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Romania

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:
This report is an update on the regulatory framework that governs imports of agri-food products into Romania.
Section I. Food Laws:

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bucharest, Romania for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT 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.

Several different Government agencies and ministries in Romania have responsibilities related to agri-food production and foodstuff imports. The most relevant legal provisions governing agricultural production, food processing and agri-food products, applicable to both domestic and imported products, are outlined below:

- Government Decision 106/2002 concerning food labeling with subsequent amendments;
- Government Ordinance 34/2000 concerning organic food along with Order 219/2007 issued by Ministry of Agriculture defining the legal framework for producers, processors, and importers of organic products;
- Order 438/2002 issued by the Ministry of Health defining and listing additives permitted for use in foodstuffs
- Order 2/2010 issued by the National Sanitary Veterinary and Food Safety Authority sets the frequency of testing for pesticide residues in non-animal origin products
- Order 387/2002 issued by Ministry of Health approving the enforcement rules on food products with particular nutritional uses
- Government Decision 1844/2005 on the promotion of the use of biofuels
- Ordinance 54/2010 for fighting fiscal evasion, followed by the Enforcement rules provided by Government Decision 768/2010

The main bodies with responsibilities covering agricultural production, food processing as well as food imports are the following:

Ministry of Agriculture and Rural Development (MARD)

The Ministry of Agriculture and Rural Development is the specialized body of the central public administration with governmental jurisdiction. It applies the Government’s strategy in the field of agriculture, food processing, as well as rural development.

Ministry of Environment and Forests (MEF)

Ministry of Environment and Forests 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. Forests Management was this year taken over from the Ministry of Agriculture and Rural Development.

National Sanitary Veterinary and Food Safety Authority (NSVFSA)

This is the main body in charge with sanitary-veterinary and food-safety activities. The Authority performs activities related to animal health and foodstuffs of animal and non-animal origin, as well as food safety.

Ministry of Health (MH)
The Ministry of Public Health 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 food and contaminants.

National Authority for Consumers Protection (NACP)

National Authority for Consumers Protection 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.

Section II. Labeling Requirements:

A. General Requirements

The principal law on food labeling is 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 was going through the process of transposing EU Directives on 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 attributes 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.

Food labeling and production methods must not give foods features of diseases prevention, treatment or cure or make reference to such features, except natural mineral water and any food with special nutrition goals.

According to the latest amendments, the labels must contain the following compulsory specifications in Romanian language:

- the name of the product;
- the 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 also to mixtures of aromatic plants and spices. The ingredients which represent less than 2 percent in the final product may be listed after all the other ingredients.

The above decision provides also a list of products for which ingredients do not need to be listed on the label, such as fresh fruits and vegetables, sparkling mineral water, vinegar, dairy products etc.

Besides these specifications, the labeling of alcoholic beverages requires the alcohol concentration to be displayed, if it is greater than 1.2% in volume. These requirements do not apply to the products classified under the HTS code 2204 (Wines of fresh grapes) and 2205 (Vermouth and other wines) of the import schedule.
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.

Illustration of fruits, vegetables and/or their fractions on labels, packages, catalogues or advertisements is permitted only when those fruits/vegetables or their parts are part of the name of the product and are listed as ingredients and the percentage is specified.

In case of drinks, which contain caffeine from any source, in a higher percentage than 150 mg/l, the label has to specify that the product has a high caffeine level, followed by the caffeine content expressed in mg/100 ml. Any drink based on caffeine or tea bearing the name “caffeine” or “tea” is exempted from this warning.

Supplementary requirements for selected product categories regarding labeling are provided by the above-mentioned decision, such as various dairy products, meat and meat products, coffee, bottled water.

All U.S. exporters are advised to ask the importer about special requirements regarding labeling of goods they intend to export.

B. Nutritional labeling

Government Decision 106/2002 on food labeling was amended in 2009 by Decision 685 bringing additional requirements for nutritional labeling.

Nutritional labeling is voluntary, unless when displaying or advertising the product, a nutritional claim is made and the nutritional labeling is mandatory. The only nutritional claims which can 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.). Starting with October 31, 2012, sale of food products not complying with the provisions of GOR Decision 106/2002/Annex no. 2 referring to nutritional labeling is prohibited.

C. Biotechnology Labeling

The national legislation on requirements for labeling foodstuffs that are based on genetically modified organism (GMO) products or contain ingredients which have been genetically modified was fully brought in line with the current EU requirements (Regulation (EC) No 1830/2003) through GOR Decision No. 173/2006, which remains valid. Romania adopted measures on thresholds for labeling, set at 0.9% 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 in place starting with January 1, 2007.

