

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 12/27/2012 GAIN Report Number: RO1230

Romania

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

Approved By: Michael Henney, Agricultural Attaché Prepared By: Monica Dobrescu, Agricultural Specialist

Report Highlights:

This report is an update on the regulatory framework that governs imports of agri-food products into Romania. The report should be read in conjunction with the FAIRS report prepared at EU level.

Section I. Food Laws:

Romania has been a member of the European Union since January 2007, but the process of the legislation harmonization started before that moment, thus Romania transposed the EU regulations and directives into national legislation. The responsibilities related to food and agricultural products are shared among several Governmental entities, listed below:

• Ministry of Agriculture and Rural Development (MARD)

The Ministry of Agriculture and Rural Development applies the Government's strategy in the field of agriculture and 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.

• National Sanitary Veterinary and Food Safety Authority (NSVFSA)

This is the main body in charge with sanitary-veterinary and food-safety activities in Romania and it is under Prime-Minister's office coordination. Animal health and safety of foodstuffs of animal and non-animal origin, either produced locally of imported, are the responsibilities of this authority.

• 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.

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 219/2007 issued by Ministry of Agriculture defining the legal framework for 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.

In general, all tests on domestic and imported food are conducted at the expense of the producer/importer, except for diseases which are 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, <u>EU Regulation 1169/2011</u>, 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:

- 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.

Besides these specifications, the labeling of alcoholic beverages requires the alcohol concentration to be displayed, if it is greater than 1.2 percent 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 communicate with the importer regarding any additional requirements regarding labeling of the goods they intend to export.

B. Nutritional labeling

Nutritional labeling is regulated by the Government Decision 106/2002. 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/Nutritional labeling is prohibited.

C. Biotechnology Labeling

EU legislation applies also on labeling of food stuff derived from genetically modified organism (GMO) products or containing ingredients which have been genetically modified, specifically the provisions of <u>Regulation (EC) No 1830/2003</u> transposed in the national legislation through Agricultural Ministry Order No. 61/2012, 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.

Section III. Packaging and Container Regulations:

Please see the specific section on the EU GAIN report.

Section IV. Food Additives Regulations:

The list of additives permitted for use in foodstuffs is provided by Order 438/2002 issued by the Ministry of Health, which was amended few times over years, but the national orders stated in the previous GAIN report remain valid.

In 2011, <u>Commission Regulation 1129/2011</u> amending Annex II to <u>Regulation (EC) No 1333/2008</u> of the European Parliament and of the Council by establishing a Union list of food additives was published. Only additives placed in Annex II of the Regulation 1333/2008 are authorized for use in food products sold on the EU market. <u>Commission Regulation 1129/2011</u> will apply starting with June 2013. The same year, <u>Commission Regulation 1130/2011</u> establishing a second list of food additives and

amending Annex III to Regulation 1333/2008 was published. This list concerns additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. <u>Commission Regulation 1130/2011</u> applies since December 2, 2011 but a transitional period of 24 months applies to preparations not complying with Parts 2, 3 and/or Section A of Part 5 of Annex III and until May 31, 2013 for preparations not complying with Parts 1 and 4 of Annex III.

Section V. Pesticides and Other Contaminants:

Every year, the National Sanitary Veterinary and Food Safety Authority establishes 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. The program for 2013 is expected to be published in January 2013.

A. Pesticides and Substances Residues

The National Sanitary Veterinary and Food Safety Authority approves yearly 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 <u>non-animal origin</u> 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 <u>animal origin</u> 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 <u>Regulation 396/2005</u> 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 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 <u>Regulation 1881/2006</u>.

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 of <u>EU</u> <u>Commission/DG Health and Consumers</u>.

The legislation regulating phytosanitary and the procedures of phytosanitary official control in case of an import from third countries or intra EU movement of plants, vegetal and related products field

remain valid. 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.

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 where the goods will be imported through can be viewed <u>here</u>.

Section VII. Other Specific Standards:

A. Novel Foods

Please see the specific section in the most recent EU FAIRS report.

B. Dietetic or Special Use Food

Please see the specific section in the most recent EU FAIRS report.

