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Romania

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Russ Nicely

Prepared By:

Monica Dobrescu

Report Highlights:

This report provides updated information on the agricultural and food legislation in Romania. The report should be read in conjunction with the comprehensive FAS USEU European Food & Agricultural Import Regulations (FAIRS) Report.

Section I. General Food Laws

Section II. Food Additives Regulations

Section III. Pesticides and Other Contaminants:

Section IV. Labeling Requirements

- A. **Food Labeling**
- B. **Nutritional labeling**
- C. **Biotechnology Labeling**
- D. **Organic Labeling**

Section V. Other Specific Standards

- A. Food Supplements
- B. Alcoholic Beverages from fruits
- C. Organic food

Section VI. Other Certification and Testing Requirements

Section VII. Import Procedures

Appendix I. Government Regulatory Agency Contacts

Section I. General Food Laws:

Romania's food laws and regulations have been harmonized with the European Union (EU) legislation. Romania, as a member of the European Union, follows the EU regulations therefore this report is recommended to be read in conjunction with the Food and Agricultural Import Regulations and Standards (FAIRS) [report](#) produced by the U.S. Mission to the EU in Brussels, Belgium.

Several Romanian governmental entities share the responsibilities related to food and agricultural products, produced locally or imported, as outlined below:

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

Ministry of Environment, Water and Forests - the main body conducting environmental risk assessment (including for genetically engineered products) and monitoring activities that might have adverse effects on human health and the environment.

National Sanitary Veterinary and Food Safety Authority - the main body in charge with sanitary-

veterinary and food-safety activities in Romania. Animal health and safety of foodstuffs of animal and non-animal origin, either produced locally or imported, are the responsibilities of this authority. National Sanitary Veterinary and Food Safety Authority publishes every year the program for surveillance, prevention and control for animal disease transmittal and the program for surveillance and control on food safety.

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

National Authority for Consumers Protection - the Government agency established with the aim of protecting the consumers' rights and interests. The authority applies the legislation related to consumer protection, including food products.

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 Ministry of Agriculture regarding the registration of producers, processors, and importers of organic products (with the subsequent amendments);
- Emergency Ordinance 43/2007 transposing Directive 2001/18 regarding the deliberate release into the environment of genetically-modified organisms;
- Emergency Ordinance 44/2007 transposing Directive 90/219 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 29/2014 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, Government Decision 1308/2012 and Government Decision 1121/2013 approving new biofuel mandates concerning the market conditions for introducing biofuels on the market;
- 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 2015.

Section II. Food Additives Regulations:

Romania follows the EU specific legislation on the additives permitted for use in foodstuffs. Order 438/2002 regarding the food additives to be used in foodstuff for human consumption has been amended several times since its initial publication in order to reflect the EU legal amendments. An updated list of permitted additives, flavorings, processing aids, enzymes provided by the EU regulations may be read [here](#). The website describes the EU legislation which applies to EU member states.

Section III. Pesticides and Other Contaminants:

Romania follows the provisions of the [EU Regulation no. 396/2005](#) on maximum residue levels of pesticides in or on food and feed of plant and animal origin with its subsequent amendments. In Romania there are three competent authorities involved in the program of elaborating and implementing the control of pesticide residues:

- **National Sanitary Veterinary and Food Safety Authority**, which yearly approves the frequency of testing for pesticide residues in food of plant and animal origins. National Institute for Veterinary Public Health is responsible for conducting tests for determining the presence and level of these pesticides in foodstuffs.
- **Ministry of Agriculture and Rural Development**, which yearly approves the national monitoring plan for pesticide residues in fruits, vegetables and grains from domestic production. The plan is implemented by the Laboratory for Pesticides Residues Control in plants and crop material.
- **Ministry of Health**, which is responsible for the control of pesticides residues in food for special purposes, as part of the Program for public health protection by preventing diseases associated with food and nutrition risk factors.

