Report Name: Food and Agricultural Import Regulations and Standards Country Report

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Report Highlights:

As a European Union (EU) member since 2007, Romania observes the EU regulations and directives, which are applied directly or transposed through national-level implementing regulations. This report updates the labeling requirements, trans fats, biotechnology, organic products, and food supplements sections over last year’s Romania FAIRS Annual Country Report. This report should be read in conjunction with the EU FAIRS Report which details specific EU regulations.

DISCLAIMER: This report was prepared by U.S. Embassy Bucharest’s Office of Agricultural Affairs for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, some information may not be completely accurate because policies have changed since its preparation, or because clear and consistent information about these policies was not available. Post strongly recommends 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.
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Executive Summary

As an EU member since 2007, Romania observes EU regulations and directives, which are applied directly or transposed through national-level implementing regulations. This report outlines the major food laws, general and specific labeling requirements, pesticides and contaminants requirements, as well as import procedures that apply to agricultural and food products.

Romania’s total population is about 19.4 million people, about 46 percent of whom live in rural areas. Agriculture plays an integral and unique role in Romania’s economy. Agriculture, forestry, and fishing employ 19 percent of the Romania’s work force, compared to the EU average of 4.1 percent of persons employed by these industries. Agriculture represents about 4.5 percent of Romania’s gross domestic product (2019 data).

In 2019, Romania’s total agricultural imports reached $9.4 billion, a 4.6 percent increase over 2018, 80 percent of which were sourced from other EU Member States (MSs). Germany, Hungary, Poland, and the Netherlands were Romania’s major trading partners in 2019. Major Romanian imports include meat, fruits and nuts, dairy products, bakery products, food preparations, soybean products, vegetables, spirits, cereals, and oilseeds. Major Romanian exports include grains, oilseeds, live animals, poultry and bovine meat, protein meals, food oils, bakery products, meat preparations, water, and wines.

The United States was a top-20 supplier of food and agriculture to Romania in 2019 with $163.2 million in total food and agricultural exports. U.S. food preparations, sunflower seeds, soybean meal, distilled spirits, and nuts were the top categories and accounted for about 65 percent of total trade. U.S. goods flow into Romania either directly from the United States (mainly bulk and intermediate) or are transshipped through the other western EU ports of entry in Italy, the Netherlands, Germany, and the United Kingdom.

Section I. Food Laws

Romania’s food laws and regulations are harmonized with EU legislation. Depending on the issuing and implementing authority, several types of regulations (laws, ordinances, orders, decisions) can govern food production, food imports, and agriculture. Major legislation includes:

- Law 150/2004 regarding of food and animal feed safety;
- Government Decision 106/2002 concerning food labeling with subsequent amendments;
- Government Ordinance 42/2004 regarding the organization of sanitary-veterinary and food safety activity with subsequent amendments;
- Order 111/2008 regarding the procedure for registering the activities of production and sale of food of animal and non-animal origin with subsequent amendments in 2019 (Order 106) and 2020 (Order 115);
- Order 35/2016 regarding the rules on surveillance, prevention, and control of animal diseases, food safety surveillance, and control program with subsequent amendments;
- Emergency Ordinance 43/2007 regarding the deliberate release into the environment of genetically-modified organisms, amended in 2020 through Emergency Ordinance 5;
• Emergency Ordinance 44/2007 referring to contained use of genetically-modified microorganisms;
• Order 438/2002 defining and listing additives permitted for use in foodstuffs, with subsequent amendments;
• Government Ordinance 34/2000 concerning organic food, amended in 2017 through Law 262, along with Order 1253/2013, regarding the registration of producers, processors, and importers of organic products, Law 352/2018 and Government Ordinance 7/2019; and

Several Government of Romania (GOR) entities share regulatory responsibilities vis-à-vis food and agricultural products, produced locally or imported, as outlined below:

**Ministry of Agriculture and Rural Development** (MARD) is responsible for drafting and implementing national agricultural policy. MARD also implements and enforces EU regulations related to agriculture, food processing, land reclamation, and agricultural research.

