

USDA Foreign Agricultural Service

# GAIN Report

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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 [EU FAIRS report E70048](#).

## **Section I. Food Laws:**

Romanian legislation in the food and agricultural sector, in general, is in line with the EU legislation and applies to both domestic and imported products. Food products of US origin may enter directly into Romania or indirectly, through other Member States. The customs procedure is applied at the first point of entry into the EU-28. The responsibilities related to food and agricultural products are shared among several Governmental entities, listed below:

**Ministry of Agriculture and Rural Development (MARD)** - is responsible with the drafting and implementing the national agricultural policy. MARD ensures the implementation of the EU regulations in the field of agriculture, food-industry, land reclamation, and research. MARD advances draft decisions for Governmental approval and may enact specific orders to be applied in the agri-food sector.

**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.

**Ministry of Health (MoH)** - is responsible for overseeing the production and registration of drugs, food additives, and medical equipment. MoH is responsible for the public health as it relates to food and contaminants.

**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;
- 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;
- 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

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.

## **Section II. Labeling Requirements:**

### **General 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 shall apply from December 13, 2014, with the exception for 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.

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;
- 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 case of ingredients list, fruits, vegetables and mushrooms used in variable proportions or used as a mixture, can be grouped in categories like “fruits”, “vegetables” or “mushrooms” followed by expression “in variable proportions” and then their list. The same provision applies to mixtures of aromatic plants and spices. The ingredients which represent less than two percent in the final product may be listed after all the other ingredients.

In the case of prepackaged frozen products, the labels should mention that “re-freezing after defrosting is prohibited.” The Romanian authorities will not accept any inconsistency between the number of establishment (producer) or the shelf life written in the export documents and the one specified on the labels. All the information written on the certificates and the labels must be comprehensible and clear, with no traces of change. The label information has to be written in such a way that it can be easily understood, clearly marked in a visible spot, readable, and prevent erasure.

In order to avoid any delays in placing the food products on the Romanian market, U.S. exporters are advised to consult with the importer on any additional requirements regarding labeling of the goods they intend to export prior to shipping.

## **B. Nutritional labeling**

Nutritional labeling is voluntary unless when displaying or advertising the product, a nutritional claim is made then nutritional labeling is mandatory. The only nutritional claims which may be made to foods are the ones referring to energy value and nutritional elements allowed by this regulation and their components (proteins, vitamins, minerals etc.). More updated information on nutritional labeling may be read in the [EU FAIRS report EU70048](#).

## **C. Biotechnology Labeling**

Agricultural Ministry Order No. 61/2012 ([Regulation \(EC\) No 1830/2003](#)) providing labeling requirements of food stuff derived from genetically modified organism (GMO) products or containing ingredients which have been genetically modified, remains valid. Romania adopted measures on thresholds for labeling, set at 0.9 percent for an adventitious presence of an authorized GM in food or feed. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable. 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. This should include 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 ordinary products.

Order 317/2006 issued by MARD stating that for organic food labeling and advertisement the emblem “ae” (agricultura ecologica = organic agriculture) should be used is still valid. The emblem belongs to the Ministry of Agriculture and can be applied on the product, on the label or on the package. The regulation refers to both domestic and foreign products. In addition, the EU approved logo may be applied on organic products.

#### **Section IV. Food Additives Regulations:**

The Order 438/2002 issued by the Ministry of Health, still valid, provides a list of additives permitted for use in foodstuffs. The EU regulations providing an updated list of permitted additives may be read in the [EU GAIN report](#).

#### **Section V. Pesticides and Other Contaminants:**

Every year, the National Sanitary Veterinary and Food Safety Authority re-issues 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.

##### **A. Pesticides and Substances Residues**

The National Sanitary Veterinary and Food Safety Authority yearly approve the frequency of testing for pesticide residues in non-animal origin products. National Institute for Veterinary Public Health is responsible for conducting tests for determining the presence and level of these pesticides in foodstuffs.

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. The corresponding legislation at EU level is [Regulation 396/2005](#) on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

##### **B. 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 [Regulation 1881/2006](#).

#### **Section VII. Other Specific Standards:**

##### **A. Food Supplements**

The marketing of Food supplements is regulated by Order 1228/2005 approved by Ministry of Agriculture and Ministry of Public Health, amended by Order 972/2007. US companies interested in placing food supplements in the Romanian market have to notify the specific Romanian authorities about their intention.

In case of food supplements containing permitted vitamins and minerals only per the provisions of [EU Directive 46/2002](#) and [EU Regulation 1170/2009](#), a notification has to be submitted 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 has to be sent to either the Institute for Food Bio-resources or the National Institute of Public Health.

Notification dossier, submitted in two copies, must include the following documents:

- Notification request
- Registration certificate for the importer
- Conformity certificate 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
- Ingredients list (quantity and quality)
- Bulletin of analysis for physical-chemical composition and microbiology issued by an accredited laboratory in the third country
- Bulletin of analysis or quality certificate for packaging
- Product label in Romanian language
- Product Prospect (optional, but mandatory in case the prospect is mentioned on the label)
- Product sample – mandatory (the same form the product will be placed on the market).

The regular timeframe for dossier analysis is 10-30 days, depending on the type of product and assuming the dossier contains all required documents. Food supplements may be placed on the market in any of the forms of tablets covered or uncovered, capsules, jellies, pastes, candies or bars, juices, liquids, powders, or other liquid forms, ampoules of liquids, drop-dispensing bottles, which contain nutritional substances for human diet.

## **B. 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 through Order 981/2013. According to the new provisions, 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).

### **C. Organic Food**

According to the provisions of Order 1253/2013, it is compulsory for the organic products trader to inform the Agricultural Office at county level quarterly or whenever requested to do so, the status of their import/export situation by product, quantity, origin country.

In June 2012, the partnership 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](#)

### **D. Fruit Juices**

The [EU Directive 2012/12](#) amending [Directive 2001/112](#) concerning fruit juices and other similar products for human consumption was transposed in Romania through Order 173/180/2013 with the implementation date October 2013. The order provides a full range of rules regarding the nature, production, ingredients quality, labeling, and packaging of fruit juices.

### **Section IX. 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. U.S. 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).

In case of imports of animal origin, the import procedure and type of 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](http://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  
[http://ec.europa.eu/food/food/biosafety/establishments/third\\_country/index\\_en.htm](http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm)

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 orders are issued by the MARD and are still valid. According to these orders, the importer must to 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.

## **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](mailto: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](mailto: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](mailto:office@ansvsa.ro)

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

### **Ministry of Environment and Forests**

12 Libertatii Blvd., Sector 5

Bucharest, Romania

Phone: (+40) 21 316 0215

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E-mail: [mmediu@mmediu.ro](mailto: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

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**National Authority for Consumers Protection**

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**National Customs Authority**

13 Matei Millo St.

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Fax: (+40) 21 313 8251

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

**Institute of Food Bioresources**

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