



Questionnaire

Part II

**Information provided by the Government of the Republic of Moldova
to the Questionnaire of the European Commission**

CHAPTER 12:

FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY

May 2022

This chapter reflects the EU's integrated approach aiming to assure a high level of public health, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. In this domain a candidate country is requested to ensure the transposition of the EU *acquis* and its progressive implementation by a properly structured and trained administration.

Implementation requires appropriate administrative structures to be able to carry out inspection and control including appropriate laboratory capacity. Coordination between the different authorities in charge of the transposition and/or implementation is crucial. In addition, training of the various control inspectors, food- and feed business operators is necessary.

I. GENERAL

1. Please describe the structure and organisation of the services in charge of food safety veterinary and phytosanitary policy. The distribution of competencies and the links between central, regional, and local level should appear clearly (degree of decentralisation/devolution of competence should be defined).

According to Government Decision No 695/2017, the body responsible for the development of the food safety, veterinary and phytosanitary policy is the Ministry of Agriculture and Food Industry¹.

The Ministry's mission, among others, is to analyse the situation and problems in the field of food safety veterinary and phytosanitary policy, to develop effective public policies in the above-mentioned field, to monitor the quality of policies and regulations, and to propose justified governmental interventions to provide effective solutions in the relevant fields of competence, ensuring the best ratio between the expected results and costs.

The responsibility for implementation, coordination, and monitoring of the public policies in the field of food safety, veterinary and phytosanitary policy are divided among different institutions subordinated to the Ministry of Agriculture and Food Industry (MAFI) or directly to the Government.

The main institution responsible for the implementation, monitoring, and coordination of policies in the field of food safety and veterinary and phytosanitary policies is the **National Food Safety Agency (ANSA)**. ANSA was created on 16 January 2013 under Law No 113/2012 on the establishment of the principles and requirements of food safety legislation² (partially harmonised with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002) later repealed and replaced by Law No 306/2018 on food safety³ (transposing into the national legislation the provisions of Regulation No 178/2002 of 28 January 2002 of the European Parliament and of the Council of 28 January 2002).

Following the central public administration reform implemented in 2017-2018, Government Decision No 51/2013 on the organisation and functioning of ANSA was also repealed and replaced by Government Decision No 600/2018 as further amended⁴. Under this Government Decision, several institutions invested with functions and tasks in several fields were merged in a single institution (sanitary-

¹ Government Decision No 695/2017 on the organisation and functioning of the Ministry of Agriculture and Food Industry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro

² Law No 113/2012 on the establishment of the principles and requirements of food safety legislation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112774&lang=ro

³ Law No 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

⁴ Government Decision No 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

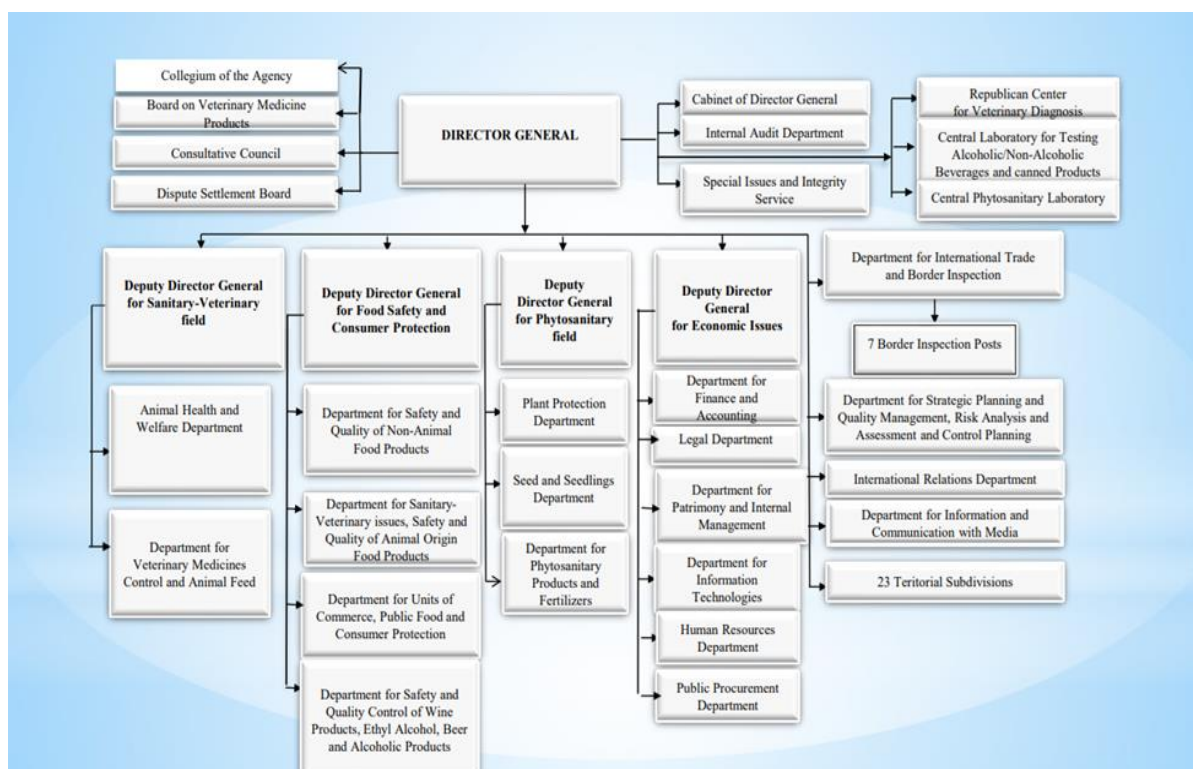
veterinary, livestock, phytosanitary and plant protection, quality, and safety of food products). Additionally, ANSA took over the responsibilities related to consumer protection for the food sector, official control of alcoholic products. Thus, the main areas of responsibility of ANSA are: 1) sanitary-veterinary and animal welfare; 2) phytosanitary and plant protection; 3) food safety and quality; 4) production and circulation of wine and alcoholic products; 5) consumer protection in the food field.

The staffing limit for ANSA is set at 1510 units, of which 181 units for the central office, and 1179 units in 23 territorial subdivisions. ANSA has 7 Border Inspection Posts, with a total staff of 150 inspectors.

Under the provisions of Government Decision No 600/2018, the National Food Safety Agency is a founding organization of 3 National Reference Laboratory's (NRL) in the field of their competence, as follows:

- Republican centre for veterinary diagnosis (CRDV) (National Reference Laboratory (NRL) in the field of food safety and animal health), which includes: laboratories in the food safety area (Centre and North) and laboratories in the animal health area (Centre, North and South).
- Central phytosanitary laboratory (NRL in the plant protection and phytosanitary field);
- Central laboratory for the testing of alcoholic/non-alcoholic beverages and canned products (NRL testing the quality and safety of alcoholic/non-alcoholic beverages).

Figure 1. Organizational Structure of ANSA



Organisational structure and competences at the central level

ANSA is the central public authority subordinate to the Government, responsible for ensuring the implementation of the policy in the sanitary veterinary field and safety of animal origin food products, empowered to organise, supervise, and control compliance with the provisions of the national legal framework, as well as the provisions laid down in the international treaties of its area of competence to which the Republic of Moldova is a party. ANSA is mandated by the Government to ensure implementation of state policies to ensure food safety and quality (including alcohol and alcohol production, wine products and beer), maintain a system of public measures to ensure animal health and plant protection, safety of food products and raw materials, as well as consumer protection in the food area.

The general objective of ANSA is to achieve a high level of food safety throughout the food chain, from the production of raw materials to the distribution of food to the consumer.

The ANSA Central Office consists of the Director-General, 4 Deputy Directors-General, 19 Departments and 3 services (**Figure 1**). In their activity, Director-General is supported by 3 advisory boards in the Agency's areas of competence. Below are presented the leadership and departments of the central level:

- Director-General
- Deputy Directors-General (4 units)

- Director-General's Office
- Dispute Resolution Council
- Internal Audit Department
- Special Issues and Integrity Service
- Animal Health and Welfare Department
- Department of Sanitary-Veterinary Safety and Quality of Food Products of Animal Origin
- Department for Food Safety and Quality of Non-Animal Origin Products
- Department for Commerce, Public Food and Consumer Protection
- Department for Safety and Quality Control of Wine Products, Ethyl Alcohol, Beer, and Alcoholic Products
- Plant Protection Department
- Department for Veterinary Medicinal Products and Feed Control and the Department for Phytosanitary Products and Fertilisers Control
- Seed and Planting Material Department
- Finance and Accounting Department
- Legal Department
- Patrimony and Internal Management Department
- Information Technology Department
- Human Resources Department
- Public Procurement Department
- International Trade and Border Inspection Department
- Border Inspection Posts (having the status of department)
- Strategic Planning and Quality Management, Risk Analysis and Assessment and Control Planning Department
- International Relations Department
- Media Information and Communication Service
- Territorial Subdivisions (having the status of department).

The Director-General, the Deputy Directors-General, and Heads of structural subdivisions of the Agency are responsible for all decisions approved within their fields of activity. A Collegium may be established within the Agency, composed of the Director-General (Chair of the Collegium), the Deputy Directors-General, the Head of the ATU Gagauzia Subdivision, the Heads of the Agency's internal subdivisions, and others. In its activity, the Collegium is governed by the regulations approved by the Director-General. Its numerical and nominal composition is approved by the Director-General but may not exceed 11 persons. At the proposal of Director-General, the Collegium may include representatives of other public authorities, as well as representatives of academia, business, and the civil society within the Agency's competence.

Organisational structure and competences at the territorial level

There are 23 territorial subdivisions for food safety of ANSA (STSA), organized as Departments, having legal personality; treasury accounts, as well as other attributes established in the regulatory framework. The main task of STSA is to carry out official control of food business operators, according to ANSA's approved standard operational procedures and the staffing limit for territorial divisions (with the status of Departments and legal personality).

No	Territorial Subdivision	Additional territorial coverage	Staffing (units) limit
1.	Anenii Noi		37
2.	Edinet	(covers the Briceni district)	71
3.	Cahul		37
4.	Cantemir	(covers the Leova district)	49
5.	Calarasi	(covers the Telenesti district)	57
6.	Causeni	(covers the Ștefan Voda district)	58
7.	Cimislia	(covers the Basarabasca district)	44
8.	Criuleni	(covers the Dubasari district)	46
9.	Drochia		33
10.	Floresti	(covers the Soldanesti district)	61
11.	Falesti	(covers the Glodeni district)	61
12.	Hincesti	(covers the Ialoveni district)	70
13.	Ocnita	(covers the Donduseni district)	54
14.	Orhei	(covers the Rezina district)	67
15.	Riscani		32
16.	Soroca		40
17.	Straseni		28
18.	Singerei		33
19.	Taraclia		27
20.	Ungheni	(covers the Nisporeni district)	62
21.	ATU Gagauzia	(covers the territorial administrative units of Comrat, Ceadir-Lunga and Vulcanesti)	83
22.	Chisinau municipality		84
23.	Balti municipality		45

Sanitary-veterinary territorial structures are set up within the STSAs, which are responsible for the implementation of the Program of Strategic Actions for the Surveillance, Prophylaxis and Control of Animal Diseases, for the Prevention of the Transmission of Diseases from Animals to Humans and for the Protection of the Environment, as well as for ensuring free identification and registration of animals from non-professional undertakings in accordance with the provisions of Law No 231/2006 on the identification and registration of animals⁵. The official controls at slaughterhouses and slaughtering units are carried out by veterinarians designated within STSA, in accordance with Government Decision No 1112/2010⁶

⁵ Law No 231/2006 on the identification and registration of animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107354&lang=ro

⁶ Government Decision No 1112/2010 for the approval of the sanitary-veterinary rules for the organization of official controls of food products of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=32671&lang=ro

on the approval of the sanitary-veterinary rules for the organization of official controls of food products of animal origin.

STSA structure

- Chief/Head of STSA
- Sanitary-Veterinary Surveillance Division
- Sanitary-Veterinary Territorial Districts — amendment approved in 2021, in the process of implementation
- Plants, Seeds, and Propagating Material Protection Control Division
- Food Safety Control Division
- Accounting and Legal Division
- Laboratory Diagnostic Division
- Auxiliary Personnel Division

Border Inspection Posts under the National Food Safety Agency

ANSA's Border Inspection Posts (BIPs) are territorial subdivisions with the management status and no legal personality. There are 7 Border Inspection Posts, which have 150 employees, as presented below:

- Leuseni – Albita Border Inspection Post (including the railway, Ungheni);
- Giurgiulesti Border Inspection Post (including Galati/Port/Reni, Cahul and Calea ferata, Etulia);
- Criva – Mamaliga Border Inspection Post (including Valcinet Railway);
- Tudora – Starokazacie Border Inspection Post;
- Chisinau Border Inspection Post (including the airport, railway and post office, Chisinau);
- Pervomaisk – Cuciurgan Border Inspection Post (including the railway, Cuciurgan);
- Goienii Noi – Platonovo Border Inspection Post.