D. Organic Labeling

Imported products should be labeled as “organic” if they were produced by organic methods confirmed by the certificate of compliance. According to GOR Ordinance 34/2000, the product label must contain: 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 Min. of Agriculture 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. More details on organic food can be found in GAIN Report RO8010.

Section III. Packaging and Container Regulations:
Section IV. Food Additives Regulations:
Order 438/2002 issued by the Ministry of Health defining and listing additives permitted for use in foodstuffs was modified several times in the past two years, reflecting the newly enacted EU legislation in this area, as following:

- Order 192/2009 issued by Ministry of Health transposing Directive 2008/84/CE laying down specific purity criteria on food additives other than colors and sweeteners.

As it can be observed, the Annex providing the list of approved additives in foodstuffs is amended several times a year, according to the EU legislation, thus it is critical that US exporters verify with FAS Bucharest the most updated list of additives or read the specific section in the EU 27 FAIRS Report E57011.

Section V. Pesticides and Other Contaminants:
Order 2/2010 issued by the National Sanitary Veterinary and Food Safety Authority establishes the program for surveillance, prevention and control for animal disease transmission and the program for surveillance and control on food safety for year 2010. 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. The Program is updated every year and it is published in the first month of the year.

A. Pesticides and substances residues

Order 2/2010 issued by the National Sanitary Veterinary and Food Safety Authority sets the frequency of testing for pesticide residues in non-animal origin products for the current year. National Institute for Veterinary Public Health is responsible for conducting tests for determining the presence and level of these pesticides in foodstuffs.


The provisions of Veterinary Order 95/2007 regarding measures for surveillance and control of certain substances and their
residues in live animals and their products, as well as residues of veterinary medicines in products of animal origin remain valid.

B. Contaminants

Order 2/2010 issued by the National Sanitary Veterinary and Food Safety Authority (Annex 2) sets 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. As mentioned above, the program is updated every year.

Section VI. Other Regulations and Requirements:

Romania applies the EU regulations in respect to animal and non-animal products imported from third countries. Detailed information on veterinary requirements for imports of animal origin products, including a list of U.S. establishments approved for EU export, can be viewed by accessing the website http://www.fas.usda.gov/posthome/useu/.

Phytosanitary regulations

New specific marketing and technical rules for cereals seeds production were approved in 2010 by the Ministry of Agriculture through Order 149. The document is transposing Commission Directive 2009/74/CE. Similar marketing and technical rules are provided for fodder plants by Order 155/2010 transposing the provisions of the previously mentioned directive.

Various orders outline specific rules for vegetables propagating and planting material, other than seeds (Order 1269/2005 amended through Order 432/2007, which is still valid), beet seeds (Order 1265/2005 amended through Order 147/2007, which is still valid), oilseeds (Order 1264/2005 amended through Order 150/2007, which is still valid), vegetables (Order 1366/2005 amended through Order 433/2007). All these regulations define types of seeds (basic seeds, certified seeds, commercial seeds etc.), standards and labeling rules for each plant variety.

In 2009, Ministry of Agriculture approved Order 336 amending Order 61/2008, which established the procedures of phytosanitary official control in case of an import from third countries or intra EU movement of plants, vegetal and related products. Prior to import, importers dealing with US products should do the following:

- notify the Phytosanitary Quarantine Inspectorate within the Custom Point through which the goods will pass the border, with 24 hours in advance about the transport, in order to facilitate the customs phytosanitary control;
- pay the phytosanitary fees, as per GOR Decision 563/2007 Annex VIII with subsequent amendments;
- inform the Phytosanitary State Unit within 24 hours when the transport entered European Union through one of the designated entry borders on any member state.

Veterinary regulations

At the end of 2007, Romania harmonized the import requirements with the EU legislation, removing the supplementary tests performed on frozen semen of bovine species upon importation. In the European Union, the import regime for bovine frozen semen originating from third countries is provided by the Council Directive 88/407/EEC laying down animal health requirements governing trade and imports into the Community of semen of domestic animals of bovine species, as amended by Directive 2003/43/EC. These directives were transposed into national legislation through Veterinary Order 45/2008, which is still valid.

Commission Decision 2006/168 regarding the requirements for bovine embryos import from third countries was transposed through Veterinary Order 38/2007. The Order includes the Health Certificate required by the local Veterinary Authority.

Section VII. Other Specific Standards:

A. Novel foods

Please see the specific section in the most recent report on Novel Foods EU 27 FAIRS Report E57011.

