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## Romania

### Food and Agricultural Import Regulations and Standards - Certification

### FAIRS Export Certificate Report

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**Report Highlights:**

Romania applies the EU regulations on imports of animal and non-animal products from third countries. National legislation is harmonized with the EU one, including the general requirements for all veterinary health certificates; however, there are specific categories of products that have additional national import requirements beside the aligned certificates. This report covers health certificates and legal entry requirements, which are different from [EU-27 Food and Agricultural Import Regulations and Standards report E60015](#). Food supplements, organic products, and wine are subject to special importation condition as stipulated in the national legislation.

## **Section I. List of All Export Certificates Required By Government (Matrix) :**

As a member of the European Union, Romania transposed into the national legislation the entire set of sanitary-veterinary requirements as approved by the European Union.

At present, all export certificates are fully consistent with the ones requested by the EU. Certificates must be drawn up in the official language of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into Romanian language.

Harmonized import requirements refer to introduction into the EU of both animal and non-animal origin products coming from third countries. The import procedure for third-country origin is described in this report.

The conditions and the sanitary veterinary procedure for import, export, and transit of live animals, products and by-products of animal origin are identical to the ones at EU level. All U.S. animal origin products are eligible for export to the EU, however, for certain ones the EU requires establishments to be pre-approved. The pre-approval process involves several U.S. agencies defining the establishments EU eligibility to export to the EU, such as: the Food and Safety Inspection Service (FSIS), the Animal and Plant Health Inspection Service (APHIS), the Agricultural Marketing Service (AMS) and the Food and Drug Administration (FDA). In addition, an EU inspection may be performed to receive the qualification for EU export. A list of EU-approved animal and animal product establishments is available on the EC DG-Health and Consumers website at the following [link](#). U.S. animal by-products exports to the EU must be accompanied by export certificates issued by the Animal and Plant Health Inspection Service (APHIS), prior to the date of export. An overview of the required certificates is available [EU-27 Food and Agricultural Import Regulations and Standards report E60015](#).

National legislation is harmonized with the EU one, including the general requirements for all veterinary health certificates; however, there are specific categories of products that have additional national import requirements beside the aligned certificates, such as alligator meat. The supplementary conditions will follow in Section V of this report. As per the [Directive 2002/99/EC, Annex IV.6](#), the certificates must be issued before the consignment to which it relates leaves the control of the competent authority of the country of dispatch. The National Sanitary-Veterinary and Food Safety Authority (ANSVSA) is the competent authority for providing the specific import conditions on non-harmonized products.

The import requirements for plants and plant products are harmonized at the EU level. The international body regulating the international trade with plant and plants products who lays down the models of certificates is the [International Plant Protection Convention of the Food and Agriculture Organization of the United Nations \(IPPC\)](#). Unlike veterinary products, there is only one model certificate for all plant products in accordance with IPPC's conventions. As per [Council Directive 2000/29/EC](#), amended by [Directive 2010/1/EU](#), in case of importations of plants or plant products from third countries the authorities responsible in such countries for issuing certificates should be, in principle, those empowered under the IPPC. Phyto-sanitary certificates, included in [Council Directive 2000/29/EC, L169/99, Annex VII - A](#), are to be issued by APHIS inspectors, who attest to specific requirements of EU legislation by making additional declarations in the relevant boxes.

## **Section II. Purpose of Specific Export Certificate(s)**

Romania applies the EU requirements and follows all procedures for import, export, and transit of product and by-products of animal and non-animal origin.

Consequently, specific requirements for the importation of products coming from third countries are available in the [Food and Agricultural Import Regulations and Standards - report E60080](#) and [EU-27 Food and Agricultural Import Regulations and Standards – Certification report E60015](#).

These reports published by the U.S. Mission to the EU in Brussels provide an overview of the food laws currently in force in the EU-27.

The National Sanitary-Veterinary and Food Safety Authority (ANSVSA) is the local competent authority formulating and applying the national specific import regulations for products originating from third countries. Contact details are included in the APPENDIX II.

## **Section III. Specific Attestations Required on Export Certificate(s)**

As a member of the EU, Romania shall ensure that products of animal origin intended for human consumption are subjected to veterinary certification where provisions adopted for animal health reasons under [Article 9 of Directive 89/662/EEC](#) require products of animal origin from a Member State to be accompanied by a health certificate, or a derogation has been granted under Article 4(3). Certificates may include details required in accordance with other Community public and animal health legislation.

The U.S. regulatory agencies issuing export certificates usually make mention of any specific requirements in their export libraries and guides. The competent U.S. agencies are mentioned below:

- AMS: Agricultural Marketing Service, USDA
- APHIS: Animal and Plant Health Inspection Service, USDA
- FDA: Food and Drug Administration
- FSIS: Food Safety and Inspection Service, USDA
- GIPSA: Grain Inspection, Packers and Stockyards Administration, USDA
- NOAA: National Oceanic and Atmospheric Administration

Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

## **Section IV. Government Certificate's Legal Entry Requirements**

All related Romanian regulations have been amended to incorporate the corresponding EU provisions.