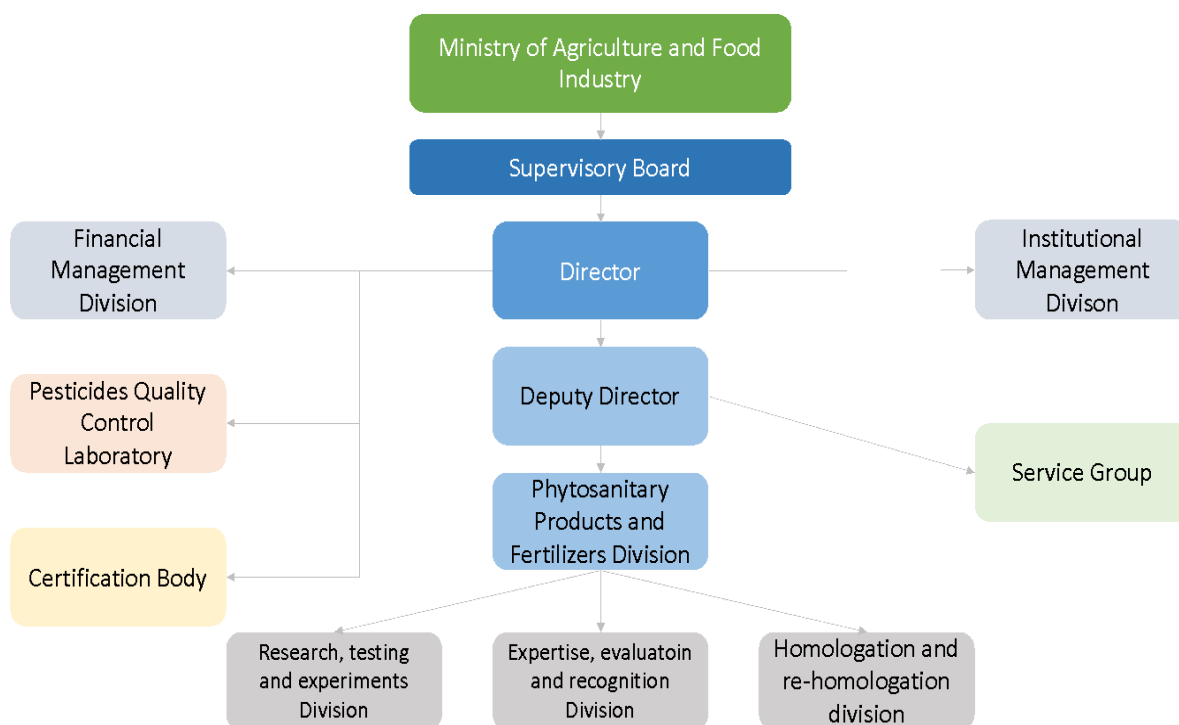
The State Service “State Centre for Attestation and Approval of Phytosanitary Products and Fertilizers” is responsible for coordination and organization of the research-testing-experimentation, approval and registration of plant protection products and fertilizers.

According to Government Decision No 960/2020⁷, the State Service “State Centre for Attestation and Approval of Phytosanitary Products and Fertilizers” has the following duties:

- research-testing-experimentation and homologation of phytosanitary products and fertilizers;
- analysis of the quality of phytosanitary products, of pesticide residues in plants, soil, and food products of vegetal origin;
- certification of the conformity of phytosanitary products and fertilizers;
- services for agriculture;
- services for forestry.

The governing body of the Centre is the Council, and the executive activity of the Centre is led by the director, selected through a competition, organized by the founder.

Figure 1. Organizational Structure of the State Centre for Attestation and Approval of Phytosanitary Products and Fertilizers



⁷ Government Decision No 960/2020 regarding the State Service “State Centre for the Attestation and Approval of Products Phytosanitary and Fertilizer Use” and operation changes in some Government decisions, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=124941&lang=ro

The Centre has the following functions:

- formation of the assortment of phytosanitary products and fertilizers for use in agriculture, forestry and in the municipal household area, as well as for the protection of stored products, in order to ensure a high level of protection of human and animal health, protection of the environment and ensuring competitiveness of the agricultural sector;
- organization, coordination, and control of the research-testing-experimentation activities of phytosanitary products and of the fertilizers at institutions, enterprises, academic and profile organizations, in order to homologate and/or extend their field of application;
- examining the requests of individuals and legal entities from the country and abroad regarding the state research-testing-experimentation of new phytosanitary products and fertilizers;
- performing the primary expertise of the product file presented for state approval / re-approval;
- requesting product samples for state tests and their transmission to institutions, enterprises, and academic and profile organizations for state research-testing-experimentation;
- establishment, in agreement with the Interdepartmental Republican Council for the approval of phytosanitary products and fertilizers, of institutions, enterprises and academic and profile organizations that will carry out the research-testing-experimentation works of phytosanitary products and fertilizers, domestic manufacturing and import;
- organization of state trials of new products manufactured in the country or abroad, within institutions, enterprises, academic and profile organizations (agricultural, public health, forestry, fisheries, environment, municipal household);
- issuance of homologation certificates for products according to the model established by the Government, within 5 working days from the date of fulfilment of the obligations assumed by the homologation applicant;
- 9) coordination of the packaging labels of the phytosanitary products and of the fertilizers in order to bring them into correspondence with the information in the file;
- carrying out laboratory tests on quality control of approved plant protection products;
- determination of pesticide residues in plants, soil, and food of plant origin;
- carrying out certification services for phytosanitary products and fertilizers;
- updating, placing on the official website of the Centre, and publishing the State Register of phytosanitary products and fertilizers allowed for use in the Republic of Moldova.

The Centre establishes, in agreement with the Interdepartmental Republican Council (IRC) for the approval of phytosanitary products and fertilizers, the scientific organizations authorized to carry out state research-testing-experiments, provided from a technical-material point of view, as well as with qualified specialists. profile, if the product is included in the State Research-Testing-Experimentation Program.

IRC consists of 11 members, representatives of the Academy of Sciences of Moldova, the Ministry of Agriculture and Food Industry, the Ministry of Environment, the Ministry of Health, the National Food Safety Agency, research institutions, and higher education institutions.

Additionally, according to Law 306/2018 on food safety, the Ministry of Health is responsible for the legislation on the limits of pesticide residues and contaminants in food having impact on public health.

2. Please describe the legislative competence in the fields of food safety, veterinary and phytosanitary legislation:

a) specification of the competent authorities (for legislation) and how the legislation is passed (primarily through parliamentary procedure or ministerial orders or decrees);

According to the Constitution, the Parliament is the sole legislative authority of the State, whose regulatory areas are not limited to certain categories of social relations. The laws establish the primary rules of conduct. In this respect, it is important to note that Article 14(1) of Law No 235/2006 on the basic principles for regulating entrepreneurial activity⁸ establishes that the material and procedural norms for initiating, conducting and liquidating business, as well as control over the business, are established **by laws**. Therefore, given that the field of food safety, veterinary and phytosanitary is mainly aimed at entrepreneurship, the primary rules in these areas are regulated **by Laws**.

Usually, the new draft laws in the above-mentioned fields are developed by the Ministry of Agriculture and Food Industry, whose competence, according to the Regulation on the organization and functioning of the Ministry of Agriculture and Food Industry, approved by Government Decision No 695/2017⁹, includes the elaboration of public policies and normative acts in the field: food safety; plant protection and phytosanitary quarantine; veterinary medicine.

However, according to Article 25 of Law No 306/2018 on food safety¹⁰, regulation of certain aspects related to food safety has been assigned to the Ministry of Health.

⁸ Law No 235/2006 on the basic principles for regulating entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107358&lang=ro

⁹ Government Decision No 695/2017 on the organisation and functioning of the Ministry of Agriculture and Food Industry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro#

¹⁰ Law No 306/2018 on Food Safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

Thus, this authority has the power of drawing up regulations in the field of food additives, food supplements, novel foods, fortified foods, foods treated with ionizing radiation, foods with added vitamins and minerals, infant formula and follow-on formula, cereal-based preparations and food for young children, foods for special medical purposes, food for weight control diet, natural mineral and potable water and their sources, contact materials, as well as labelling, including nutrition and health claims.

Organization of law enforcement ensured under Government Decisions and, in exceptional cases only, through the Orders of the Ministry of Agriculture and Food Industry.

The legislative process consists of the following stages:

- publication of the announcement regarding the legislative initiative to develop a normative act and the publishing of the research study;
- development of the draft normative act;
- issuance, approval, or adoption of the normative act;
- promulgation, if the normative act as a law;
- publication of the normative act.

At the same time, the process of drafting Government acts is more developed and includes the following stages:

- publication of the announcement regarding the draft legislative initiative and, as the case may be, publication of the research study, in case of draft normative acts, and the elaboration of the initial version of the draft;
- registration and announcement of initiation of the draft's approval;
- approval/expertise of the draft, and public consultation;
- examination of differences and identification of solutions in inter-ministerial meetings of the general secretaries of the ministries and, as the case may be, during the working meeting of the members of the Government;
- finalization and presentation of the draft for examination to the Government;
- preparation of the draft by the State Chancellery for examination in the Government meeting;
- examination and adoption of the act by the Government;
- finalization after adoption, signing, issuance and publication of the Government act.

The announcement regarding the initiation of the elaboration process and the draft normative act is published by the public authority on the official web page and on

particip.gov.md web page. According to Law No 239/2008 on transparency in the decision-making process, the deadline for submitting the recommendations to the draft by interested parties is at least 10 days from the date of its publication¹¹.

As a rule, the text of the draft normative act is drawn up by a single civil servant according to the provisions of Law No 100/2017 on normative acts¹².

Should the draft contain rules governing entrepreneurial activity, the civil servant shall carry out analysis of the impact that is further forwarded for expertise to the Working Group of the State Commission for the Regulation of the Entrepreneurial Activity. Moreover, if the draft normative act aims at harmonizing the legislation, a concordance table is drawn up, and the draft is submitted to compatibility expertise by the Centre for legal approximation within the State Chancellery (Law No 100/2017 on normative acts).

Impact analysis is performed in accordance with the Methodology of impact analysis in the process of substantiating draft normative acts, approved by Government Decision No 23/2019¹³. It should be noted here that draft acts containing rules governing the entrepreneurial activity are not registered by the State Chancellery in case when the initial version of the impact assessment has not been submitted for expertise by the Working Group of the State Commission for the Regulation of Entrepreneurial Activity. The expertise procedure of the impact analysis document is established in the Regulation of the Working Group of the State Commission for the Regulation of Entrepreneurial Activity, approved by Government Decision No 1429/2008¹⁴.

The process of harmonization of the legislation is carried out in accordance with the Regulation on harmonization of the legislation of the Republic of Moldova with the legislation of the European Union, approved by Government Decision No 1171/2018¹⁵. It applies to all draft normative acts which are aimed at approximating the national legislation with the EU legislation (having the EU logo), and establishes the principles, conditions and stages, criteria, methods, and instruments of legislative harmonization (the Explanatory Note and Tables of Concordance), as well as the national-level coordination and monitoring of the harmonization process. This Government Decision provides practical guidance

¹¹ Law No 239/2008 on transparency in decision-making, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106638&lang=ro

¹² Law No 100/2017 regarding the normative acts, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105607&lang=ro

¹³ Government Decision No 23/2019 on the approval of the Impact Assessment Methodology in the process of substantiating draft normative acts, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119960&lang=ro

¹⁴ Government Decision No 1429/2008 on review and optimization of the regulatory framework for entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=115427&lang=ro#

¹⁵ Government Decision No 171/2018 on the approval of the Regulation on harmonisation of the legislation of the Republic of Moldova with the legislation of the European Union, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109962&lang=ro

and explanations for practitioners regarding the approximation process and is directly linked to Law No 100/2017 (Articles 11 and 12).

Upon finalizing the initial version of the draft, its author requests registration of the draft at the State Chancellery. The application for the registration of the draft is examined in the meeting of the General Secretaries of line ministries, where a decision is made whether it is ready for the initiation of the procedure of approval/expertise and public consultation.

The announced drafts are approved by the authorities mentioned in the minutes of the General Secretaries' meeting. The opinion represents an analysis of the text of the draft normative act, carried out by the authorities, others are done by the author of the draft, whereby they state their objections and proposals. The deadline for submitting the opinion is usually 10 days. For large or complex draft documents, the deadline for approval may be extended to 30 days.

Based on the objections and proposals, the author finalizes the draft and prepares a summary of the objections and proposals, that includes the arguments of the draft author on each objection or proposal made. Should there be any objections from the public authorities, the final draft and the summary shall be referred back to them for approval. If, following repeated approval, no objections have been raised, the draft shall be considered approved and submitted to the Government for consideration and adoption. Should the objections be rejected or partially accepted, the draft author shall convene a joint inter-ministerial meeting or organize the procedure of electronic examination of the objections.

Should the interministerial meeting result in a consensus on the objections expressed, the draft is considered approved, otherwise the author either submits the draft for examination at the meeting of the secretaries general of the ministries or withdraws it. The draft, which was accepted at the meeting of the secretaries-general of the ministries, is submitted by the author for examination to the Government.

The draft normative acts adopted by the Government are translated into Russian and published in the Official Gazette (Monitor) of the Republic of Moldova.

