-3, Cristian Popisteanu Str., sector 1, 010024 Bucharest, Romania				
Phone: (+40) 21 307 2500/2600	Fax:	(+40) 21 307 2671		
Website: <u>http://www.ms.gov.ro</u>				
National Sanitary-Veterinary and for Food Safety Authority				
P-ta Presei Libere nr. 1 Corp D1 Sector 1				
013701 Bucharest, Romania				
Phone: (+40) 312 4987	Fax:	(+40) 21 312 4967		
E-mail: office@ansvsa.ro	Website:	http://www.ansvsa.ro		

Ministry of Environment, Water and Forestry

12 Libertatii Blvd., Sector 5 Bucharest, Romania Phone: (+40) 21 4089605 E-mail: <u>mmediu@mmediu.ro</u>

Website: http://www.mmediu.ro

National Agency for Environment Protection

 294 Splaiul Independentei, Sector 6, București, 060031

 Phone:
 (+40) 21 207 1101/1102

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 (+40) 21 207 1103

 E-mail:
 office@anpm.ro

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 http://www.anpm.ro/

National Authority for Consumers Protection

Bd. Aviatorilor nr. 72, sector 1 Bucuresti, Romania Phone: +40 21 307 6762 E-mail: cabinet@anpc.ro Web site: www.anpc.ro

The National Customs Authority

Str. Matei Millo nr. 13, Sector 1 Bucuresti, Romania Phone: +40 21 3155858, +40 21 3155859 Fax: +40 21 3138251 Email: <u>relatiipublice@customs.ro</u> Web site: <u>www.customs.ro</u>

Institute of Food Bioresources

6 Dinu Vintila St., Sector 2, Bucharest Phone: (+40) 21 210 9128 Website: <u>http://www.bioresurse.ro</u>

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Central Laboratory for Seeds Quality

10 Aleea Constantin Sandu Aldea St.Sector 1 BucharestPhone: (+40) 21 2240264E-mail: lccsms@b.astral.roFax: (+40) 21 2240291Website: http://www.lccsms.bvl.ro

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