**Ministry of Environment, Water and Forests** (MOEWF) is in charge of national environmental protection policies, the green economy, biodiversity, waste management, sustainable development and climate change, water and forests. MOEWF is the main environmental and risk assessment regulator, including for genetically engineered (GE) products and for monitoring activities that may affect human health, and the environment.

**National Sanitary Veterinary and Food Safety Authority** (ANSVSA) is the main body charged with sanitary, veterinary, and food-safety activities in Romania. It regulates animal health, and food and feed safety, either produced locally or imported. ANSVSA publishes annual information on the surveillance, prevention, and control of animal diseases and for the surveillance, and control of food safety.

**Ministry of Health** (MOH) is responsible for overseeing the production and registration of drugs, food additives, and medical equipment. MOH also regulates food contaminants and food supplements under its mandate to protect public health.

**National Authority for Consumers Protection** (ANPC) protects consumer rights and interests by drafting and enforcing consumer-protection legislation, including food products. ANPC also regulates food labeling.

**Section II. Labeling Requirements**

**General requirements**

The primary food labeling law remains Government Decision 106/2002, which outlines the food labeling methodology and requirements, accompanied by its implementing regulations. Decision 106/2002 was amended several times since its publication, as Romania has gone through the process of transposing various EU Directives. Generally, food labels cannot mislead consumers regarding product
characteristics, especially regarding its nature, identity, features, composition, amount, durability or its origin, as well as the manufacturing or production methods.

Food labels must contain the following compulsory specifications in the Romanian language:

• Name of the product;
• Ingredients 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;
• Net content (weight/capacity) for prepackaged products;
• Expiration date; in case the expiration date includes the day, the expression “to be consumed, preferably, before…” should be used, while in case only the month or month and year are printed, the expression “to be consumed, preferably, until the end…” should be used
• 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;
• Lot identification, which must correspond with the number written in the export documents, with few exceptions;
• Name and address of the producer/packager/distributor registered in EU; in case of food products imported from third countries, name and address of importer/distributor registered in Romania; and
• Date of manufacturing.

Most Romanian language labels are applied in Romania, but exporters and importers may agree to attach Romanian labels in the country of origin or at the EU port of entry. To avoid delays, U.S. exporters are advised to consult in advance with their Romanian customers about new or additional labeling requirements prior to shipping. Updated information on food labeling regarding allergens, minimum durability, additives and flavorings, may be found in EU FAIRS Report.

Other specific labeling requirements

a. Country of origin labeling (COOL)
In addition to EU-level COOL rules, Romania requires COOL for milk and dairy products. Law 88/2016 concerning mandatory supplemental labeling for fresh milk and dairy products, was later amended under law 192/2017, and implemented in January 2018 (see the Romania Amends COOL on Milk and Dairy for more specific information). COOL rules for meat products approved through Law 150/2016 concerning food products trading were eliminated in 2020 through Law 28.

b. Biotechnology labeling
Biotech labeling is regulated through Order No. 61/2012, which transposed Regulation (EC) No 2003/1830, which provides labeling requirements of GE-derived foods and/or ingredients containing GE. Animal feed, if produced from GE crops, is required to be labeled, according to Government Decision 256/2006. Voluntary labeling is permitted, and some manufacturers choose to apply non-GE labels on their products (e.g. soy-based or dairy products).

c. Organic labeling
Government Ordinance 34/2000 provides specific information on organic labeling. Organic product labels should include the name and address of the producer/processor, name of the product, ecological
production method, name and mark of the inspecting authority and certifying institution, storage conditions, terms of validity, and any product-storage prohibitions along with conventional products.

d. **Frozen food labeling**
Order 183/2016 regulates consumer information for certain foods produced from frozen food products. This order applies to hotels, restaurants, and institutions which use frozen products to prepare meals. Suppliers and foodservice companies which offer bread and baked goods, pastry products, meat and meat products, vegetables, and fruits that were previously frozen must display the wording “defrosted product or from defrosted product” in a visible way, which is readable and easy to understand, either on the package label or on restaurant menus.

e. **Trans fats**
In 2020, the Romanian Parliament approved Law 182/2020 which transposed the EU Regulation 2019/649 amending Annex III to Regulation (EC) No 1925/2006 as regards trans fat, other than trans fat naturally occurring in fat of animal origin. According to the new provisions, food operators must ensure a maximum limit of trans fat in food of 2 grams per 100 grams of fat. ANSVSA, MOH and ANPC share responsibilities on checking compliance. Provisions of Law 182/2020 enter into force on April 1, 2021 and will apply to both domestic and imported foods.