Draft laws approved by the Government are registered by the Secretariat of the Parliament and are subject to approval in the Standing Parliamentary Committees and by the Legal Directorate of the Secretariat of the Parliament. For each draft, the President of the Parliament shall appoint a Standing Committee to prepare a report on the draft.

Upon presenting the report of the Standing Committee on the merits, the opinions of the other committees, the results of the public consultations and the opinion of the Legal Department of the Secretariat of the Parliament, the Permanent Bureau decides to place the draft on the agenda of the sitting of Parliament.

Draft laws included in the agenda of the Parliamentary session are usually debated in two readings. Draft ordinary laws, at the decision of Parliament, may be adopted in a single reading. Draft organic laws are adopted only after they have passed the debate in the second reading. Draft constitutional laws, draft organic laws on matters of budget, finance, economics that require considerable financial expenditure, complex bills, as well as bills on important issues, at the decision of the Parliament, may be debated in the third reading.

The adopted laws are sent for promulgation to the President of the Republic of Moldova. The President of the Republic of Moldova may request the Parliament, only once, to re-examine the law for any reason that makes the law as a whole or part of it unacceptable. In case when, upon reviewing the law, the Parliament upholds the previously adopted decision or makes changes to the law in accordance with the objections of the President of the Republic of Moldova, the President is obliged to promulgate the law within 2 weeks from the date of registration of the law in the Presidential Administration.

The promulgated laws are published in the Official Monitor of the Republic of Moldova.

b) explanation of how co-ordination is ensured in terms of alignment, implementation, and policymaking to ensure that the food chain is fully covered

In order to ensure coordination of the process of legislative harmonization in the period of 2007-2016, the Government of the Republic of Moldova approved, by a Government Decision, the annual plans of legislative harmonization, which included the title of the Community act to be transposed into national law, elaboration of the draft and the term for its presentation for adoption by the Government. The annual harmonization plans were drawn up on the proposal of the public authorities to avoid overlapping the transposition of the same Community act by different authorities.

Upon the signature of the Association Agreement between the Republic of Moldova, on the one hand, and the European Union and the European Atomic Energy Community and their Member States, on the other hand, the first National Action Plan for the Implementation of the Association Agreement for 2014-2016 (NAPPIA 2014-2016) was approved by Government Decision No 808/2014¹⁶. Along the same concept lines, for each European legal act, NAPPIA provides for an authority that should be responsible for the drafting of the national normative act to be transposed. This version of NAPIAA totalled 452 pages and included 1778 implementation measures, of which 257 had to be finalized in 2014 according to the established deadlines. Another NAPIAA for the period 2017-2019 was approved by Government Decision No 1472/2016¹⁷ and is totalling 348 pages and

¹⁶ Government Decision No 808/2014, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=88616&lang=ro

¹⁷ Government Decision No 1472/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110448&lang=ro

was later revised in early 2018. The implementing measures were divided into three blocks (Laws transposing the EU legislation; by-laws transposing the EU legislation and the implementing measures) to allow a more systematized and simpler monitoring of the implementation process. The AA implementation deadline for a specific commitment was added to the timeframe column. In an attempt to provide more specific information on the costs and financial sources for the listed implementation measures, the financial coverage column was replaced by an estimated costs and source of expenditure column. After the period of the 2017-2019 NAPIAA ended in 2019, no new plan was adopted, but the outstanding activities from the 2017-2019 NAPIAA were included in the Governmental Action Plans (2019-2020; 2021-2022). That being said, the Governmental Action Plan for 2021-2022, approved by Governmental Decision No 235/2021¹⁸ is currently the only programming document in force establishing the implementation of AA commitments, including the legal approximation obligations. In addition, as soon as the new Association Agenda is approved, Moldova will develop a new overarching planning document covering the entire AA and all the obligations contained therein, as well as the Association Agenda commitments.

At the national level, institution-wise, the following institutions are in charge of coordination of the European integration issues:

- the ***Ministry of Foreign Affairs and European Integration (MFAEI)*** responsible for overseeing and coordinating the planning of European integration as an overall process;
- the ***Ministry of Economy*** responsible for coordinating the transposition and implementation of the EU *acquis* set out in the Deep and Comprehensive Free Trade Area Agreement (DCFTA) which is a part of EU-MD Association Agreement;
- the ***Centre for legal approximation*** within the State Chancellery is in charge of coordinating and monitoring the process of legal approximation to the EU legislation and ensuring the compatibility of the national legislation to the EU legislation and conducts the EU compatibility expertise of national legal acts.
- the ***Governmental Commission for European Integration*** is the main decision-making and monitoring platform, is responsible for coordinating the implementation of commitments deriving from the Moldova-EU documents and agreements. It is composed of all ministries and is headed by the Prime Minister of Moldova;
- the ***Parliamentary Committee for Foreign Affairs and European Integration*** ensures parliamentary control over the Government's foreign and European integration policy.

¹⁸ Government Decision No 235/2021, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128407&lang=ro

In terms of policymaking, each line ministry is responsible for its area of competence.

In this respect, as mentioned above, the Regulation on the organization and functioning of the Ministry of Agriculture and Food Industry, approved by Government Decision No 695/2017, makes provisions for the competence of the Ministry of Agriculture and Food Industry to develop public policies and regulations in the field: food safety; plant protection and phytosanitary quarantine; veterinary medicine.

On the other hand, Article 25 of Law No 306/2018 on food safety has invested the Ministry of Health with the function of developing regulations in the field of food additives, food supplements, novel food, fortified food, food treated with ionizing radiation, food with added vitamins and minerals, infant formula and follow-on formula, cereal-based preparations and food for young children, food intended for special medical purposes, food for the replacement of a total diet for weight control, natural mineral and potable water and their sources, contact materials, and labelling, including nutrition and health claims.

ANSA is the central public authority for food supervision whose general objective resides in the implementation of food safety policy, including feed, at all stages of the food chain, from primary production, processing, storage, transport, marketing until their import and export. Its areas of competence are exhaustively regulated by Article 24 (2) of Law No 306/2018 on food safety.

The control of the implementation of the legislation in the field assigned to the Ministry of Health is performed by the Public Health Agency, and in the case of practices of ionizing radiation treatment of food products and ingredients the supervision is performed by the National Agency for Regulation of Nuclear and Radiological Activities.

c) legal possibility to adopt legislation which will be implemented progressively, and which can incorporate EU notions and cross-reference to other pieces of EU legislation

The process of approximating Moldova's legislation with the specified EU *acquis* is a key instrument for achieving the goals set in the Association Agreement. The legal approximation process in RM is defined through two main normative acts, namely, Law No 100/2017 on normative acts¹⁹ and Government Decision No 1171/2018 on the approval of the Regulation on the harmonization of the

¹⁹ Law No 100/2017 on normative acts, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105607&lang=ro

legislation of the Republic of Moldova with the legislation of the European Union²⁰.

A detailed overview of coordination in terms of aligning the national legislation of the Republic of Moldova with the relevant EU *acquis* is provided in the answers to questions 25 and 46 in Political Criteria.

Regarding cross-references to EU legislation, taking in account the fact that the Republic of Moldova has the status of EU associated country at the moment, the current legislative framework does not allow cross-references to other pieces of the EU legislation. The only reference to an EU legal act is possible through a *harmonization clause*. Article 44 of Law No 100/2017 defines the use and the substance of the harmonization clauses of the normative act. The harmonization clause indicates the type, number and official name of the EU acts that are transposed in the normative act, including the series, number and date of the Official Journal of the EU which published these EU acts, as well as the measure where these are being transposed. This is compulsory for all draft normative acts which aim at transposing the relevant EU legislation into the national legislation of the Republic of Moldova and it is necessary in order to ensure the effective monitoring of the degree of harmonization of the national legislation with the EU law.

3. Please provide information on the control and enforcement activities in the fields of food (and feed) safety, veterinary and phytosanitary policy, including details on the organisation of controls as regards their frequency, the choice of establishments, the procedure of sampling and procedures in case of infringements. Please specify which bodies are in charge of control activities and enforcement and their respective responsibilities. Please describe mechanisms of co-ordination.

ANSA is the only control body in the following areas: sanitary-veterinary, phytosanitary, food safety, and materials that come into contact with foodstuffs, wine production and circulation, and alcohol products, throughout the food chain, consumer protection related to the consumption of food. Also, ANSA is authorized to verify compliance with the licensing conditions according to the related field.

The control activity over the entrepreneurial activity performed by ANSA is regulated by Law No 131/2012²¹, which provides the criteria for drawing up the control plan. In accordance with the provisions of Article 16 of Law No 131/2012, the Control Plan is drawn up by the control bodies based on the risk criteria established according to the particularities of the control object, persons subject to

²⁰ Government Decision No 1171/2018 on the approval of the Regulation on harmonization of the legislation of the Republic of Moldova with European Union law, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=109962&lang=ro

²¹ Law No 131/2012 on state control over entrepreneurial activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro

control and preceding relations with the control body, preceding non-compliance registered.

Development of the Control Plan

Each year, before November 20th, ANSA elaborates, approves and includes in the State Register of Controls (hereinafter RSC) — the electronic system of the State Chancellery — the *Plan of official controls for all areas of competences* for the following year. The frequency of controls is based on risk analysis, in line with the Methodology of state control over entrepreneurial activity based on the risk criteria related to the ANSA's areas of competence, approved by Government Decision No 1280/2018²². Based on the risk criteria approved in the methodology for different domains, different criteria of risk are applied:

1. The risk criteria used in planning the controls of the entrepreneurial activity in the field of food safety and quality are:

- the type of food and raw materials used (R1);
- the process of food processing/handling, which determines the risk of food contamination (R2);
- implementation of the principles of risk analysis and critical control points (HACCP) (R3);
- the number and categories of consumers potentially affected by possible non-compliance with food safety requirements (R4);
- the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of the last control (R5).

2. The planning of the controls of entrepreneurial activity in the sanitary-veterinary and zootechnical area is made on the basis of the risk criteria classified as follows:

- risk criteria for the animal health and welfare sub-domain:
 - compliance with biosecurity requirements (R1);
 - animal health status of the establishment (holding) (R2);
 - history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);
- risk criteria for the feed sub-domain:
 - the field/subdomain of economic activity of the person subject to control in the field of feed (R1);

²² Government Decision No 1280/2018 on the approval of the Methodology on state control over entrepreneurial activity based on the risk analysis related to the areas of competence of the National Food Safety Agency, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=127585&lang=ro

- implementation of the principles of risk analysis and critical control points (HACCP) (R2);
- the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);
- risk criteria for the veterinary pharmaceutical sub-domain:
 - the sub-domain of the veterinary pharmaceutical activity of the establishment (R1);
 - type of veterinary product (R2);
 - the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);

3. The planning of the controls of entrepreneurial activity in the *phytosanitary field and the plant protection* is carried out based on the risk criteria provided for:

- the seed subdomain;
- the subdomain of plant protection and management of plant protection products and fertilizers.

The risk criteria for the *seed subdomain* are:

- the field/domain of economic activity of the FBO subject to control (R1);
- the area of agricultural land used annually, ha (R2);
- estimated production volume for the next year in tonnes (R3);
- the number of cultivated agricultural crops (R4);
- the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R5).

The risk criteria for the sub-domain of plant protection and management of plant protection products and fertilizers are the following:

- for the category of plants and plant products:
 - the field/subdomain of economic activity of the person subject to control (R1);
 - the area of agricultural land used annually, ha (R2);
 - estimated production volume for the next year, kg (R3);
 - number of cultivated agricultural crops (R4);
 - the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of the last control (R5);

- for the category of management of plant protection products and fertilizers:
 - the field/domain of economic activity of the FBO subject to control (R1);
 - volume of managed products in tons (R2);
 - assortment of managed products (trade names) (R3);
 - volume of stored product in tons (R4);
 - the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of the last control (R5).

4. The planning of the control of entrepreneurial activity in the *field of production and circulation of wine and alcoholic products* is made based on the following risk criteria:

- the field/domain of economic activity of the FBO subject to control (R1);
- the production volume and the manufactured assortment, arising from the field of economic activity of the FBO subject to control (R2);
- the period of activity of the person subject to control (R3);
- technical-technological equipment and the existence of quality management systems (R4);
- the time lapsed from the date of the last control (R5);
- the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of the last control (R6).

The classification of FBO subject to control for food safety is based on the sum of the points accumulated for each of the risk criteria.