B. Dietetic or special use food

Order 387/2002 issued by Ministry of Health approving the enforcement rules on food products with particular nutritional uses has been amended last time in 2007 through Order 972 (transposing Commission Directive 2006/34/CE and 1764 (transposing several EU Directives). The order sets rules for the composition and labeling for infant milk formulae and follow-on formulae for babies, cereals-based baby food including a list of pesticides which cannot be under any circumstances used in production of cereals for baby-food, dietetic food, low-energy food for weight reduction. The Order also lists a series of substances which can be added for specific nutritional purpose into foods with specific food purpose (vitamins, minerals, amino-acids) as well as their maximum inclusion levels.


C. Food Supplements


According to order 972/2007, food supplements can 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.

It is prohibited to introduce on the market food supplements which are not notified to the specific institution, Institute for Food Bio-resources. Notification dossier for domestic or imported products includes the following documents:

- notification request
- registration certificate for the importer
- the product technical sheet, mentioning that the product falls into the category of food supplements, or for imported products the conformity certificate and the country of origin
- ingredients list (quantity and quality)
- bulletin of analysis for physical-chemical composition and microbiology issued by an accredited laboratory in the third country
- product label in Romanian language
- package certificate per the current legislation.

D. Organic Food

Order 219/2007 issued by the Ministry of Agriculture regarding the rules for registering operators in organic agriculture has been amended several times during the past two years. The most recent changes occurred in 2010 with the purpose to modify the registration sheets in order to allow operators to have access to specific aid for improving the quality of organic production, such as Order 252/2010 and Order 214/2010 issued by the Ministry of Agriculture. Order 4/2010 issued by Ministry of Agriculture brings more details about the date of conversion from conventional agriculture to organic agriculture.

According to Order 219/2007 and its amendments, published in addition to Emergency Ordinance 34/2000 on organic products, all operators in this field have to register with the Ministry of Agriculture, through its specialized county departments. The order provides instructions for producers, processors, and importers of organic products and the models of
application forms.

Order no. 51/2010 issued by the Ministry of Agriculture and Food Safety Authority approves the national rules for authorization of imports of organic products from third countries, transposing parts of the Regulation 834/2007 regarding organic production and labeling and its enforcement rules approved through Regulation 1235/2008. According to these provisions, the organic products importers have the following duties:

- have to register each year as operators of organic production with the Ministry of Agriculture
- submit an initial inquiry for introducing on the EU market organic products originating from third countries according to a certain model, along with all the necessary documents as required by the provisions of Directive 834/2007
- keep for at least two years the certificate of inspection/control in original or excerpts
- inform the Ministry of Agriculture regarding the amount of imported organic products.

E. Products derived from Biotechnology

Regulation (EC) No 1830/2003 to ensure full traceability of biotech products was transposed in Romania through the Government Decision 173/2006. According to this decision, 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. Accurate information concerning the presence of GMOs must be kept for at least five years. The regulation covers all products, including food and feed, containing or derived from GMOs that received a national authorization. Regulation (EC) No 1829/2003 regarding GM animal feed and GM foods was transposed through Government Decision 256/2006.

Order 237/2006 issued by Ministry of Agriculture specifies rules for authorization procedure in case of farmers planting biotech crops. The order provides information regarding the co-existence rules that have to be observed by farmers in order to avoid cross-contamination. When delivering the GM products further on the commercial chain, farmers have to clearly specify on the accompanying documents and labels the GM product unique identifier and the fact that the products are genetically modified.

In 2009 the competent authority for environment protection issued Order 1205 for publication of detailed information about the farmers planting biotech crops. The catalog is called “national register regarding the locations used for deliberate release of GMOs into the environment”, with two sections, one for biotech crops intended for testing and one for biotech crops intended for commercial use. The electronic version of the register is available on the website of Ministry of Agriculture.

F. Excisable goods

In June 2010, Romanian Government approved Ordinance 54/2010 for fighting fiscal evasion, followed by the Enforcement rules provided by Government Decision 768/2010, with significant effects on distilled spirits importers.

Prior to this new trade regime, excisable goods were allowed to be placed under a duty-deferment regime for storage in bonded warehouse. Excises were due at the moment of release from the warehouse. Starting with September 1, 2010 authorizations for bonded warehouses for excisable products storage were revoked and existing products were subject to excises, regardless the sales moment. Exclusive storage of alcoholic drinks under duty-deferment regime can now only take place in bonded warehouses owned by the warehouse keepers authorized for production of such products.

