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Romania

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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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. Food Laws:

Romania's food laws and regulations have been harmonized with the EU legislation. Romania, as a member of the European Union, follows the EU regulations, thus 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. This is available at [here](#).

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

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

Ministry of Environment and Climatic Changes (MECC) - is the main body conducting environmental risk assessment (including for genetically modified organisms) and monitoring activities that might have adverse effects on human health and the environment.

National Sanitary Veterinary and Food Safety Authority (NSVFSA) - is 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. Every year, the National Sanitary Veterinary and Food Safety Authority publishes the program for surveillance, prevention and control for animal disease transmittal and the program for surveillance and control on food safety. The annexes contain examination programs and sample collection procedures from non-animal products specifically for contaminants, pesticides residues, prohibited food additives, radioactive contamination and genetically modified organisms.

Ministry of Health (MoH) - is 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, including only vitamins and minerals.

National Authority for Consumers Protection (NACP) - is the Government agency established with the aim of protecting the consumers' rights and interests. NACP is actively involved in proposing, endorsing and promoting legislation related to consumer protection, including food products.

The major pieces of legislation which govern the production and import of food 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 issued every year by the National Sanitary Veterinary and Food Safety Authority setting the frequency of testing for pesticide residues in non-animal origin products; tests required by the legislation to be performed on the domestic and imported food products regularly are in general at the expense of the producer/importer, except for animal origin products for diseases enlisted in the Surveillance and Monitoring Program approved yearly by the Veterinary and Food Safety Authority and which are covered by the national budget.
- Government Decision 935/2011 on the promotion of the use of biofuels amended by Government decision 918/2012 and Government Decision 1308/2012 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.

Section II. Food Additives Regulations:

Romania follows the EU specific legislation on the additives permitted for use in foodstuffs. The Order 438/2002 regarding the food additives to be used in foodstuff for human consumption has been amended several times since its initial publication, with the most recent alteration made in 2011 through Ministry of Health Order 276/2011. An updated list of permitted additives, flavorings, processing aids, enzymes provided by the EU regulations may be read on the USEU [website](#).

Section III. Pesticides and Other Contaminants:

There are three competent authorities in Romania involved in the program of elaborating and implementing the control of pesticides 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.

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. The maximum levels of pesticides residues in and on fruits, vegetables, grains and other products of non-animal origin are provided by Order 12/2006, issued by Veterinary Authority jointly with Ministry of Agriculture and Ministry of Public Health. The maximum levels for pesticide residues in and on foodstuffs of animal origin are set by the Order 23/2007 issued by the National Sanitary Veterinary and Food Safety Authority and amended by Veterinary Orders 61/2008 and 207/2007.

Concerning the contaminants, The National Sanitary Veterinary and Food Safety Authority establishes the testing frequency for contaminants, such as aflatoxin, ochratoxin A, cadmium, lead, 3-MCPD, nitrates etc. National Institute for Veterinary Public Health is 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](#).

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. The Decision 106/2002 was amended several times since its publication, as Romania has gone through the process of transposing EU Directives.

At EU level, a new regulation on the provision of food information to consumers was approved in 2011, EU Regulation 1169/2011, bringing new rules on labeling of food products. The regulation entered into force starting with December 13, 2014, with the exception of the nutrition declaration which will apply from December 13, 2016.

A. Food Labeling

As a general rule, the info 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. Furthermore, the info on the label cannot attribute effects or features of food which in fact do not exist and cannot suggest the food product has special

characteristics when in fact similar products have the same characteristics.

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 in 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/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;
- 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 in the USEU [website](#).

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 modified organism (GMO) products or containing ingredients which have been genetically modified, remaining valid. Animal feed, if produced from GM crops, is required to be labeled, according to GOR Decision 256/2006, which has not been altered.

D. Organic Labeling

GOR 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 in essence states the need for 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 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, there are two entities regulating food supplements: the Ministry of Health and the Institute for Food Bio-resources, depending on the composition of the food supplements. Food supplements may be placed on the market within the limits set by Order 1228/2005 approved by Ministry of Agriculture and Ministry of Public Health, amended by Order 972/2007.

In case of food supplements containing permitted vitamins and minerals only, per the provisions of [Directive 46/2002](#) and [Regulation 1170/2009](#), the business operators must submit a notification dossier to the Ministry of Health, both electronically and by mail, along with the product label. 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 (or the National Institute of Public Health – part of the Ministry of Agriculture).

In case of imported food supplements, the notification dossier, submitted in two copies, must 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).

All of the above requirements along with more details on the information to be included on the label may be found [here](#).