Based on the sum of the points provided for the respective risk criteria, the maximum score that can be obtained is 25, and the minimum score is 5 points. The classification of the FBO subject to control, according to the accumulated score, and the frequency of controls according to the risk category of the person shall be established according to Table below:

Accumulated score by the FBO subject to control	Risk category of the person subject to control	Frequency of checks
21–25	maximum risk	4 times per year
16–20	increased risk	3 times per year
11–15	medium risk	2 times per year
6–10	low risk	1 time per year

For the sanitary veterinary, phytosanitary, production and circulation of wine and alcoholic products domain/field, the total risk is calculated according to the formula. For every domain of control, every risk criterion has been weighted as follows:

1. For the sanitary veterinary field:

Risk criteria weights for animal health and welfare subdomain:

Risk criteria	Weight (W)
compliance with biosecurity requirements (R1);	0,3
animal health status of the establishment (holding) (R2);	0,4
the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);	0,3
TOTAL:	1,0

Risk criteria weight for the feed sub-domain:

Risk criteria	Weight (W)
the field / subdomain of economic activity of the person subject to control in the field of feed (R1);	0,4
implementation of the principles of risk analysis and critical control points (HACCP) (R2);	0,3
the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);	0,3
TOTAL:	1,0

The weight of the risk criteria for the veterinary pharmaceutical sub-domain:

Risk criteria	Weight (W)
the sub-domain of the veterinary pharmaceutical activity of the establishment (R1);	0,3
type of veterinary product (R2);	0,4
the history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of last control (R3);	0,3
TOTAL:	1,0

The weight of the risk criteria for the field of plant protection and the management of plant protection products and fertilizers is as follows:

Risk criteria	Weight (W)
Plants and plant products:	
field / subdomain of economic activity of the person subject to control (R1);	0,3
area of agricultural land used annually, ha (R2);	0,2
estimated production volume for the next year, kg (R3);	0,1
number of cultivated agricultural crops (R4);	0,2
history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the result of the last control (R5);	0,2
TOTAL	1,0
2. Management of plant protection products and fertilizers:	
field / domain of economic activity of the FBO subject to control (R1);	0,3
volume of managed products in tons (R2);	0,2
assortment of managed products (trade names) (R3);	0,2
volume of stored product in tons (R4);	0,1
history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the result of the last control (R5).	0,2

Risk criteria weight for the seed subdomain:

Risk criteria	Weight (W)
field / domain of economic activity of the FBO subject to control (R1);	0,3
area of agricultural land used annually, ha (R2);	0,2
estimated production volume for the next year in tonnes (R3);	0,1
number of cultivated agricultural crops (R4);	0,2
history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the results of the last control (R5).	0,2
TOTAL:	1,0

Risk criteria weight for production and circulation of the wine and alcoholic products domain

Risk criteria	Weight (W)
field /domain of economic activity of the FBO subject to control (R1);	0,2
production volume and manufactured assortment, arising from the field of economic activity of the FBO subject to control (R2);	0,1
period of activity of the person subject to control (R3);	0,1
technical-technological equipment and existence of quality management systems (R4);	0,2
period from the date of the last control (R5);	0,1
history of compliance with the legislative provisions, as well as with the prescriptions of the Agency, according to the result of the last control (R6).	0,3
TOTAL	1,0

The weighted average of the degrees of risk in the domain of activity subjected to control is calculated separately for each FBO, based on the following formula:

$$R_g = (w_1 R_1 + w_2 R_2 + \dots + w_n R_n) \times 200$$

or

$$R_g = \left(\sum_{i=1}^n w_i R_i \right) \times 200$$

where:

R_g – the degree of global risk associated with the potential subject of control;

1, 2, n – risk criteria;

w – weight of each risk criterion, where the sum of the individual weights will be equal to one (1);

R – degree of risk for each criteria.

As a result of applying this formula, the overall risk is between 200 and 1000 units, and the FBO that has accumulated 200 units is associated with the lowest degree of risk. Depending on the score obtained on the application of the formula, the subjects of control are listed, at the top of the ranking being placed the persons

subject to control who have accumulated the maximum score (1000 units). People at the top of the rankings are associated with a high degree of risk and are to be controlled as a matter of priority.

The same control body is **not entitled to carry out the planned control more than once in a calendar year** at one and the same FBO or at the same object of control if the person has several separate objects, headquarters placed separately and other objects, **unless a higher frequency of controls is required according to the control planning methodology** based on the risk criteria applied to the control area concerned.

Based on the ranking, the ANSA draws up the draft annual plan of controls and registers them in the State Register of controls, in the manner and term established in the Regulation on keeping the State Register of controls, approved by Government Decision No 464/2018²³. When drafting the plan, ANSA takes into account the available human and technological resources.

Control Plan drafting and approval

Annually, by the 20th of November, ANSA prepares the Control Plan including the list of FBOs to be verified based on the risk criteria. The plan is officially made public and the FBOs can find it on ANSA web page²⁴.

After the plan is approved in the system, according to the provisions of Law No 131/2012 the integrated control plan is coordinated (controls made by the different control authority in the same period).

In 2021, ANSA has approved the General Procedure for preparing and performance of the control made by ANSA²⁵.

STSAs draft plans for their respective areas of administrative coverage based on the total risk calculated at the last control of the FBOs and coordinate it with the profile department. The Department for strategic planning and quality management, risk analysis and assessment and control planning at the ANSA's central level is responsible for merging the plan and including it in the RSC

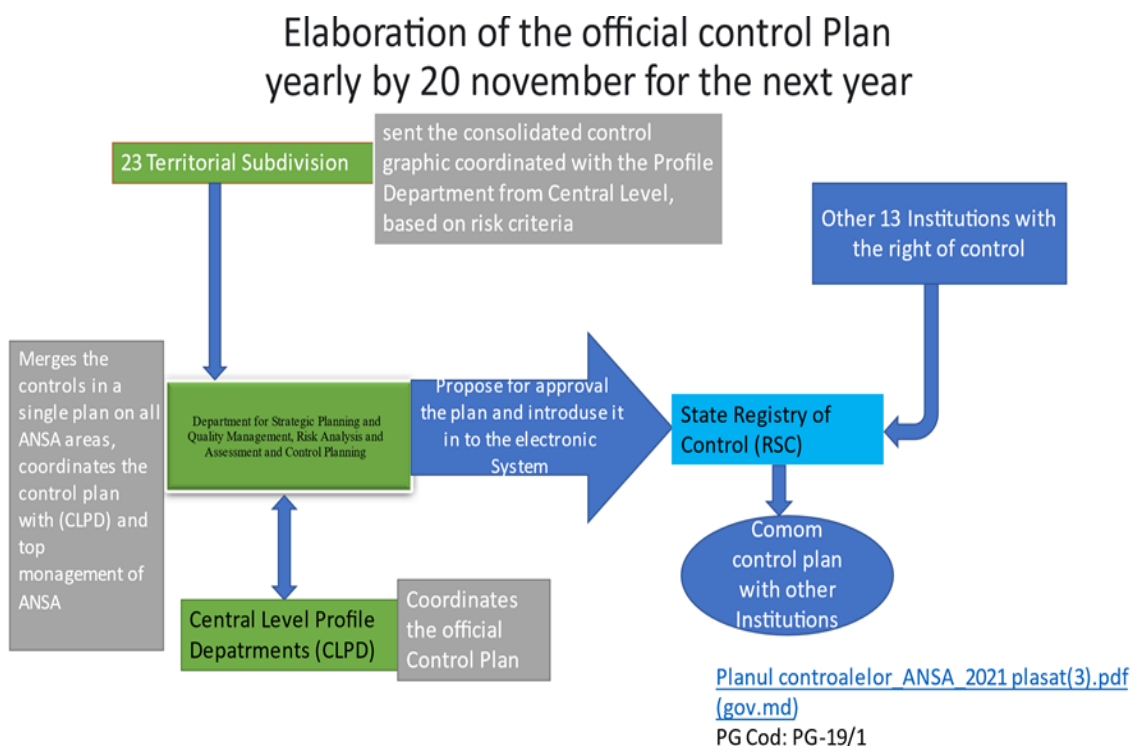
²³ Government Decision No 464/2018 on the approval of the Regulation on keeping the State Register of Controls, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=101732&lang=ro

²⁴ ANSA Order No 435/2021 Regarding the approval of the Annual State Controls Plan for 2022, available in Romanian at: https://www.ansa.gov.md/uploads/files/Ordinele%20ANSA/2021/Ordinul%20435%20din%2019_11_2021%20integral.pdf

²⁵ ANSA Order No 122/2022 on the approval of the "General procedure for the preparation and performance of controls on the area of competence of ANSA", available in Romanian at: www.ansa.gov.md/uploads/files/CONTROALEoficiale/2022/PG-19_02%20Pregatirea%20si%20efectuarea%20controlului%20pe%20domeniile%20de%20competență%20ANSA%20%2C%20Ordin%20N%20122.pdf

electronic system, as well as coordinating it with profile departments and proposing for approval to Director-General.

Below is the Control Plan drafting and approval diagram:



Implementation/monitoring/supervision of the control Plan

Starting with 2019, ANSA includes in the electronic RSC system the data regarding the planned controls. All the planned and unannounced official controls that refer to the entrepreneurial activity were included in the system in 2021. At the central ANSA level, the Department for strategic planning and quality management, risk analysis and assessment and control planning are responsible for the monitoring of the plan's implementation and prepares monthly/quarterly/half-yearly/annual reports on controls and presents it to Director-General²⁶. Controls are planned quarterly, so at the end of each quarter the controls that have been planned and not performed can no longer be initiated except as based on an unannounced control. By the end of each year, ANSA prepares the Annual Report that is submitted to the State Chancellery and published on its web page.²⁷

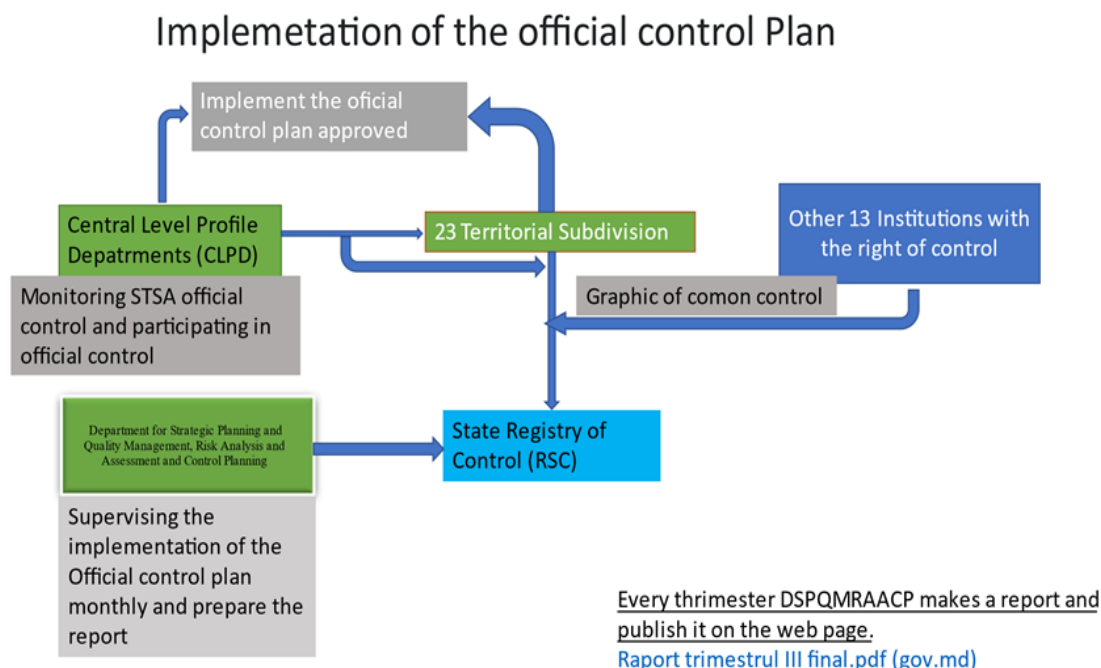
In order to support inspectors in the use of RSC, procedures have been approved that describe the stages of initiating controls in RSC: PG-19/1 "Preparation and carrying out official control on ANSA's areas of competence"²⁸ and PG-18/01

²⁶ Data on the official controls are publicly available on the ANSA website, available in Romanian at: www.ansa.gov.md/ro/content/rezultatele-controalelor-oficiale

²⁷ Report on the implementation of the National Multiannual Control Plan for 2021, available in Romanian at: <https://www.ansa.gov.md/uploads/files/Transparenta/RAPOARTE/Raport%20scanat%20pentru%20plasare.pdf>

²⁸ ANSA Order No 122/2022 on the approval of the "General procedure for the preparation and performance of controls on the area of competence of ANSA", available in Romanian at:

“Use of the state register of controls by inspectors of the National Food Safety Agency”²⁹.



To verify the documents related to the official control introduced in RSC by STSA, ANSA issues make an annual issuance of internal administrative acts approving the list of persons responsible for the monitoring the quality of control documents and providing information on areas of competence quarterly to the Department for strategic planning and quality management, risk analysis and assessment and control planning.