C. Food Supplements

Food supplements marketing is regulated by Order 1228/2005 amended by Order 972/2007 (transposing <u>Commission Directive 2006/34/CE</u>) approved by Ministry of Agriculture and Ministry of Public Health. 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

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 <u>here</u>.

E. Products Derived from Biotechnology

<u>Regulation (EC) No 1830/2003</u> to ensure full traceability of biotech products was transposed in Romania through the Government Decision 173/2006, replaced in 2012 by Order 61. 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. The new order brings changes regarding the documents templates: authorization, statutory-declaration, inventory maintenance. <u>Regulation (EC) No 1829/2003</u> regarding GM animal feed and GM foods was transposed through Government Decision 256/2006, which remains valid.

F. Biofuels

In October 2010, Government Decision 829/2010 on the promotion of the use of energy from renewable sources imposed new requirements for biofuels and feedstock intended to be introduced in Romania. According to its provisions, biofuels should have come from raw materials harvested in an EU agricultural area, thus denying the access of feedstock and biofuels from United States on the Romanian market.

In 2011, the Romanian Government approved Decision no. 935 eliminating the import barriers imposed on third-country origin biofuels and feedstock.

Section IX. Import Procedures:

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. The exact 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.

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.

According to these orders, the importer has to provide the border entry point through which the goods will pass detailed information about the shipment with 24 hours before arrival. In this regard, the

importer will submit the "Document of entry of food products of non-animal origin", part A. Each shipment has to be accompanied by this notification in original. The importer has to submit to the entry point all documents accompanying the shipments in original, such as health certificate, bulletin of analysis, certificate of origin and the document attesting the product quality/product conformity. 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 set in the provisions of <u>EU Regulation No. 1152/2009</u> imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins. Imports originating from the United States should be accompanied by the aflatoxin analysis performed by an USDA approved laboratory for aflatoxin analysis.

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; +40 21 307 2345; +40 21 307 8500 Fax: +40 21 307 8685 E-mail: comunicare@madr.ro Web site: <u>http://www.madr.ro</u>

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 Web site: http://www.apia.org.ro

Ministry of Health

1-3, Cristian Popisteanu Str., sector 1, 010024 Bucharest, Romania Phone: +40 21 307 2500; +40 21 307 2600 Fax: +40 21 307 2671 Web site: <u>http://www.ms.ro</u>

National Sanitary-Veterinary and for Food Safety Authority

P-ta Presei Libere nr. 1 Corp D1 Sector 1 013701 Bucharest, Romania Phone: +40 37 415 0200 Fax: +40 21 312 4967 E-mail: office@ansvsa.ro Website: <u>http://www.ansvsa.ro</u>

Ministry of Environment and Forests

12 Libertatii Blvd., Sector 5 Bucharest, Romania Phone: +40 21 316 0215 Fax: +40 21 316 0243 E-mail: mmediu@mmediu.ro Website: <u>http://www.mmediu.ro</u>

National Agency for Environment Protection

294 Splaiul Independentei, Sector 6, București, 060031

 Phone:
 +40 21 2071101; +40 21 2071102

 Fax:
 +40 21 2071103

 E-mail:
 office@anpm.ro

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

National Authority for Consumers Protection

72 Aviatorilor Blvd., Sector 1 011865, Bucharest, Romania Phone: +40 37 213 1951 Fax: +40 21 314 3461 E-mail: office@anpc.ro Web site: http://www.anpc.ro

National Customs Authority

13 Matei Millo St. Sector 1 Bucharest Phone: +40 21 315 5858; +40 21 315 5859 Fax: +40 21 313 8251 E-mail: relatiipublice@customs.ro Web site: 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 Web site: <u>http://www.bioresurse.ro</u>

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

Foreign Agricultural Service (FAS) Bucharest American Embassy, Bucharest, Romania 4-6 Liviu Librescu Street Sector 1, Phone: +40 21 200 3374; +40 21 200 3356 Fax: +40 21 316 0690 E-mail: <u>AgBucharest@fas.usda.gov</u>