### **Animal-origin products**

The conditions and the sanitary veterinary procedure for import, export, and transit of live animals, products, and by-products of animal origin are identical to the ones at EU level.

Imports of red meat, meat products, farmed and wild game meat, ratites, milk and milk products,

seafood, bovine embryos and semen, porcine and equine semen, gelatin, animal casings and animal by-products to the EU from the U.S. may only originate from EU approved U.S. establishments. For more information see EC DG-Health and Consumers webpage at:

[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 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/EC](#).

The import of live animals and animal origin products is regulated by Sanitary-Veterinary and for Food Safety National Authority Order 7/2010, which amends several orders governing imports of this commodity.

### **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. The Order 80/2008 provides the list of non-animal origin products which are subject to border inspection.

As per these orders, the importer has to provide the border entry point through the goods will pass the "Document of entry of food products of non-animal origin," part A, containing detailed information about the shipment with 24 hours before arrival. Each shipment has to be accompanied by this notification in original. In general, the importer has to provide to the entry point the documents accompanying the shipments:

- Document of entry of food products of non-animal origin (original document) – as per Annex 2 of Veterinary Order 145/2007;
- Sanitary-Veterinary and Food Safety Registration document – demonstrating the importer's activity in non-animal products importation on Romania's territory;
- Veterinary Inspection payment document – as per the Veterinary Order 1/2006 approving the fees for sanitary-veterinary border inspection services;
- Certificate of origin for the product (original document)
- Health Certificate (original document)
- Product quality/conformity document (original document)
- Analysis bulletin (original document) – proving the product food safety conformity
- Notification certificate – for the food supplements – issued by the Ministry of Human Health or Ministry of Agriculture and Rural development, in accordance with national applicable legislation
- Documents that will insure identity check evaluation and product traceability (information such as: type of product, batch, quantity, packaging size, exporter and importer contact details, etc)

Specific import requirements for products coming from third countries, reflecting the aflatoxin risk contamination, are established by Order 215/2008 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. As per the provisions of [Commission Decision 2008/47/EC](#) the consignment shall

be accompanied by: the results of sampling and analysis performed by a USDA approved laboratory and a health certificate set out in the Annex, completed, signed and verified by an authorized representative of the USDA. Each consignment of foodstuffs shall be identified with a code which corresponds to the code on the report of the results of the sampling and analysis and on the certificate referred to. Each individual bag, or other packaging form, of the consignment shall be identified with the same code.

Import of plant protection products from third countries is permitted based on an authorization certificate, as per 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 is required to submit a dossier with all the required documentation in order to obtain the authorization, to announce the Phyto-sanitary Office on any modification that may occur after submitting the documents and to use the authorization certificate just for its issued purpose.

## **Section V. Other Certification/Accreditation Requirements**

In addition to the health certificates that are mandated by EU legislation and issued by US Government authorities, a number of other certificates are used in international trade. These certificates serve mainly as quality guarantees.

### **Alligator Meat**

According to the Veterinary and Food Safety Authority, import of alligator meat from third countries is subject to requirements provided by [EC Decision 97/78/CEE](#) laying down the principles governing the organization of veterinary checks on products entering the Community from third countries. The products origin must be from establishments authorized to export to the EU by the authority of the third country, complying with [EC Regulations 852/2004](#) and [853/2004](#) laying down specific hygiene rules for food of animal origin.

The alligator meat shipment has to be accompanied by a Health Certificate as shown in Appendix I. This certificate is not new; it is meant to state the current requirements for alligator meat imports, which differ from other EU Member states. In addition, the official veterinarian responsible for the exporting plant has to provide a declaration containing the following statements:

- alligator meat has been examined according to provisions of article 13 of [EC Regulation 2075/2005](#) setting up the specific rules for official control of trichinae in meat;
- alligator meat complies with the requirements laid down in art. 14, paragraphs 1 and 2 of [EC Regulation 2075/2005](#) setting up the specific rules for official control of trichinae in meat.

### **Bovine frozen semen**

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 [Commission Decision 2008/120/CE](#). These directives are transposed into national legislation through of Veterinary Order 45/2008.

In addition to the Health Certificate for import of bovine frozen semen provided U.S. authorities, the National Sanitary-Veterinary and for Food Safety Authority issued sanitary and quality requirements that products have to comply with. This means that upon importation, the importer has to provide

samples that are subject to additional tests for certain diseases, such as Brucellosis, performed by the Animal Health and Diagnosis Institute. Although the importer submits documents issued by the U.S. authorities certifying that the animals are free of these diseases, the Romanian Veterinary Authority requires local testing for Brucellosis. As of September 2012, this requirement applies only to semen originating from new-to-market bulls.