When initiating planned/unannounced official controls in RSC, based on the Order approving official controls for the current year, or in case of unannounced controls based on complaints, petitions, notifications of other bodies, or self-notifications, internal administrative acts issued by ANSA, the ANSA inspector must follow certain steps for the initiation of the control and the procedure for preparing for the official control. The procedure for preparing and motivating the official control is described in 1 PG 04_3-002 “Preparation of inspection, official control” placed on the ANSA website³⁰.

https://www.ansa.gov.md/uploads/files/CONTROALEoficiale/2022/PG-19_02%20Pregatirea%20%C8%99i%20efectuarea%20controlului%20pe%20domeniile%20de%20competen%C8%9B%C4%83%20ANSA%20%2C%20Ordin%20%E2%84%96%20122.pdf

²⁹ General procedure for the use of the state register of controls by ANSA inspectors, available in Romanian at: [https://www.ansa.gov.md/uploads/files/CONTROALEoficiale/GHIDURI/web%20PG-18_01%20Utilizarea%20RSC%20de%20c%C4%83tre%20inspectorii%20ANSA%20\(1\).pdf](https://www.ansa.gov.md/uploads/files/CONTROALEoficiale/GHIDURI/web%20PG-18_01%20Utilizarea%20RSC%20de%20c%C4%83tre%20inspectorii%20ANSA%20(1).pdf)

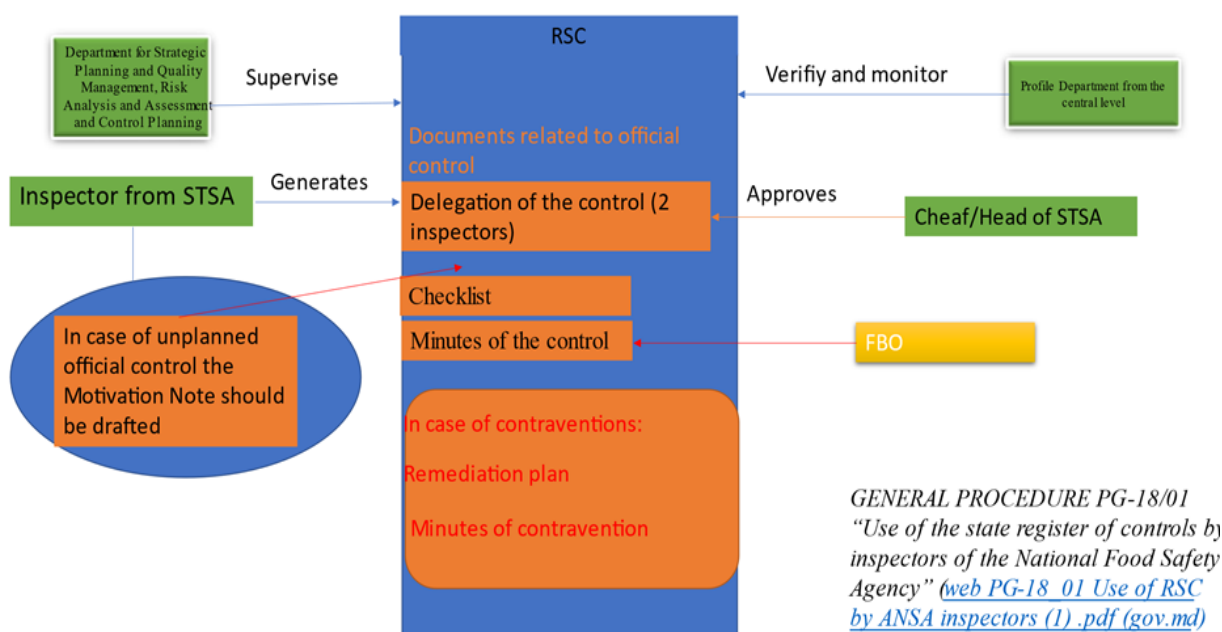
³⁰ General procedure for the preparation of official controls, available in Romanian at: http://www.ansa.gov.md/uploads/files/Transparenta/PROCEDURI/1_%20PG%2004_3-002%20Pregatirea%20inspectiei%2C%20controlului%20oficial.pdf

To ensure confidentiality and impartiality, the ANSA staff sign the Declaration of confidentiality and impartiality, which is kept in the personal file of each employee at the Human Resources Department. The standard form of this declaration, as well as the procedure, are placed on the ANSA website.³¹

In accordance with Article 28(4) of Law No 131/2012 and the procedure approved by ANSA PG-19/1 “Preparation and performance of official controls on areas of competence”, STSA inspectors and the central ANSA staff shall draft protocols concerning the results of the official controls conducted by them.

Also, during the official controls conducted by ANSA inspectors the check lists approved by the Ministry of Agriculture and Food Industry and published in the Official Gazette.³²

Graphic of the process of official control in RSC



Control protocols shall include a description of the purpose of the control, the methods used, the results of the control and, where appropriate, the measures to be implemented by the feed or food business operator subject to screening. When finalizing the official control procedure, the inspector drafts the Control protocol in 2 copies signed by all the inspectors who performed the official control and by the FBO, in accordance with the procedure approved by ANSA.

³¹ General procedure on impartiality, conflict of interest, confidentiality, available in Romanian at: http://www.ansa.gov.md/uploads/files/Transparenta/PROCEDURI/5_%20PG-15_01%20Impar%C8%9Bialitatea%2C%20conflictul%20de%20interese%2C%20confiden%C8%9Bialitatea.pdf

³² Order of the Ministry of Agriculture No 79/2019 on the approval of checklists for ANSA control areas, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130930&lang=ro

Within ANSA, an Internal Audit Department was established that operates in accordance with the provisions of Law No 229/2010 on public internal financial control³³, Law No 50/2013 on official controls for verifying compliance with legislation on food and feed and animal health and welfare rules³⁴, Government Decision No 600/2018 on the organization and functioning of the National Food Safety Agency in order to verify the areas related to ANSA³⁵. The mission of the Internal Audit Department is to provide objective advice and assurance on the effectiveness of ANSA's internal control system, contributing to the added value and making recommendations for its improvement.

Drafting and implementation of the monitoring programs

Moreover, based on the provisions of the Article 24(1) of Law No 306/2018 on food safety³⁶, Article 7(1), letter d) of Law No 50/2013 on official controls to verify compliance with the legislation on feed and food and with the rules of animal health and welfare³⁷, Article 4(2) and Article 36(3) of Law No 221/2007 regarding veterinary and sanitary activity³⁸, Article 4(4) letter c) and Article 1(1) letter a) of Law No 228/2010 on plant protection and phytosanitary quarantine³⁹, Article 5(2) letter b) of Law No 68/2013 on seeds⁴⁰, Article 33(1) of Law No 57/2006 of vineyards and wine⁴¹, Article 13(2) of Law No 119/2004 on phytosanitary products and fertilizers⁴², ANSA annually develops National Monitoring and Surveillance Programs in areas of food safety, feed and veterinary medicinal products, plant health and quality of plant protection products.⁴³

Profile Departments of the central level of ANSA are responsible for drafting the monitoring the plans, subsequently implemented by STSAs.

³³ Law No 229/2010 on public internal financial control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125252&lang=ro

³⁴ Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

³⁵ Government Decision No 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=r

³⁶ Law No 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

³⁷ Law No 50/2013 the official controls for compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

³⁸ Law No 221/2007 on veterinary health activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

³⁹ Law No 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

⁴⁰ Law No 68/2013 on seeds, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106318&lang=ro

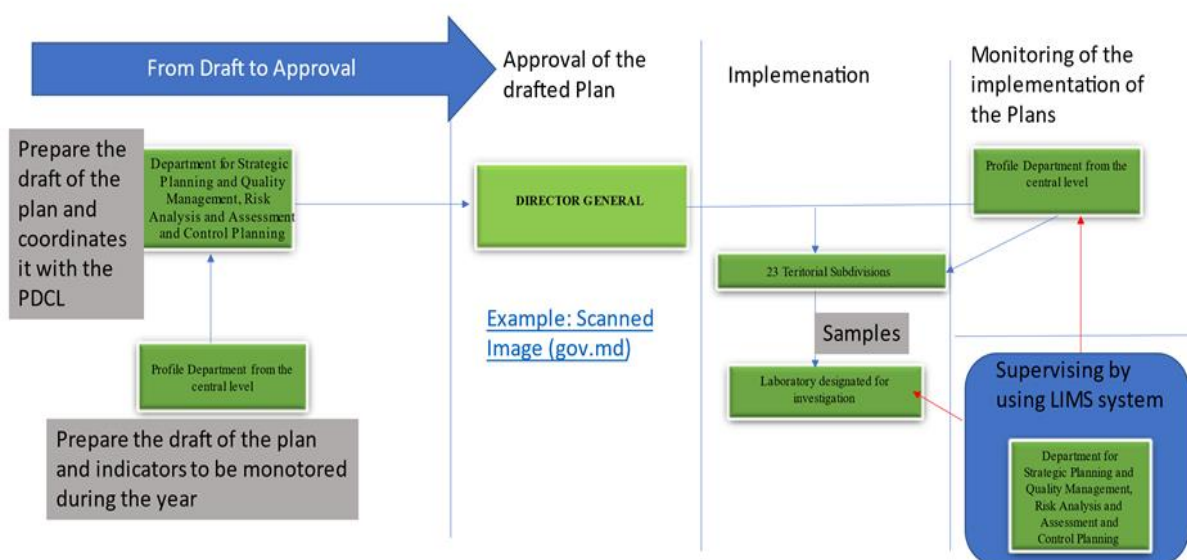
⁴¹ Law No 57/2006 on vineyards and wine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=131005&lang=ro

⁴² Law No 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

⁴³ ANSA Order No 490/2021 on the approval of the National Monitoring and Surveillance Programs in the fields of food safety, feed and veterinary medicinal products, plant health and quality of plant protection products for 2022, available in Romanian at: https://ansa.gov.md/uploads/files/Ordinele%20ANSA/2021/Ord_490%20din%2021_12_2021.pdf

The STSAs role is to implement the official control plan and the sampling plans based on the procedures approved by the central level and to participate in training programs.

Process from drafting to aproval the ofNational Monitoring and Surveillance Program



Responsibilities of the ANSA Central Level:

ANSA is responsible for planning, preparing, and conducting official controls of food business establishments. Thus, national control plans and monitoring programs are developed annually and establish the type and number of samples for sampling. The ANSA Central level is responsible for training and empowering inspectors in order to implement the current procedure.

The responsibilities of the ANSA central level also include coordination of the inspectors' activity within STSAs and the control over the implementation of procedures, as well as centralization of reports on the activity related to the implementation of official controls and sampling plans on the level of STSA.⁴⁴

Responsibilities of STSA management:

The head of STSA and the deputy head of STSA are responsible for organizing and implementing official control plans on the establishments level. They are

⁴⁴ ANSA Order No 499/2021 on the approval of reporting forms and the schedule for the presentation of control reports for 2022, available in Romanian at: <https://ansa.gov.md/uploads/files/Ordinele%20ANSA/2021/Ordin%20%E2%84%96%20499.pdf>

responsible for ensuring the implementation of national programs on the territorial level and drawing up annual and monthly control plans.

Responsibilities of inspectors:

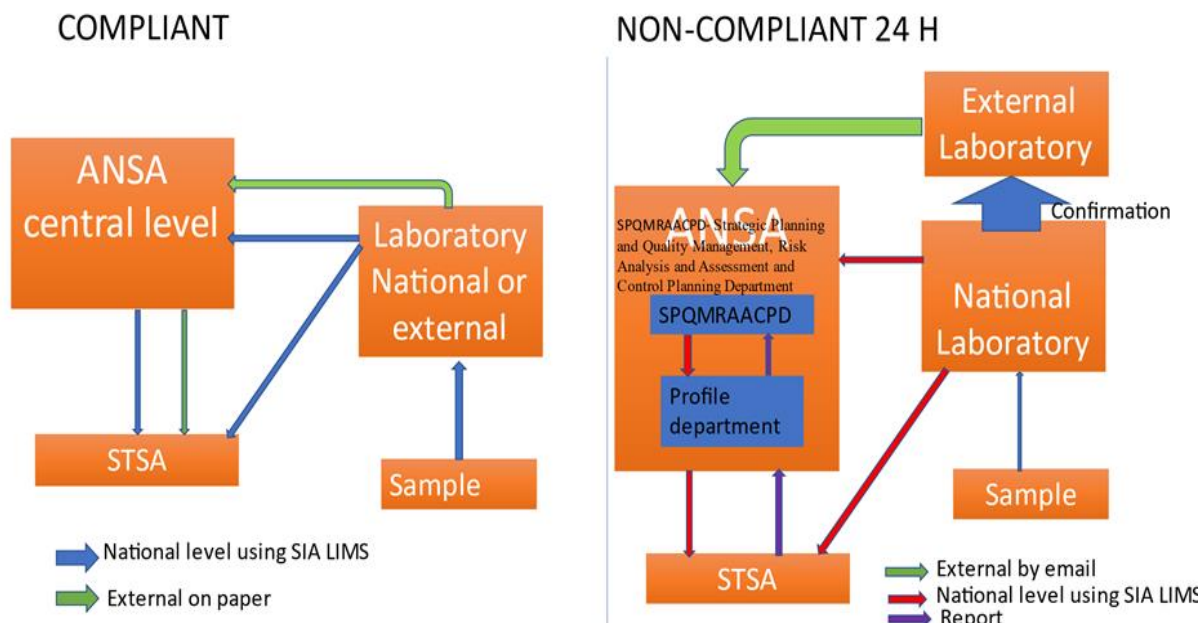
According to the functional duties (described in the Job Description), the inspectors are directly responsible for carrying out official controls at establishments (FBOs). Official controls should be carried out in an objective, impartial, efficient manner and in accordance with the procedures approved by ANSA, these being compulsory. The Authority ensures the impartiality of the staff and the absence of conflict of interest of employees who are responsible for carrying out official controls by signing the Declaration of confidentiality and impartiality according to Procedure PG-15/01 “Impartiality, conflict of interest, confidentiality.pdf (gov.md)”.⁴⁵

Should cases of violation of the legislation be found in the performance of official controls, ANSA inspectors apply Contravention sanctions.