**Section III. Packaging and Container Regulations**

a. **Size and content**
Please consult the EU FAIRS Report.

b. **Packaging waste management**
As part of the EU effort to reduce packaging waste, Romania implemented legislation concerning packaged-waste management in 2005, transposing EU Directive 94/62. Law 249/2015 concerning packaging waste was amended in 2018 through Law 87/2018 and Emergency Ordinance 74/2018 to transpose the EU Directive 2015/720 regarding reducing consumption of lightweight plastic bags. According to its provisions, as of January 1, 2019 Romania prohibited the sale of the lightweight plastic bags (below 50 microns) and very lightweight plastic carrier bags (below 15 microns). Reporting requirements vis-à-vis quantities of recyclable waste were established by Law 211/2011 and amended through Emergency Ordinances 68/2016 and Emergency Ordinance 74/2018. According to these provisions, business operators must recover some packaging materials for recycling. The provisions apply to food operators, producers, importers and traders, and industries dealing with packaged products, such as the canning industry, dairy industry, soft drinks industry, mineral water, wine, etc. regardless the origin, domestic or foreign.

c. **Food waste reduction**
Romania approved Law 217/2016, which obliges companies to donate or sell at reduced prices food products that are close to expiration dates. Law 200/2018 provided additional rules stating that food-sector stakeholders must prevent food waste during production, processing, storage, distribution, and sale. Enforcement rules for the food waste reduction law were set through the Government Decision 51/2019.
Section IV. Food Additive Regulations

Romania follows EU legislation on the additives for food processing. Most recent EU legislation on food additives, applicable in Romania, can be found in the EU FAIRS Report.

Section V. Pesticide and Other Contaminants

Pesticides
European Parliament and Council Regulation 1107/2009 establishes regulations for plant protection products (PPPs). Only PPPs containing approved active substances as established in the Commission implementing Regulation 540/2011 may be authorized for use in the EU. Before any PPP can be commercialized, it must be approved in the relevant MS. Following MS approval, PPP can be mutually recognized and authorized within the EU.

Romania follows EU standards on maximum residue levels (MRLs) established under EU Regulation 2005/396 on food or feed of plant and animal origin, organized by the EU in a database. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients.

In Romania the competent authorities overseeing the National Monitoring Program for pesticide residues are ANSVSA, MARD, and MOH. ANSVSA develops Romania’s pesticide residue program in cooperation with MARD and MOH. The program establishes the number of samples for foods of plant and animal origin imported from MSs and third countries, the sampling locations, and the active substances subject to analysis. While ANSVSA implements the National Program for Surveillance and Control for foods of plant and animal origin, MARD is responsible for the national pesticide residue monitoring plan in fruits, vegetables, and cereals. MOH monitors and controls the pesticide residues from special nutrients foods.

Contaminants
Detailed information regarding food contaminants is included in the EU FAIRS Report.

Section VI. Other Requirements, Regulations, and Registration measures

In Romania, U.S. exporters are not required to register with the Romanian authorities. However, exports of certain U.S.-origin products must originate from EU-approved production facilities, notably products of animal origin including red meat, meat products, farmed and wild game meat, fish and seafood, eggs, milk and milk products, embryos and semen, and animal by-products. See here for specific information.