In addition, according to the new requirements, in case of products subject to marking for which the exporter accepts to apply the strip stamps (for instance distilled spirits), they shall be sent as acquired by importers to the mail address of the US exporter, who is to apply them on products. In case of products subject to marking for which the exporter does not apply the strip stamps, the strips as acquired by importers shall be applied by them in authorized places, namely customs warehouses, free-trade warehouses and free-trade zones.

Importers have to apply and become “authorized importers” in order to conduct import operations with excisable products. Excises are due the 25-th day of the month following the date upon which the goods were received at the warehouse, regardless the exit moment, with significant financial pressure on the importer.
G. Biofuels

The blending percentages for biofuels set by Government Decision 1844/2005 on the promotion of the use of biofuels were recently increased through Government Decision 829/2010, taking effects starting with October 25, 2010.

Apart from setting new blending percentages for the time-frame 2011-2018, Decision 829/2010 is introducing new requirements for biofuels. According to its provisions, biofuels can be introduced on the market only if they comply with the following conditions:

1. come from raw materials harvested in an EU agricultural area, obtained through technologies which comply with the good agricultural and environment conditions (GAEC)
2. lead to a reduction of minimum 35% of the CO₂ emissions compared to the conventional fuel
3. comply with the technical specifications imposed by the EU regarding the social and environment provisions.

Companies will provide the Ministry of Economy, Trade and Affairs once a year with information certifying biofuels comply with the requirements above. The new decision denies access of US exporters, since neither raw materials (soybeans/soybeans oil), nor biofuels imported from outside EU can be subject to blending with conventional biofuels. According to the new draft Decision prepared by the above-mentioned Ministry, these restrictions will be removed.

Section IX. Import Procedures:

The animal and products list which must undergo examination at the Romanian entry borders is provided by Order 155/2007, which is transposing Commission Decision 2007/275/CE. The border points where import, export and transit of vegetal and related products are permitted are stipulated in Order 33/2010 issued by the Ministry of Agriculture.

Non-animal origin products

The import and export 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.

As per 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 has to send 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, such as health certificates, bulletins of analysis and other documents which prove the goods comply with EU legislation. In addition, the importer has to submit the registration document for food safety for activities of storing food products of non-animal origin. Order 80/2008 provides the list of non-animal origin products which are subject to border inspection.

Specific import requirements for products coming from third countries, reflecting the aflatoxin risk contamination, are established by Order 215/2007 issued by Ministry of Agriculture, transposing Commission Decision 2006/504/CE. Article 8 of the above mentioned order contains the supplementary conditions for imports coming from United States of America. The aflatoxin analysis must be conducted by a USDA certified laboratory or a laboratory which is under certification process in conformity with EN ISO/IEC 17025. The Health Certificate which should accompany the transport is included in the annex of the referred order.

Import of plant protection products from third countries is permitted based on an authorization certificate, as per provisions of the Ordinance 38/2007 approved through Law 22/2008. The authorization certificate is issued by Phyto-Sanitary Local Offices, under the supervision of Ministry of Agriculture, on the importer’s name and attests the authorization to import these products into Romania. The buyer/importer needs to submit a dossier with all the required documentation in order to obtain the authorization, to announce the Phyto-Sanitary Office of any modification that may occur after submitting the documents and to limit the use of the authorization certificate to the purpose it is issued.

Animal origin products
Romania applies the EU requirements and the sanitary veterinary procedures for import, export, and transit of live animals, products and by-products of animal origin.

In 2010, the Sanitary-Veterinary and for Food Safety National Authority published Order 7 which amends several orders governing import of live animals and animal origin products. In case of import of frozen bovine and swine semen, all collection and storage centers from Romania have to be registered with the local veterinary authorities and given a registration number. In the same time, imports are approved only if they originate from a collection/storage center approved in the third country and listed in the EU Official Journal. The competent authority in the third country has to provide guarantees that the collection/storage centers fulfill all the authorization requirements, are officially certified for export to European Union, and they are under the surveillance of a veterinarian and are inspected at least twice a year by an official veterinarian.

Similar provisions exist in case of import of embryos coming from bovines, all embryos collection teams from Romania have to be registered with the local veterinary authorities and given a registration number. In the same time, imports are approved only if they originate from collection team approved in the third country and listed in the EU Official Journal. The competent authority in the third country has to provide guarantees that the embryos collection teams fulfill all requirements for authorization as well as for embryo collection, processing, storage and transport. Those teams have to be officially authorized for export to European Union and are inspected at least twice a year by an official veterinarian.

For further details on health certificates and import requirements you can read [EU 27 FAIRS Report E57011](#).

### Appendix I. Government Regulatory Agency Contacts:

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#### Agency for Payments and Intervention in Agriculture
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