Should a noncompliant laboratory result be found in the implementation of the monitoring programs, the investigation of the case should start immediately upon making the laboratory result available by the laboratory, but not later than 24 hrs from the moment the result is made available. For foodstuffs, the necessary measures are applied in accordance with General procedure PG-12/01 “Action taken in relation to non-compliant foodstuffs”.

⁴⁵ General procedure for impartiality, conflict of interest, confidentiality, available in Romanian at: http://www.ansa.gov.md/uploads/files/Transparenta/PROCEDURI/5_%20PG-15_01%20Impar%C8%9Bialitatea%2C%20conflictul%20de%20interese%2C%20confiden%C8%9Bialitatea.pdf

Flow chart on the laboratory result



Department for strategic planning and quality management, risk analysis and assessment and control planning within the ANSA's central level is responsible for supervising the monitoring program; at the same time, the central level profile departments are responsible for the monitoring of the program's implementation. The Directorate-General for Health and Food Safety of the European Commission has approved 5 Residue monitoring programs for animal origin products submitted by the Republic of Moldova (milk, honey, poultry meat, egg, fish). Annually, the Residue monitoring programs of the Republic of Moldova are submitted for evaluation and approval by the relevant services of the European Commission.

4. Implementation: For each of the following items covered by the food safety, veterinary, and phytosanitary policy, listed below please give details of the measures taken to ensure proper implementation of the legislation with reference as relevant to the following activities (indicative list), as well as sanctions in case of non-implementation/non-compliance:

a) laboratories used in hygienic, veterinary, phytosanitary, food and feed analysis (chemicals, microbiology, GMOs, etc.); activities present or planned to comply with EU systems, the accreditation schedule under EU law with the name of the accreditation body, methods of sampling and analysis (generally for contaminants, food contact materials, etc.) and the chain of command; provide a specific description of the reference laboratory system, if any; otherwise, indicate where Moldova is with the preparations for the relevant legislative acts to provide for their application.

In accordance with the provisions of Government Decision No 600/2018 ANSA is founder at 3 Public Institutions, which are accredited according to requirements of ISO 17025/2018 by MOLDAC, as follows:

No	Name of public institution	Field of activity	Certificate of accreditation and accreditation field access link
1.	Public Institution “Republican Centre for Veterinary Diagnosis” (CRDV)	Laboratory investigations: 1. animal health; 2. food and feed safety and quality; 3. verification of the safety and hygiene criteria of food chain operators; 4. verification of the quality and safety of veterinary medicinal products.	CRDV - Centrul Republican de Diagnostic Veterinar
2.	Public Institution “Central Laboratory for the Testing of Alcoholic/Non-Alcoholic Beverages and canned products”	1. Providing analysis services on the safety and quality of foodstuffs, raw materials, and alcoholic production; 2. Organizing laboratory and sensory analyses for alcohol and food production; 3. Providing services for assessing the conformity of alcohol and food production; 4. Testing the quality and safety of alcoholic production, taken by the control and supervision bodies of alcoholic production; 5. Conducting arbitration tests (tests) on the quality and safety of alcohol production; 6. Providing methodological assistance to enterprises in carrying out quality control and implementing new methods for verifying the quality and safety of alcohol production; 7. Elaboration, revision and of the technical-normative documentation; 8. Implementation of the methods for verifying the quality and safety of alcohol production in accordance with European Union and international practices.	Accreditations – LCTBANPC
3.	Public Institution Central Phytosanitary Laboratory	1. Verification and identification of phytosanitary status, plant protection and nutrition, soil fertility; 2. Verification of pesticide residues in plants and plant products; 3. Verification of the quality of seed and planting material, quality of agri-food products and products involved in eco farming; 4. Providing testing services on the safety of products in its areas of competence;	Accreditation – Laboratorul Central Fitosanitar (carantina.md)

These laboratories implement monitoring programs of official controls performing tests in laboratories using accredited methods. Where there are no accredited methods, ANSA uses the services offered by national or external laboratories. The contracted laboratory should be accredited in accordance with the requirements of

ISO 17025:2018, and have accredited methods for the established indices, to participate in PT tests with satisfactory results. All these requirements are mentioned in the Procedure for the designation of laboratories.

At the national level, the accreditation of laboratories is carried out by the National Accreditation Centre, designated as a single national accreditation body, with the abbreviated name MOLDAC, signatory of EA, IAF, ILAC.

Details about MOLDAC can be consulted by accessing the following link <https://acreditare.md/despre-2/prezentarea-general-a/>

MOLDAC is a signatory of the Bilateral Recognition Agreement with the European Accreditation Cooperation and the signatory of the Mutual Recognition Agreement with the International Cooperation for the Accreditation of ILAC-MRA Laboratories.

At national, European, and international level, the National Accreditation Body is a member of:

EA European Cooperation for Accreditation

ILAC International Cooperation for the Accreditation of Laboratories

IAF International Accreditation Forum

EASC Euro-Asian Council for Standardization, Metrology and Certification

IRSA Interregional Standardization Association

Description of the laboratories

1. Public Institution "Republican Centre for Veterinary Diagnosis"

Republican Centre for Veterinary Diagnosis (hereinafter I.P. CRDV) is a public institution, founded by ANSA. I.P. CRDV operates in accordance with the provisions of Government Decision No 1211/2018 on the approval of the statute of Public Institution "Republican Centre for Veterinary Diagnosis"⁴⁶.

According to Law No 221/2007 on veterinary and sanitary activity, Chapter II, Article 3(2), letter b)⁴⁷ and Government Decision No 1211/2018 on the approval of the Statute of Public Institution "Republican Centre for Veterinary Diagnosis" Chapter II, p. 6, I.P. CRDV is declared a National Reference laboratory in the field of veterinary and food and feed safety.

⁴⁶ Government Decision No 1211/2018 on the approval of the Statute of the public institution "Republican Centre for Veterinary Diagnosis", available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128878&lang=ro

⁴⁷ Law No 221/2007 on veterinary sanitary activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

The areas of competence of IP CRDV are the following:

- laboratory investigations in the field of animal health;
- laboratory investigations in the field of food and feed safety and quality;
- laboratory investigations for the verification of the safety and hygiene criteria of the food chain operators;
- laboratory investigations for the verification of the quality and safety of veterinary medicinal products;
- risk assessment and scientific research in the fields of activity;
- other areas assigned by normative acts, including the acts of the founder, in the competence of the Centre.

IP CRDV has the following functions:

- carrying out laboratory investigations for the purpose of assessing animal health and ensuring the implementation of surveillance measures under the conditions laid down in veterinary legislation and for the safety of products of animal origin;
- laboratory investigations in the field of food and feed safety and quality, hygiene criteria at the food establishments;
- laboratory investigations for the verification of parameters influencing feed safety and quality;
- laboratory investigations in the field of quality control and safety of veterinary medicinal products;
- monitoring animals' health status;
- collecting, disseminating, and analysing scientific information;
- participation in the process of registration of veterinary medicines in accordance with the functions assigned by the normative acts and by the founder;
- performing laboratory tests in order to establish or extend the shelf life of food products;
- providing advice and expertise in the field of laboratory testing and methodological support/organization of training for laboratory staff at enterprises that are part of the food chain.

I.P. CRDV is accredited according to the requirements of the SM EN ISO IEC 17025: 2018 standard "General requirements for the competence of testing and calibration laboratories", for its areas of competence (except control of veterinary medicinal products): diagnosis and animal health, food safety, feed, and water (including drinking water).

Within the I.P. CRDV, in order to comply with the requirements of ISO 17025 are implemented the Quality Manual and 17 General Procedures and 8 operational procedures, for the areas of competence of laboratories, documents of the management system, which transpose the requirements and compliance with ISO 17025.

I.P. CRDV collaborates with laboratories and institutions on European and international level in all its areas of competence, including training, exchange of experience and participation in PT / ILC:

- Institute of Veterinary Hygiene and Public Health (IISPV, Bucharest, Romania);
- National Food and Veterinary Risk Assessment Institute of Lithuania;
- FAPAS, BIPEA, LGC;
- Institute of Diagnosis and Animal Health (IDSA, Bucharest, Romania)
- EURL, European Union Reference Laboratory for African Swine Fever, Animal Health Research Centre (CISA-INIA), Madrid, Spain;
- EURL, European Union Reference Laboratory for Foot-and-mouth disease
- The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Belgian Veterinary and Agrochemical Research Centre (CERVA)
- EURL, European Union Reference Laboratory for RABIES, Nancy, France
- EURL, European Union Reference Laboratory for BRUCELLOSIS, ANSES, France
- EURL, European Union Reference Laboratory for Avian Influenza & Newcastle disease, Experimental Zooprophyllactic Institute of Venice (IZSve), Legnaro, Italy
- PIWet, National Veterinary Research Institute, Pulawa, Poland
- VETQAS, APHA, UK
- EURL, European Union Reference Laboratory for Capripox Viruses, Elsenne, Belgium.

I.P. CRDV has in its structure 6 (six) subdivisions:

- Diagnostic and Animal Health Laboratory (LDSA) based in Chisinau, which covers laboratory investigations for the whole country, especially for the Centre region;
- Laboratory of Diagnosis and Animal Health, (LDSA) subdivision or. Drochia, covering laboratory investigations for the North region;

- Laboratory of Diagnosis and Animal Health, (LDSA) subdivision or. Cahul, covering laboratory investigations for the South region;
- Food testing laboratory (LÎPA), headquartered in. Chisinau, covering laboratory investigations for the whole country, especially for the Centre region;
- Food testing laboratory (LÎPA), subdivision or. Donduseni, covering laboratory investigations for the North region;
- Laboratory for the control of animal feed and veterinary medicines based in mun. Chisinau, covering laboratory investigations for the whole country.

According to Staff Regulations, the I.P. CRDV has 102 positions, of which 63 are specialists and laboratory technicians, directly responsible for carrying out laboratory tests. Within the I.P. CRDV, there are three Doctors of Sciences, veterinarians, chemists and technologists and technical staff with specialized secondary education.

The Diagnostic and Animal Health Laboratory is structured into:

- reception of samples;
- bacteriology and parasitology (laboratory tests of pathological material, abortions, semen, washing of machinery and rooms, water, food, faeces, dust, feathers, milk, fish, bees, bee brood in all bacteriological diseases for domestic animals, laboratory research on Anthrax, Brucellosis, Campylobacteriosis, Listeriosis, Redness, Salmonellosis, Colibacillosis, Pasteurellosis, American Loca, European Loca, Pseudomonosis, Aeromonosis, total number of germs in water, Mastitis, Staphylococcus, etc. parasitology – testing for the presence of gastrointestinal parasitic diseases, the presence of parasitic diseases of internal organs, the presence of ectoparasitosis in mammals, aquatic animals, bees and birds; the presence of parasites of the genitals; the presence of hemoparasites);
- morphopathology;
- serology; (RBT (Rapid Seroagglutination Reaction on Pink-Bengal Antigen-Stained Blade, SAT (Slow Seroagglutination Reaction in Tube), RFC (Complement Fixing Reaction - Micro- and Macro-Technique) and RFC Overnight).

AGID (agar gel immunodiffusion test), ELISA (immunoassay test), RMA (microagglutination reaction), Hematology (absolute lymphocyte count), for the diagnosis of diseases: brucellosis (bovis, B. melitensis, B. suis), epididymitis infectious rams (ovis), enzootic bovine leukosis (VLB), and many others by the above-mentioned tests);

- virology (detection of antibodies specific for avian influenza virus by ELISA method; identification of avian pseudopest virus genome (Newcastle disease) by PCR technique; identification of genome of avian influenza virus (Matrix) by PCR technique; of viral diseases, namely:

ELISA method antibody and antigen detection: African swine fever, foot-and-mouth disease, bluetongue, avian influenza, classical swine fever Real-time RT-PCR method of viral genome detection: African swine fever, avian influenza, Newcastle, classical swine fever (RHA / RIHA method antigen and antibody detection: avian influenza, Newcastle disease; IFD method antigen detection: rabies, classical swine fever. Biotest method: rabies, Aujeszky's disease).

- radiology (determination of radionuclide content: Cesium-137; Strontium-90, determination of the equivalent dose range gamma (level of contamination)).

The Diagnostic And Animal Health Department is located in arranged spaces and in accordance with the requirements of the Biosafety Guide and equipped with sufficient equipment (checked and calibrated periodically in accordance with the requirements of ILAC G: 24), for the determination of molecular-biological methods (real time PCR), viral direct immunofluorescence (DFI) methods, immunoenzymatic, radiological and classical bacteriological methods, according to the Accreditation Domain.