B. Alcoholic Beverages from fruits

In April 2014, Ministry of Agriculture approved Order 426/2014 concerning production, labelling and marketing of alcoholic fermented beverages, other than beer and wine. The provisions establish rules regarding the process used for flavoring and sweetening of the beverages. The name under which such beverages may be marketing is “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 label must contain the following information:

- Name under which the product is sold; characters will have the same size, font and color;
- The list of ingredients, in a descending order;
- Alcoholic concentration, followed by the sign “%”;
- Date of minimal duration for beverages with less than 10% alcohol; this specification is not needed in case of products with more than 10% alcohol;
- Storage conditions;
- Name of the producer/packer/distributor in the EU;
- Batch and date of packaging;
- List of allergens.

The new order sets clear provisions of 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.

C. 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 business along the commercial chain must transmit and retain information about products that contain or are produced from GMOs at each stage of placing them on the market. The regulation covers all products, including feed, containing of or derived from GMOs that received a national authorization. GM animal feed and GM 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 in 2013. According to Order 891/2013 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, Ministry of Agriculture published Order 1573/2014 regarding the official control of seeds quality through tests of non-genetically modified varieties for contamination with genetically modified organisms, to be enforced starting with June 1, 2015. Seed testing is conducted through methods approved by the Reference EU Laboratory for GE food and feed. The maximum percentage of contamination with GE seeds for batches of corn intended for cultivation is 0.1 percent. All batches with a higher contamination percentage than maximum allowed or contaminated with 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.

D. Organic Food

In June 2012, the partnership agreement signed by the United States with the European Union entered into force. This means that as long as the terms of the equivalence arrangement are met, organic operations certified to the USDA organic or EU organic standards may be labeled and sold as organic in both countries. More details on requirements and documentation can be viewed [here](#).

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 through Order 1438/2013 which brought additional clarification regarding the registration of

organic operator. The order sets 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. Several articles of this order were modified through Order 737/2014 and Order 987/2014 by the Ministry of Agriculture, each of these updating the conditions for organic associations founding.

Section VI. Other Certification and Testing Requirements

Seeds and seedling material

Order 34/2011 published by the Ministry of Agriculture provides rules for quality and phyto-sanitary control regarding import and export of seeds and seedling material. The import approvals issued by the Ministry of Agriculture for Seeds and seedling material are valid six months. In order to receive the import approval, the importer must submit a set of documents:

- Official Request per the model published in the above order, submitted with minimum 10 days before goods arrival at the border, in which 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 specie, 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 modified or non- genetically modified)
- Other documents which may be required by the Ministry of Agriculture.

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. Each border inspection point is authorized to perform a certain set of checks depending on the type of commodity, therefore, US Exporters should verify 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 setting up the principles which regulate the veterinary controls on products entering the European Union from third countries

was amended in 2014 by the Veterinary and Food Safety Authority through Order 166/2014, with the purpose to transpose provisions from various EU directives.

In case of imports of animal origin, the import procedure and type on control for each category of products (beef, poultry, seafood, dairy products, egg products etc.) is described on the website of the National Veterinary Authority, at Border Control Procedures (www.ansvsa.ro). The list of U.S. establishments approved for EU export, can be viewed by accessing the website of [EU Commission/DG Health and Consumers](#).

The import conditions for products of non-animal origin are regulated by the Veterinary 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. According to these orders, the importer must provide the border entry point through which the goods will pass detailed information about the shipment with 24 hours before goods 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. In addition, the importer has to submit the registration document for food safety for activities of food products of non-animal origin storage. Order 80/2008 provides the list of non-animal origin products which are subject to border inspection.

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 [Directive 29/2000](#). The above Government 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 2014, the decision was altered several times in order to accommodate the legislative changes at EU level. Order 234/2014 issued by the Ministry of Agriculture provides the tariff positions for each plant category included in the Government Decision 563/2007, while Government Decision 1030/2014 cancelled few provisions of the original document. Government Decision 810/2014 transposed the provisions of the [EU Directives 78/2014](#) and [Directive 83/2014](#), bringing significant amendments to the original piece of legislation. Romanian Government approved Government Decision 352/2014 for transposing the [EU Directive 19/2014](#) on protective measures amending Government Decision 563/2007. Considering the complexity of this legal act, given by the multitude of restrictions imposed to different geographical areas, US 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 2300/2345/8500 Fax: (+40) 21 307 8685

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 (such as beef meat)

17, Bd. Carol I, sector 3

Bucharest, Romania

Phone: (+40) 21 305 4899 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 Fax: (+40) 21 312 4967

E-mail: office@ansvsa.ro Website: <http://www.ansvsa.ro>

Ministry of Environment and Climate Change

12 Libertatii Blvd., Sector 5

Bucharest, Romania

Phone: (+40) 21 316 0215 Fax: (+40) 21 316 0243

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

Web site: <http://www.anpm.ro/>

National Authority for Consumers Protection

72 Aviatorilor Blvd., Sector 1

011865, Bucharest, Romania

Phone: (+40) 37 213 1942

E-mail: office@anpc.ro

Fax: (+40) 21 314 3461

Web site: <http://www.anpc.ro>

National Customs Authority

13 Matei Millo St.

Sector 1 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>

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