Seeds and seedling-material imports and exports are regulated by Order 34/2011 amended through order 860/2013 and order 443/2019 on quality and phytosanitary controls. The later amendments clarify definitions of ‘small quantities’ of plants and vegetal products and the flow of documents. In order to enter the Romanian market with seeds/seedling material, the importer must apply for an import approval, after submitting to MARD the set of documents listed below:

- Official request per the model published in order 34/2011, submitted with minimum 10 days before goods arrival at the border, in which the importer should specify the purpose of utilization
and types of seeds: "seeds from non-genetically modified varieties", "organic seeds", "seeds from genetically modified varieties";

- Authorization for producing, processing or marketing the seeds and seedling material;
- Importation contract or a similar document which shows the species, variety, seed category, total amount, compliance with the EU rules, multiplication rights, and seed type;
- Multiplication contract;
- The consent of the author or variety owner, in case the seeds are under the framework of property rights on the Romanian territory;
- Self-declaration regarding the seeds (GE or non-GE); and
- Other documents which may be required by MARD.

Section VII. Other Specific Standards

a. Food supplements
Currently in Romania, food supplements are regulated by Order 1228/2005 amended by Order 972/2007. MOH and MARD are the two Romanian entities regulating food supplements. Their responsibilities are separated based on the composition of the food supplements.

For food supplements containing permitted vitamins and minerals, the provisions of the EU Directive 2002/46 and the EU Regulation 2009/1170, transposed through Order 1069/2007, amended in by Order 2134/2020, are applicable. According to these rules, business operators (producers/importers) must submit a notification dossier to the MOH, both electronically and by mail. The notification procedure is not fee-based.

In case of food supplements containing permitted vitamins and minerals mixed with other substances, a notification dossier must be submitted to either MARD’s Institute for Food Bio-resources or MOH’s National Institute of Public Health (Cluj Napoca, Iasi, Timisoara).

The notification dossiers for imported food supplements must include two copies and should include the following documents:

- Notification request
- Registration certificate for the importer
- Self-declaration (Self-commitment) per the model published on the website
- Certificate of conformity and the country of origin
- Product technical sheet, including information regarding the nature of the product, active substances and their effect on the human body, toxicity, relevant literature
- Full list of ingredients (quantitative or in percentages)
- Proof of the quality of ingredients, such as bulletins of analysis for physical-chemical composition and microbiology for each ingredient or excipient
- Bulletins of physical-chemical and microbiology analysis for final product
- Bulletin of analysis or quality certificate for packaging material
- Product label in Romanian language
- Product Prospect (optional, but mandatory if the prospect is mentioned on the label)
- Sample – mandatory (the same form the product will be placed on the market).
Additional information for placing food supplements on the Romanian market is available on the website of Food Bio-resources Institute (Institutul de Bioresurse Alimentare) (English language) and at MOH (Romanian language).

b. Organic food
At the EU level, Council Regulation (EC) 2007/834 regulates organic production and organic product labeling. In May 2018, the EU approved new rules through Regulation 2018/848.

In Romania, Order 1253/2013 requests organic traders to notify county Agricultural Offices quarterly or whenever requested to do so, regarding import/export date by product, quantity, and country of origin. MARD has since amended the Order several times in an effort to clarify concerns regarding organic operator registration, most recently through Order 241/2020. The Order set a five-year prohibition if an inspection and certification body cancelled its previous certification as a result of a major fraud. Order 98/2019 issued by MADR and ANSVSA clarifies the responsibilities of each entity regarding authorizing organic food imports from third countries, as well as the consignment inspection process at the border. ANSVSA verifies the import documents for imported organic food from third countries.

c. Biocides
As the main authority responsible for biocides1, MOH issued Order 726/2015 concerning measures to conduct official inspection and Government Decision 617/2014 that transposes the EU Regulation 2012/528 regarding the commercialization of biocidal products. The decision provides, among others, information on the approval, renewal and review of approval of active substances, and the national authorization of the biocide products.

Section VIII. Trademarks, Brand Names and Intellectual Property Rights

Rules on the protection of trademarks in the EU are set in EU Directive 2015/2436. Commission Implementing Regulation 2018/626 sets out detailed rules on application procedures. Trademarks can be registered at the national, regional or EU level. In Romania, the office responsible for applications is the OSIM office.