The Food Safety Testing Laboratory (LÎPA) is structured into:

- reception of samples and organoleptic (sensory analysis in food of animal origin)
- residues and metabolic products (determination of drug residues – tetracyclic, beta-lactam, macrolides, sulfonamides, chloramphenicol, nitrofurans, metronidazole, streptomycin in food, heavy metals (lead, Cd, As, Hg) in food and foreign fats in dairy products);
- physico-chemistry (determination of quality indices in food, including animal origin – proteins, fats, chlorides, phosphates, nitrites, oxymethylfurfural, sucrose, water content, starch, diastase index, hydroxyproline, freezing point, etc.);
- microbiology (determination of hygiene and microbiological safety criteria in foodstuffs – determination of *Listeria monocytogenes* and *Listeria* spp., determination of Enterobacteriaceae, determination of Sulfite-reducing Clostridia, determination of Coliform Bacteria, determination of yeasts and molds, determination of Lactic Acid Bacteria, determination of Somatic Cell Number, determination of *Campylobacter* spp.).
- for the determination of quality indices (sensory methods, volumetric, gravimetric, spectrophotometric, refractometric, potentiometric, cryoscopic, butyrometric methods), in accordance with the Accreditation Domain;
- for the determination of microbiological indices (classical reference methods, according to EN, ISO standards for which equipment such as thermostats, homogenizers, microscopes, laminar hoods, vortex, water

baths, fluoro-opto-electronic methods, for determining the number of somatic cells, etc.);

- for the determination of residues of medicinal products, heavy metals, and foreign fats in dairy products (gas chromatography, LC / MS / MS - liquid chromatography coupled with mass spectrometry, ELISA – immuno-enzymatic method, Flame atomic absorption spectrometry and graphite furnace, Hydride atomic absorption spectrometry, flame-free atomic absorption spectrometry, immunofluorescence liquid chromatography (HPLC)).

Feed and veterinary medicine Laboratory:

- reception of samples;
- determination of mycotoxins (Aflatoxin B1, sum of Aflatoxins B1, B2, G1, G2., Ochratoxin A1, in food and feed (immunoenzymatic method);
- determination of saturated/unsaturated fatty acids, including trans in food (gas chromatography);
- determination of quality indices in feed and water (volumetric, gravimetric, spectrophotometric methods);
- determination of quality indices, including active substance in veterinary medicinal products (liquid chromatography).

Training of laboratory staff.

I.P. CRDV participants in training activities of each specialist, identifying along the way their individual needs in professional training.

The I.P. CRDV institution ensures the training and instruction of the staff according to the Internal Training Program and the External Training Program (Code: F PI 6.2-04 L).

Food Safety Testing Laboratory

In 2021, 19 trainings were planned, which included all the points from the standard SM EN ISO/IEC 17025: 2018 and trainings regarding the national and international normative documents in force, from which 11 trainings were performed, by merging the trainings regarding the points from SM EN ISO / IEC 17025. 2018, with the participation of all specialists in the laboratory. Thus, the internal training program for 2021 was 100% completed.

Diagnostic and Animal Health Laboratory

For 2021, 18 trainings were planned, which included all the points from the standard SM EN ISO/ IEC 17025: 2018 and trainings regarding the national and international normative documents in force, which were carried out with the

participation of all LDSA specialists, regarding the points from SM EN ISO / IEC 17025. 2018.

Participation in PT/ILS

According to the requirements of ISO 17025, point 7.7 Ensuring the validity of the results and General and operational procedures of the management system, applicable in the laboratory, EA-4/18 G: 2021 Guidance on the level and frequency of proficiency testing participation, EA-4/21 INF: 2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation, ILAC P9: 06/2014 ILAC Policy for Participation in Proficiency Testing Activities, in order to demonstrate technical competence, Laboratories (LÎPA, LDSA, LCHM), plans to participate in national and international comparisons and participate in proficiency testing, where available and relevant, in accordance with the proficiency testing plan prepared so that all accreditation indices are included in an accreditation cycle.

In the field of animal health, I.P CRDV collaborates with External Laboratories, in order to exchange experience and participation in PT/ILC.

2. Public Institution “Central Laboratory for the Testing Alcoholic/Non-Alcoholic Beverages and canned products” (I.P. "LCTBANPC")

I.P. LCTBANPC operates in accordance with the provisions of the Government Decision No 1210/2018⁴⁸.

a) The areas of competence of the I.P. LCTBANPC:

- providing analysis services on the safety and quality of food products, raw materials, and alcohol production;
- organization of laboratory and sensory analysis for alcohol and food production;
- providing services for assessing the conformity of alcohol and food production;
- other fields assigned, by normative acts, including the acts of the founder, in the competence of the laboratory.

In accordance with the provisions of Government Decision No 1210/2018, I.P. LCTBANPC has the status of a national reference laboratory for its areas of competence. Within I.P. LCTBANPC, there is a certification body as a conformity assessment body, accredited to the standard SM EN ISO/IEC 17065: 2018 “Conformity assessment. Requirements for bodies certifying products, processes, and services”, for 5 certification schemes (No 1, 1b, 2, 3, PDO/PGI) and the following codes according to the Combined Nomenclature of Goods (NCM):

⁴⁸ Government Decision No 1210/2018 on the approval of the Statute of Public Institution “The central alcohol testing laboratory/non-alcoholic and canned products”, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128879&lang=ro

- 9 codes for wine, alcohol, and beer products (2009, 2106, 2202, 2203, 2204, 2205, 2206, 2207, 2208);
- 6 codes for confectionery, pastry, tea, coffee (0901, 0902; 1704, 1806, 1905, 2101);
- 2 codes for tobacco products (2402, 2403).

I.P. LCTBANPC as a conformity assessment body, is accredited to the standard SM EN ISO/IEC 17025: 2018 General requirements for the competence of testing and calibration laboratories, as of 01 January 2022 by MOLDAC, being accredited 42 methods in the field of wine/alcoholic products, and 102 methods in the field of food/canned products.

IP LCTBANPC is managed by the director, who is also the head of the certification body.

There are 4 structural subdivisions within the institution, including:

- the certification body, which is a conformity assessment body;
- the testing laboratory, which is also a conformity assessment body;
- accounting;
- human resources and administration.

I.P. LCTBANPC has 40 employees, representing the internal staff of the institution.

External trainings

In 2021, the staff of the institution participated in 9 external training activities, 8 of which had as organizers entities within the country – I.P. "National Office of Vine and Wine", Technical University of Moldova, and one organized by the Central Institute for Surveillance and Testing in Agriculture in the Czech Republic.

Participation in PT Tests

In order to ensure the quality of laboratory test results, I.P. "LCTBANPC" constantly participates in the proficiency tests organized by the accredited European tester BIPEA (Bureau Inter Professionnel d'Etudes Analytiques, France).

In 2021, the testing laboratory of the institution participated in 11 PT schemes organized by BIPEA in the field of wine and alcoholic products and food / canned products.

By the testing laboratory under I.P. LCTBANPC, internal methods of analysis have been validated (specific procedures):

- for the determination of the levels of lead, cadmium, mercury, inorganic tin in food products in accordance with the provisions of Government Decision No 941/2010 on the approval of the rules on sampling and analysis methods for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in food products⁴⁹. Those rules are harmonized with the provisions of Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs;
- for the determination of mycotoxin levels (aflatoxins B1, B2, G1, G2, deoxynivalenol, zearalenone, ochratoxin A and patulin) in food – in accordance with the provisions of Government Decision No 208/2013 on the approval of sampling methods tests to determine the level of mycotoxins in food⁵⁰.

The methods partially transpose the provisions of Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Note: Government Decision No 208/2013 transposes the sampling methods and the requirements for the methods of analysis of mycotoxins (Annex No 11), including the parameters for validation. It should be noted that these methods cover more than a half of the safety indices determined by the institution's food testing laboratory.

All internal procedures of the test laboratory management system for the validation/verification of test methods are developed exclusively on the basis of European or international documents.

3. Public Institution Central Phytosanitary Laboratory

The laboratory operates in accordance with the provisions of the Government Decision No 1209/2018⁵¹.

⁴⁹ Government Decision No 941/2010 on the approval of the rules on sampling and analysis methods for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in food products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=103303&lang=ro

⁵⁰ Government Decision No 208/2013 on the approval of sampling methods tests to determine the level of mycotoxins in food, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125620&lang=ro

⁵¹ Government Decision No 1209/2018, regarding approval Statute of the Public Institution "Central Phytosanitary Laboratory", available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128880&lang=ro

IP LCF has the mission to coordinate and organize the activities aimed to ensure the implementation of public policies in the areas of competence established in its Statute.

The laboratory is designated as the National Reference Laboratory for its areas of competence.

The areas of competence of the IP LCF are the following:

- Verification and identification of phytosanitary status, plant protection and nutrition, soil fertility;
- Verification of pesticide residues in plants and plants products;
- Verification of the quality of seed and planting material, quality of agri-food products and products involved in organic farming;
- Providing testing services on the safety of products in its areas of competence;

IP LCF includes several testing laboratories in the field of testing the production of plant origin and has 32 employees.

The Phytosanitary Quarantine Laboratory includes the following areas:

- Morpho-biometric testing: Entomology, Nematology, Herbology;
- Microbiological testing: Mycology, Bacteriology, Virology;
- Molecular Biology.

The laboratory determines quality indices in the following products: cereals and derived products, oilseeds (sunflower, rapeseed, soybean, flax), raw material for fodder (grated, meal, fishmeal, meat and bone meal, protein products) and fodder, vegetable oils.

Quality indicators: organoleptic (appearance, colour, taste, smell), humidity, impurities, hectolitre weight, wet gluten, fall index, infestation, ash, pH.

The Seed Testing and Certification Laboratory is the only in the Republic of Moldova accredited by the International Seed Testing Association (ISTA), to perform seed material quality testing and to issue International Seed Quality Certificates.

The laboratory performs tests for: determining the purity and number of seeds of other crops, determination of germination, determination of viability by tetrazole, determination of humidity, determining the mass of one thousand seeds, identification of variety purity by the method of protein electrophoresis.

The Residue Control Laboratory: performs tests for products of non-animal origin using the techniques that allow multiresidue analysis of pesticides from complex matrix (products) of non-animal origin: fruits, vegetables, cereals, fodder, green plants.

Genetically Modified Organisms (GMOs) testing Laboratory uses the PCR (Polymerase Chain Reaction) technique – a method of in vitro enzymatic amplification of a DNA sequence (qualitative) from soybeans, maize, rapeseed, seeds.

IP LCF applies the requirements of the standard SM SR EN ISO/IEC 17025: 2018. Laboratory specialists have been trained in various reference laboratories in: Poland, Romania, Israel, Czech Republic, Italy, Austria, Russian Federation) and participated in various PT/ILS, confirmation of result with: ANSES, BIPEA, France, FAPAS UK, Slovenia, LCF and IISPV Romania. The analytical methods and techniques used are at the level of those regulated or accepted by the international bodies and have the respective normative documents (ISO, ISTA, OEPP, GOST standards as well as methods drafted within the IP LCF.

In order to maintain and confirm the analytical skills, the Laboratory regularly participates in proficiency tests and interlaboratory tests (PT/ILC). Thus, in the last accreditation period, the laboratory had 93 participations in comparison tests (attached by fields) to different methods in its field of accreditation.

All methods used for controls are developed and implemented in accordance with European requirements, except for the method for determining nitrates and some methods for determining the quality of cereal products.

b) Crisis management

The **crisis and emergency management** related to food and feed are provided for by Government Decision No 680/2018 approving the General plan for crisis management in the field of food safety and feed.⁵²

The relevant authorities with responsibility in the food safety field are the following: the Ministry of Agriculture and Food Industry, the Ministry of Health, via National Agency for Public Health, the Ministry of Internal Affairs, the Ministry of Defence, the Ministry of Finance, via Customs Service, and the National Food Safety Agency (ANSA), which has the role of coordinator for food safety authorities in the regional level.

Crisis management is a gradual process including five phases, as follows:

- Phase I: observing the indicators and warning of a potential or specific crisis;
- Phase II: assessing the crisis situation in terms of its development and potential and determining the implications for individual and national security;
- Phase III: development of the recommended response options to guide the decision-making process;

⁵² Government Decision No 680/2018 approving the General Management Plan of crises in the food and feed sector, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125704&lang=ro#

- Phase IV: planning and execution of decisions;
- Phase V: return to normal.

Food and feed safety dangers are classified into the following categories:

- Biological hazards;
- Chemical hazards;
- Physical hazards.

Within ANSA, via ANSA Order No 11/2022⁵³, the Emergency Operations Centre was established, which receives primary information through the responsible institutions and public authorities' subdivisions, other operational centres, the media, the Rapid Alert System for Food and Feed at national level, the hotline or other information sources. The Operations Centre makes the primary assessment and, in the events, where the incident is considered major, the National Crisis Cell is activated and convened, which in turn informs the Commission for Exceptional Situations of the Republic of Moldova about the crisis' evolution and the measures that need to be applied.

In the sanitary-veterinary field regarding animal diseases, the management of crisis and emergencies are regulated by Article 29 of Law No 221/2007 on veterinary and sanitary activities⁵⁴, through:

- Prohibition of the import of live animals, products, and by-products subject to veterinary surveillance and control which may pose an imminent risk to animal or human health;
- Implementation of the Program on strategic actions for the surveillance, prophylaxis and control of animal diseases, prevention of animal diseases' transmission among humans, and the environment protection, which is reviewed annually and approved by the ANSA Director-General's Order.