The same three authorities listed above are responsible for approving the testing frequency and the testing methods for contaminants, such as aflatoxin, ochratoxin A, cadmium, lead, 3-MCPD, nitrates etc. Specific laboratories, such as National Institute for Veterinary Public Health, are responsible for conducting tests for determining the presence and level of these contaminants in foodstuffs. The maximum levels are provided in the annex of the [EU Commission Regulation 1881/2006](#) setting up the maximum levels for certain contaminants in foodstuffs. More details about contaminants may be read [here](#).

The tests required by the legislation to be performed on the domestic and imported food products are in general at the expense of the domestic producer/importer, except for animal origin products in case of disease enlisted in the Surveillance and Monitoring Program issued by the Veterinary and Food Safety Authority and which case expenses are covered by the national budget.

Section IV. Labeling Requirements:

The principal law on food labeling remains Government (GOR) 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. In addition, the provisions of the [EU Regulation 1169/2011](#) are applicable in Romania. The regulation entered into force on December 13, 2014, with the exception of the nutrition declaration which will apply from December 13, 2016.

A. Food Labeling

According to the legislation in force product labels must contain the specifications provided by the

legislation 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 to the product;
- The net content (weight/capacity) for prepackaged products;
- The expiration date (best before);
- The 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;
- Information meant to help the lot identification, which has to correspond with the number written in the export documents, with few exceptions;
- The name and address of the producer, if produced in Romania, or importer in case of imported food products;
- Date of manufacturing.

In order to avoid any delays in placing the food products on the Romanian market, U.S. exporters are advised to check in advance about any additional requirements regarding labeling of the goods they intend to export.

B. Nutritional labeling

The new EU regulation on labelling 1169/2011 brings new rules also on nutritional labeling. Please read the updated information on nutritional labeling [here](#).

C. Biotechnology Labeling

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

D. Organic Labeling

Ordinance 34/2000 provides information regarding the content of the organic product label. 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.

In August 2014 Ordinance 34/2000 was amended by Government Ordinance 29/2014 which request all organic operators to observe the provisions of several more recent EU regulations, such as [Regulation 834/2007](#) and [Regulation 889/2008](#) concerning organic production and organic labelling. Order 29/2014 has not been amended since its enactment. Order 317 issued by Ministry of Agriculture in 2006

specifies the types of logos which may be attached to organic food on the product directly, on the label or on the package. The regulation applies to both domestic and imported products.

Section V. Other Specific Standards:

A. Food Supplements

In Romania food supplements may be placed on the market within the rules set by Order 1228/2005 approved by Ministry of Agriculture and Ministry of Health, amended by Order 972/2007. There are two entities regulating food supplements: Ministry of Health and Ministry of Agriculture. Their responsibilities are separated based on the composition of the food supplements.

In case of food supplements containing permitted vitamins and minerals only, the provisions of [EU Directive 46/2002](#) and [EU Regulation 1170/2009](#), transposed through Order 1069/2007 by the Ministry of Health, 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. Information regarding the set of documents and notification procedure is available on the Ministry of Health [website](#).

In case of food supplements containing permitted vitamins and minerals mixed with other substances, 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)
- Proofs 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 [here](#) (English language) and [here](#) (only Romanian language).

B. Alcoholic Beverages from fruits

In 2015 Ministry of Agriculture published Order 1219, repealing Order 426/2014 concerning production, labelling and marketing of alcoholic fermented beverages, other than beer and wine. The new order establishes rules regarding 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 new 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 Romania Order 1253/2013 issued by the Ministry of Agriculture instructs 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 1253/2013 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.

Section VI. Other Certification and Testing Requirements

- **Seeds and seedling material**

Ministry of Agriculture issued Order 34 concerning quality and phyto-sanitary 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 are specified: "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)

- 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.

- **Products Derived from Biotechnology**

Order 61/2012 ensures full traceability of biotech products as provided in [Regulation \(EC\) No 1830/2003](#). 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 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](#).