Section IX. Import Procedures

Romania follows the same regime for importing animal and non-animal products originating from third countries as the EU. Depending on the type of imported agricultural or food product, specific authorities have responsibilities for clearing the shipments, namely MARD, ANSVSA, and the MOF’s Customs Directorate. Legislation in this regard has not changed recently.

Each border inspection point (BIP) is authorized to perform a certain set of checks depending on the type of commodity. Prior to shipping, U.S. exporters should verify if the commodities bound for Romania are authorized and/or if competent authorities will inspect the products (frozen, live, plant-based etc.). The same border point should be indicated on the documents accompanying the goods. The list of designated products and points for inspection is here.

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1 Biocidal products are used to control unwanted organisms that are harmful to human or animal health or to the environment, or that cause damage to human activities. Source: https://ec.europa.eu/health/biocides/overview_en

For non-animal products from non-EU countries, provisions of the Regulation (EU) 2017/625 and Regulation (EC) No 2002/178 apply. In case of plant imports, the provisions of the Government Decision 563/2007, most recently amended in 2019, on introducing harmful organisms to plants or plant products and against their spread apply. Apart from setting the import requirements, the decision provides the phytosanitary certificate models.

According to the above-mentioned legislation, the importer has to notify BIP in advance by submitting the Common Veterinary Entry Document (CVED) into the Trade Control and Expert System TRACES or by email, depending on the type of product. The importer must 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. The same rules apply to mail order food shipments.

In case of consignments of animals and goods in transit, transshipment and onward transportation through the EU, Regulation (EU) 2019/2124 provides rules for official controls.

a. Import process
The import process for both animal and non-animal origin products consists of several stages: pre-notification, documentary check, identity check, and physical check. The chart below outlines the steps for each stage. Additional details on the import process are included in the guidelines for third-country imports are available on the ANSVSA website (Romanian) or on the European Commission website (English).
b. Samples
Implementation of legislation governing sample imports varies by product. In case of some food products, local importers must provide the BIP inspectors a self-statement assuring that the samples will not be sold and that will be solely used for marketing purposes in Romania. In other cases, samples are treated as regular commercial shipments subject to import requirements. Therefore, it is recommended that U.S. exporters interested in shipping samples to a Romanian partner to contact FAS Bucharest or the competent authorities listed at the end of the report.

c. Duties, taxes and excises
Romania applies the customs regime adopted by the EU under EU Regulation 2013/952. Import duties are determined by the tariff classification of goods and by the customs value. As all MSs apply the same tariffs, upon being cleared in one MS, the product may move freely to any other MS. For specific rules applied to the products subject to importation, the U.S. exporters are advised to consult the Integrated Tariff of the Community.

Other taxes applicable to agricultural and food products are the value added tax (VAT) and excises. Romania’s VAT rate is 9 percent for food products and agricultural inputs (such as fertilizers and
pesticides), 5 percent for organic food and a standard 19 percent rate for other items. Alcoholic beverages are also subject to excise taxes upon entry. The list of excise levels applicable is published annually by the Ministry of Public Finances.

Section X. Trade Facilitation

a. Electronic Certificates

Please read the EU FAIRS report for detailed information.

b. Import control fees

Romania applies various types fees for the official control of food products, feed ingredients and pet food imports. The types of inspection fees and their level transportation vehicle and per consignments of germinal products, animal-origin products, animal by-products, composite products and non-animal origin products are provided by Order 96/2014 issued by ANSVSA, amended several times, most recently in 2020.

c. Average release time

The average release time for consignments depends on the type of products subject to verification. In general, the analysis of the import dossier and release of goods takes one to several days. Missing documents, incomplete or incorrect certificates may generate supplementary delays.