According to the Sanitary Veterinary Norm, the bovine semen should comply with the following sanitary or quality requirements after thawing:

1. As a result of the bacteriological tests done by an authorized veterinary laboratory, the frozen semen in vials should be free from specific pathogen germs: *Brucella* sp., *Listeria monocytogenes*, *Leptospira interrogans*, *Actinomyces pyogenes*, *Campylobacter foetusvenerealis*, *Mycobacterium tuberculosis*, *Staphylococcus aureus*, *Streptococcus* (groups Lancefield A and D), *Escherichia coli*, *Pseudomonas aeruginosa*, *Bacillus* sp., *Corynebacterium* sp., *Salmonella* sp., *Serratia marcescens*, *Nocardia asteroides*, *Chlamydia psittaci*, *Mycoplasma bovis*, *Fusobacterium nucleatum* and other anaerobic germs;
2. As a result of the quantitative bacteriological tests done by an authorized veterinary laboratory, the total number of germs should not exceed  $5 \times 10^3$ /ml;
3. As a result of the virusology, mycology or parasitology tests done by an authorized veterinary laboratory, the frozen semen should be free from the viruses IBR-IPV, BVD-MD, fungus from the genus *Candida* sp., *Aspergillus* sp., *Rhizopus* sp., *Mucor* sp., *Absidia* sp. and the protozoa *Trichomonas bovis*, *Toxoplasma gondii*, *Neospora* sp.
4. After thawing, the bull semen should present:
  - a) minimum 30% mobility (spermatozoa with forward physiological movements);
  - b) a concentration of minimum 7.5 million useful spermatozoa per dose;
  - c) spermatozoa with a normal morphology: over 70% of total spermatozoa number.

Import requirements for bovine embryos are regulated by the Veterinary Order 38/200, which transposes the [Commission Decision 2006/168](#) regarding the import requirements from third countries. The Order includes the Health Certificate required by the Veterinary Authority.

General requirements regarding non-animal food products importation from third countries, other than EU legislation are addressing food supplements, organic products and wines.

### **Food Supplements**

Food supplement products are subject to special importation conditions as stipulated in the national legislation. As per the provisions of Order 1228/244/63/2006 issued by the Ministry of Agriculture and Rural Development regarding the food supplements placement on the market, these products require special food products packaging and Romanian language labeling. The same order is providing guidance on the procedure to obtain a notification certificate necessary at the border control.

### **Organic Products**

Organic product importation into Romania is regulated by Order 56/51/2010 issued by Veterinary Authority and Ministry of Agriculture and Rural Development, as well as by the [Commission](#)

[Regulation 1235/2008/EC](#) laying down detailed rules for implementation of [Council Regulation \(EC\) No 834/2007](#) as regards the arrangements for imports of organic products from third countries.

## **Wine**

In addition to the EU requirements, wine products must observe the provision of national specific legislation: Law 244/2002 (republished) referring to common wine market organization and Government Decision 1134/2002 approving the enforcement rules of previously mentioned law.

More information about the special conditions requirements applied to the non-animal products imports from third countries can be found on the Romanian Sanitary-Veterinary and Food Safety website at: [http://www.ansvsa.ro/documente/admin/1%20Conditii\\_speciale\\_la\\_importul\\_de\\_produce\\_alimentare\\_d\\_e\\_origine\\_nonanimala\\_18271ro.pdf](http://www.ansvsa.ro/documente/admin/1%20Conditii_speciale_la_importul_de_produce_alimentare_d_e_origine_nonanimala_18271ro.pdf)

Certain feed and food of non-animal origin are subject to an increased level of official controls. [Commission Regulation \(EU\) No 212/2010](#) amending [Regulation \(EC\) No 669/2009](#) lays down rules concerning the increased level of official controls to be carried out on imports of specific feed and food of non-animal origin at points of entry into the EU territories. The Annex of the same regulations specifies the frequency of physical and identity checks per specific products.

## **Appendix I. Electronic Copy or Outline of Each Export Certificate Electronic copy of fishery products export certificate**

**CERTIFICAT DE SANATATE  
PENTRU PRODUSELE DIN PESCUIT DIN U.S.A.  
DESTINATE EXPORTULUI IN ROMANIA**

***HEALTH CERTIFICATE  
FOR FISHERY PRODUCTS FROM U.S.A.  
INTENDED FOR EXPORT INTO ROMANIA***

Numar de referinta/Reference No. ....

Tara care expediaza /Country of dispatch: UNITED STATES OF AMERICA  
Autoritatea competenta<sup>(1)</sup> / Competent authority<sup>(1)</sup>: Food and Drug Administration (FDA), or  
National Marine Fisheries Service – National Oceanic & Atmospheric Administration (NMFS-  
NOAA).....