Order 1348/2005 issued by Ministry of Agriculture concerning the varieties testing and registration, was amended through Order 836/2014 and Order 891/2013 by the enacting authority. According to these amendments, varieties and hybrids, including their parental lines, registered in the National Catalog based on the report issued by a competent authority in another Member State, will be subject to field-testing in Romania for two years (versus one year before).

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 VII. 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 product subject to import, specific authorities have responsibilities for clearing the shipments, namely National Sanitary Veterinary and Food Safety Authority, Ministry of Agriculture 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. List of designated points for inspection of imported products may

be found on the Customs Division website ([Annex](#)).

Order 206/2006 issued by the National Sanitary Veterinary and Food Safety Authority set up the principles which regulate the veterinary controls on animal products entering the European Union from third countries. The order was amended in 2014 by the same authority through Order 166/2014, with the purpose to transpose provisions from various EU directives. The import procedure and type on control for each category of products (beef, poultry, seafood, dairy products, egg products etc.) are described on the website of the National Veterinary Authority, at [Border Control Procedures](#).

The import conditions for products of non-animal origin are regulated by the Order 145/2007 amended by Order 80/2008 and Order 125/2010, both issued by the Ministry of Agriculture and Rural Development and still valid. Further guidance on import procedure is available [here](#).

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. 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. After being amended several times in 2014 Decision 563/2007 was enriched again with provisions regarding the introduction and placing in Romanian or protected territories from Romania of certain organisms harmful to plants or plant products for experimental or scientific purposes. Considering the complexity of this legal area, given by the multitude of restrictions imposed to different geographical areas, U.S. exporters are advised to verify in advance the import requirements for the goods intended to be exported to Romania.

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: <http://www.ms.gov.ro>

National Sanitary-Veterinary and for Food Safety Authority

P-ta Presei Libere nr. 1 Corp D1 Sector 1

013701 Bucharest, Romania
Phone: (+40) 37 415 0200
E-mail: office@ansvsa.ro

Fax: (+40) 21 312 4967
Website: <http://www.ansvsa.ro>

Ministry of Environment, Water and Forestry

12 Libertatii Blvd., Sector 5
Bucharest, Romania

Phone: (+40) 21 4089605
E-mail: mmediu@mmediu.ro

Website: <http://www.mmediu.ro>

National Agency for Environment Protection

294 Splaiul Independentei, Sector 6, București, 060031

Phone: (+40) 21 207 1101/1102
E-mail: office@anpm.ro

Fax: (+40) 21 207 1103
Website: <http://www.anpm.ro>

National Authority for Consumers Protection

72 Aviatorilor Blvd., Sector 1
011865, Bucharest, Romania

Phone: (+40) 307 6784
E-mail: office@anpc.ro

Fax: (+40) 21 314 3462
Website: <http://www.anpc.ro>

National Customs Authority

34-40 Alexandru Ivasiuc St. Bl. 5
Sector 6 Bucharest

Phone: (+40) 21 315 5858/5859
E-mail: relatiipublice@customs.ro

Fax: (+40) 21 313 8251
Website: <http://www.customs.ro>

Institute of Food Bioresources

6 Dinu Vintila St., Sector 2, Bucharest

Phone: (+40) 21 210 9128

Fax: (+40) 21 211 3639
Website: <http://www.bioresurse.ro>

Central Laboratory for Seeds Quality

10 Aleea Constantin Sandu Aldea St.

Sector 1 Bucharest

Phone: (+40) 21 2240264
E-mail: lccsms@b.astral.ro

Fax: (+40) 21 2240291
Website: <http://www.lccsms.bvl.ro>

For further information on this report, please contact the following office in Bucharest:

Foreign Agricultural Service (FAS)

American Embassy Bucharest

4-6 Liviu Librescu Street Sector 1

Bucharest, Romania

Phone: (+40) 21 200 3374

Fax: (+40) 21 200 3442

E-mail: AgBucharest@fas.usda.gov