Appendix I. Government Regulatory Key Agency Contacts

Ministry of Agriculture and Rural Development
Bd. Carol I nr. 2-4, sector 3 Bucuresti, Romania
Phone: +4021 3072446; +4021 3078682
E-mail: comunicare@madr.ro; relatii.publice@madr.ro   Website: http://www.madr.ro/en

Agency for Payments and Intervention in Agriculture – in case of imports subject to tariff quotas (for instance, beef)
Bd. Carol I 17, sector 3 Bucuresti, Romania
Phone: +40 21 305 4802; +40 21 305 4815
E-mail: secretariat@apia.org.ro   Website: http://www.apia.org.ro/

National Agency for Environment Protection (biotech products)
Splaiul Independentei nr. 294, sector 6 Bucuresti, Romania
Phone: +4021 207 1101; 021 207 1102
E-mail: office@anpm.ro   Website: www.anpm.ro

National Sanitary-Veterinary and for Food Safety Authority
Piata Presei Libere nr.1, Corp D1, sector 1 Bucuresti, Romania
Phone: +40 372 184977
E-mail: office@ansvsaro Website: http://www.ansvsaro

Ministry of Environment, Waters and Forestry
Libertatii Blvd. 12, Sector 5 Bucuresti, Romania
Phone: +40 21 4089605
E-mail: mmediu@mmediu.ro Website: http://www.mmediu.ro

Ministry of Health (food supplements)
Str. Cristian Popisteanu nr. 1-3, sector 1, Bucuresti, Romania
Phone: +40 21 3072500, +40 21 3072600
Email: relatii.publice@ms.ro Website: http://www.ms.ro/

National Authority for Consumers Protection
Bd. Aviatorilor nr. 72, sector 1, Bucuresti, Romania
Phone: +40 21 3076793
E-mail: cabinet@anpc.ro Website: http://www.anpc.ro

The National Customs Authority
Str. Alexandru Ivasiuc nr. 34-40, Bl. 5, Sector 6, Bucuresti, Romania
Phone: +40 21 3155858, +40 21 3155859
Email: relatiipublice@customs.ro Website: www.customs.ro

The State Institute for Variety Trials and Registration
Bd. Marasti nr.61, Sector 1, Bucuresti, Romania
Phone: +40 21 3184380
E-mail: office@istis.ro Website: http://www.istis.ro

National Phytosanitary Authority
Bvd. Voluntari nr. 11, Voluntari, Ilfov, Romania
Phone: +40 21 2703254 / +40 21 270 3256
E-mail: anf@anfdf.ro, fitosanitar@anfdf.ro Website: www.anfdf.ro

Patent and Trademark Office - OSIM
Ion Ghica St. 5, Bucuresti, Romania
Phone: +40 21 3060800 / +4021 3060801
E-mail: office@osim.ro Website: www.osim.ro/en

Institute of Food Bioresources (food supplements)
Dinu Vintila St. 6, Sector 2, Bucuresti, Romania
Phone (general): +40 21 2109128
Phone (food supplements notifications): +40 751 022762
https://bioresurse.ro/

Appendix II. Other Import Specialist Technical Contacts

Central Laboratory for Seeds Quality
Sandu Aldea Street 10, Bucuresti, Romania
Phone: +40 21 2228420
Institute for Diagnosis and Animal Health
Str. Dr. Staicovici nr. 63, Sector 5 Bucuresti, Romania
Phone: +40 374 322013 / +40374 322000
E-mail: office@idah.ro Website: http://www.idah.ro/

Ministry of Agriculture and Rural Development (seeds)
General Department for Control and Inspection
B.dul Carol I nr. 24, sector 3 Bucuresti, Romania
Phone: +4021 307 86 63, +4021 307 24 28
http://www.incs.ro/incshome.htm

National Sanitary-Veterinary and for Food Safety Authority
Official testing laboratories List
Piata Presei Libere nr.1, Corp D1, sector 1
Bucuresti, Romania
Phone: +40 372 184977
E-mail: office@ansvsa.ro Website: http://www.ansvsa.ro

Romanian Food-Industry Federation - ROMALIMENTA
Str. Av. Petre Cretu 49, et.1, apt.2, Sector 1 Bucuresti, Romania
Phone: +4 021 3124442
Email: office@romalimenta.ro Website: www.romalimenta.ro

Organic Food Products Association - BIOROMANIA
Bld Octavian Goga, 2, CCIR Business Center, tronson 1, et.7 Sector 3 Bucuresti, Romania
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E-mail: office.bio.romania@gmail.com

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Attachments:
No Attachments