### **I. IDENTIFICAREA PRODUSELOR DIN PESCUIT**

## DETAILS IDENTIFYING THE FISHERY PRODUCTS

Descrierea produselor din pescuit <sup>(1)</sup>/Description of fishery/aquaculture<sup>(1)</sup> products:.....

Specia(iile) (denumirea stiintifica)/ Species (scientific name):.....

Starea sau modul de tratare <sup>(2)</sup>/ Presentation of product and type of treatment <sup>(2)</sup>:.....

Numarul lotului (daca este cazul)/Code number (where available):.....

Tipul de ambalaj / Type of packaging:.....

Numarul ambalajelor/Number of packages: .....

Greutatea neta / Net weight .....

Temperatura ceruta in timpul pastrarii si transportului /

Requisite storage and transport temperature:.....

## II. ORIGINEA PRODUSELOR ORIGIN OF PRODUCTS

Numele si numarul(ele) de aprobare pentru export in U.E. a obiectivului(lor) aprobate sau inregistrate de catre FDA sau NMFS\_NOOA <sup>(1)</sup>  
/ Name(s) and official number(s) of premise(s) approved or registered by FDA NMFS-NOOA <sup>(1)</sup> for export to the  
E.C:.....

## III. DESTINATIA PESTELUI SAU A PRODUSELOR DIN PESCUIT DESTINATION OF FISH OR FISHERY PRODUCTS

Produsele sunt expediate de la/ The products are to be dispatched from:

(locul de expeditie / place of dispatch)

La/ To:.....

(tara si locul de destinatie / country and place of destination)

Cu urmatorul mijloc de transport/ by the following means of transport:.....

Numele si adresa expeditorului / Name and address of dispatcher:.....

Numele si adresa locului de destinatie /Name of consignee and address at place of  
destination:.....

(1) A se taia daca nu este cazul/Delete as appropriate

(2) Vii, refrigerate, inghetate, sarate, afumate, conservate/Live, refrigerated, frozen, salted, smoked, preserved

## IV. ATESTARE DE SANATATE HEALTH ATTESTATION

Subsemnatul, inspector oficial certifica ca produsele din pescuit descrise mai sus /  
The official inspector hereby certifies that the fishery products specified above:

1. Au fost capturate si manipulate la bordul vaselor de pescuit si au fost debarcate si cand este cazul preparate, procesate, congelate, decongelate, impachetate, marcate, depozitate si transportate cu respectarea standardelor de igiena si sanatate publica prevazute in Codul Regulamentului Federal al U.S.A., care au fost recunoscute ca fiind echivalente standardelor Uniunii Europene stabilite in Decizia Comisiei nr. 98/258/CEE/Were caught and handled on board vessels and were landed, handled and where appropriate prepared, processed, frozen, thawed, packaged, marked, stored and transported hygienically and in compliance with the relevant United States public health standards requirements of the Code of Federal Regulation which have been recognized for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC;

2. Au fost supuse controalelor organoleptice, parazitologice, chimice si microbiologice cu rezultate satisfatoare pentru fiecare categorie de produse din pescuit in conformitate cu standardele de igiena si sanatate publica prevazute in Codul Regulamentului Federal al U.S.A., care au fost recunoscute ca fiind echivalente standardelor Uniunii Europene stabilite in Decizia Comisiei nr. 98/258/CEE/Have satisfactorily undergone health controls and organoleptic, parasitological, chemical and microbiological checks laid down for certain categories of fishery in compliance with the relevant United States public health standards requirements of the Code of Federal Regulation which have



been recognized for this purpose as equivalent to the European Community standards as prescribed in Council Decision 98/258/EC;

3. Nu provin de la speciile toxice sau speciile care contin biotoxine/*Do not come from toxic species or species containing biotoxins;*

4. Suplimentar , in cazul molustelor bivalve congelate sau procesate, acestea au fost colectate din zone supuse conditiilor cel putin echivalente celor descrise in Directiva Consiliului 91/492/EEC din 15 iulie 1991 care stabileste conditiile de sanatate pentru producerea si plasarea pe piata a molustelor bivalve vii/*In addition, in the case of frozen or processed bivalve molluscs, the latter have been gathered in production areas subject to conditions at least equivalent to those laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs.*

Intocmit in / *Done at*....., la / *on* .....  
(locul / place) (date / data)



Semnatura si numele cu majuscule ale inspectorului oficial<sup>(1)</sup>/  
*Signature and name in capital letters of official inspector<sup>(1)</sup>*

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(1) Culoarea stampilei si semnaturii trebuie sa fie diferita fata de celelalte inscrieri/The color of the stamp and signature must be different from that of the other particulars in the certificate

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