In the phytosanitary field, the management of crisis and emergencies is carried out in accordance with the provisions of Section IV of the Law No 228/2010 "Quarantine phytosanitary regime and phytosanitary risks".⁵⁵

Should quarantine organisms be discovered, a quarantine regime should be imposed within the area where the quarantine organism is spread, the threatened or the protected zones, and immediate measures are taken to locate and eliminate the outbreaks.

⁵³ Government Decision No 11/2022 on the approval of the sanitary and veterinary rule on animal by-products and derived products not intended for human consumption, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130906&lang=ro

⁵⁴ Law No 221/2007 on veterinary health activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

⁵⁵ Law No 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro#

In the territory where there is a phytosanitary quarantine regime, a threatened or protected area, the introduction and release of plants, plant products, means of transport and other related goods subject to the phytosanitary quarantine regime are restricted, being supervised, monitored, and inspected, disinfected, heat treated or destroyed.

c) Risk management and risk assessment

Risk assessment is defined in the national legislation by Law No 306/2018 on food safety⁵⁶, which establishes for the risk assessment a scientific data-based process of 4 stages: hazard identification, hazard characterization, exposure assessment and risk characterization. Law No 306/2018, under Section IV, assigns to ANSA competencies related to the risk identification, assessment, management, and communication in the field of food and feed safety. One of the main principles regarding food safety under the Law No 306/2018 is the principle of risk analysis, and Article 3 provides that food regulations are based on risk analysis. Risk assessment is based on available scientific information and is conducted in an independent, objective, and transparent manner. Risk management takes into account the results of the risk assessment and, in particular, the opinions of national and international food safety institutions, other legitimate factors in the field, and the precautionary principle.

In order to provide consumers with safe food, ANSA ensures the development and implementation of monitoring programs for food safety and quality, feed, monitoring programs for animal and plant health as well as for monitoring phytosanitary products and fertilizers.⁵⁷

Risk assessment is carried out when there are no limits for contaminants or residues provided in the legislation on some kinds of foodstuffs. In such cases ANSA consults with other institutions' opinions in order to ensure that only safe products will be placed on the market.

The requirements for ensuring the safety of foodstuffs are imposed by the Sanitary and Phytosanitary Measures Agreement (SPS) of the World Trade Organization, to which the Republic of Moldova is a party. They are established on the basis of a human health risk assessment and are enforceable.

The aforementioned requirements are based on the scientific research results regarding the particularities of food and nutrition and the population health, on the identification and estimation of the safety and potential hazards of food and food contact materials, on the risk assessment and analysis of endangering human health

⁵⁶ Law No 306/2018 the food safety, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

⁵⁷ ANSA Order No 490/2021 the approval of the National Monitoring and Surveillance Programs in the fields of food safety, feed and veterinary medicinal products, plant health and quality of plant protection products for 2022, available in Romanian at:

https://ansa.gov.md/uploads/files/Ordinele%20ANSA/2021/Ord_490%20din%2021_12_2021.pdf

as a result of their consumption, on the estimation of the social and economic consequences of the consumption of dangerous and/or unsafe food.

Compliance of a foodstuff with the specific requirements applicable to that foodstuff does not prevent the competent control body from restricting its placing on the market or requesting its withdrawal from the market if there is a suspicion that, despite such compliance, the foodstuff is unsafe.

It is forbidden the production and/or placing on the market of foodstuffs and food contact materials which: do not comply with the applicable foodstuffs regulations, are dangerous and may affect human health under normal conditions of use by the consumer, taking into account the information contained in the label or made available to the consumer in another way, are unfit for human consumption, being contaminated and/or impure, or showing signs of deterioration, are falsified, did not include on the packaging or label the information provided in Article 8 of Law No 279/2017 on informing the consumer about food products⁵⁸, have expired, are not able to have their origin determined and are not traceable.

Food and food contact materials which are considered to be in breach of food regulations shall be subject to conditional use or destruction.

In determining whether any food is hazardous to health, consideration shall be taken of the following: not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations, the probable cumulative toxic effects; the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

In case of detection during the implementation of self-monitoring programs by economic operators of some products that do not correspond to the quality or safety indices, they apply the product recall procedure and announce ANSA. ANSA in turn will apply the verification of the measures implemented during the controls and will apply the risk analysis criterion to the subsequent planning of the monitoring programs by increasing the number of planned tests for certain indices, for example the application of the risk criteria provided in the Procedure on implementation and monitoring of the National Residue Monitoring Plan for live animals and animal origin products (PS/SA-PA-07/01).⁵⁹

For the implementation of the monitoring programs, ANSA uses accredited laboratories that have accredited methods for the indices monitored both nationally and internationally. The interpretation of the results obtained is based on the approved regulations.

⁵⁸ Law No 279/2017 on informing the consumer about foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105652&lang=ro

⁵⁹ The specific procedure regarding the implementation and monitoring of the National Waste Plan for live animals and products of animal origin, available in Romanian at: [http://ansa.gov.md/uploads/files/Informatii%20publice/2021/Procedura%20\(1\).pdf](http://ansa.gov.md/uploads/files/Informatii%20publice/2021/Procedura%20(1).pdf)

In the process of approving the import of certain goods, ANSA applies the import risk analysis, by checking the health status performed by the OIE. The policy on the importation of consignments of live animals is defined by the status of its membership of the OIE and the agreements signed on veterinary cooperation. Similarly, in the risk assessment, ANSA relies on the risk assessment results carried out by the OIE and the European Union.

Risk management which ensures that preventive and control measures are applied to reduce, eliminate, or avoid risks to human health from food consumption is based on the results of the risk assessment, the application of effective measures, the impartiality of the competent authority and the application of non-compliant foodstuffs in accordance with the PG-12/01 procedure.⁶⁰

Actions taken in the case of non-compliant foodstuffs. In case of identifying non-compliant results in the implementation of monitoring programs, ANSA initiates investigations and applies the requirements of normative acts in order to protect the consumer, to correctly inform the authorities and consumers about possible dangers. In order to inform consumers and society, ANSA has communication mechanisms with both state authorities and the media.

d) Establishment of the Rapid Alert System for Food and Feed (RASFF)

According to the National Action Plan for the implementation of the Association Agreement between the Republic of Moldova and the European Union, in the period 2017-2019, one of the ANSA's tasks is "Elaboration of the technical concept of the automated information system for the transmission, reception and recording of food and feed alerts".

The Rapid Alert System for Food and Feed (RASFF), at European level, is a robust automated system made up of contact points in all the European Union's member states, member organizations and in the European Commission, which exchange information on any kind of danger to consumer health. Vital information exchanged through RASFF can lead to products being recalled from the market in order to protect the consumer and ensure food safety in the European Union and beyond. The Republic of Moldova, through ANSA, has a national contact point of communication with the European Union's RASFF team.

At national level, are created premises for the regulation of a national alert system approved by Government Decision No 59/2017⁶¹, which designates the Ministry of Agriculture and Food Industry responsible for elaborating the technical concept of the system.

⁶⁰ https://www.ansa.gov.md/uploads/files/Transparenta/PROCEDURI/PG-12_01)

⁶¹ Government Decision No 59/2017, on the approval of implementing measures in the implementation of the rapid alert system for food and feed nationwide, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125631&lang=ro

To date, ANSA has carried out the following actions in order to facilitate the implementation of this regulation:

- designation of a national contact point within ANSA, responsible for receiving, transmitting the verification, withdrawing, and modifying a notification, as well as for communication between the alert networks' members;
- designation of the contact points by the alert network's members, responsible for the operation of the RASFF system at national level and the communication of the information to the national contact point;
- creation of a mailbox (e-mail) for the national contact point as well as for the network's members, where will be sent the notifications that are received through the RASFF system of the European Union;
- constantly monitoring of the European-level RASFF network. The forms for sending notifications to the members of the alert network (by e-mail) are being developed, as well as the specific internal procedure for the operation of the RASFF network at national level has already been developed.

If the Republic of Moldova is concerned about a non-compliance, either as a country of origin or destination, ANSA receives notifications by e-mail, after which, in order to protect consumers, it orders the application of the necessary measures in accordance with the legislation in force.

II. VETERINARY POLICY

5. Please provide information on the legislative framework on veterinary policy;

The veterinary policy in the Republic of Moldova is governed by the following regulatory acts:

- **Law No 221/2007 on sanitary and veterinary activity**⁶² establishing the main rules on:
 - Organization and operation of sanitary and veterinary services;
 - Strategic sanitary and veterinary activities;
 - Natural and legal persons duties and responsibilities in the sanitary veterinary field;
 - Authorization/registration of economic agents' sanitary and veterinary activities;
 - Sanitary and veterinary requirements for animal health and germinal products of animal origin;
 - Veterinary requirements for the movement of animal products and by-products;
 - Sanitary and veterinary requirements for the protection of veterinary public health;
 - Import, transit, and export of goods subject to state sanitary and veterinary control;
 - Veterinary requirements for animal protection and welfare;
 - Financing and material and technical support of sanitary and veterinary activities;
 - Delimitation of functions between supervisory and control authorities in the field of animal products' movement.
- **Law No 121/2020 on the organization and practice of the profession of veterinarian**⁶³ establishing and regulating the organization and forms of exercising the profession of veterinarian, as well as the establishment, organization, and operation of the College of Veterinarians of the Republic of Moldova as an autonomous, apolitical, and non-profit professional organization, to which all veterinarians of the Republic of Moldova belong.

⁶² Law No 221/2007 on sanitary and veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

⁶³ Law No 121/2020 on the organization and exercise of the profession of veterinarian, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122521&lang=ro

- **Government Decision No 600/2018 on the organization and functioning of the National Food Safety Agency**⁶⁴ establishing the mission, fields of activity, functions, rights, and organizational structure of the Agency.

6. Please provide information on the respective fields of responsibilities, organisation and powers of the competent institutions and authorities, in particular regarding rules on control.

In accordance with Article 3 of Law No 221/2007 on sanitary veterinary activity⁶⁵, the veterinary services in the Republic of Moldova are organized and operates as a single veterinary system, that is structured as follows:

- State sanitary veterinary services;
- Free practice sanitary veterinary activities.

State sanitary veterinary services constitute a single system, being structured from:

- ANSA, is subordinate to the Government, and has the following structure:
 - Central Apparatus;
 - territorial subdivisions for food safety, as subdivisions of the Agency with legal personality;
 - the territorial sanitary veterinary services within the territorial food safety subdivisions;
 - border inspection posts, without legal personality, operating within the structure of the Agency;
- Republican Veterinary Diagnostic Centre - the National Reference Laboratory in the veterinary and food safety field, administratively and technically subordinated to the Agency;
- Veterinary services of the Ministry of Defence, the Ministry of Internal Affairs, the Ministry of Justice, and other state institutions, technically subordinated to the Agency.

The National Food Safety Agency is the authority that ensures the organization and coordination of actions in the main areas of competence such as food safety

⁶⁴ Government Decision No 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

⁶⁵ Law No 221/2007 on sanitary veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

and quality, sanitary, veterinary, phytosanitary and food consumer protection at all stages of the food chain.

In order to carry out strategic state sanitary veterinary activities related to vaccinations, diagnostics, control, and eradication of outbreaks of infectious diseases in animals, etc., the National Food Safety Agency has recently employed 146 veterinary specialists.

Official controls are planned, executed, and included in the State Register of Controls (Automated Electronic System managed by the State Chancellery). The frequency of controls is assessed on the basis of risk assessment, a procedure approved by Government Decision No 1280/2018 for the approval of the Methodology for State control of entrepreneurial activity based on risk analysis related to the areas of competence of the National Food Safety Agency.⁶⁶

Official controls are carried out in all establishments, including export in accordance with the provisions of Law No 131/2012 on State control of entrepreneurial activity⁶⁷, Law No 50/2013 on official controls to verify compliance with feed and nutrition legislation and animal health and welfare rules⁶⁸ as well as in accordance with the General Procedure PG-19/02 "Preparation and performance of official control on the areas of competence of the National Food Safety Agency".

It should be noted that official controls are carried out using checklists drawn up in accordance with the legislation in force specific to the activity controlled. The checklists have been drawn up for all areas of competence and approved by the Order of the Ministry of Agriculture, Regional Development and Environment No 79/2019 on the approval of checklists for the control areas of the National Food Safety Agency.⁶⁹

7. Please provide information on the control system in the internal market:

a) Live animals; semen, ova, and embryos;

According to the *Law No 121/2020* on veterinary sanitary activity⁷⁰, the trade and internal movement of live animals and germplasm of animal origin is carried out

⁶⁶ Government Decision No 1280/2018 for the approval of the Methodology regarding state control over entrepreneurial activity based on the risk analysis related to the areas of competence of ANSA, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112486&lang=ro

⁶⁷ Law No 131/2012 on state control over entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro#

⁶⁸ Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

⁶⁹ Order of the Ministry of Agriculture No 79/2019 on the approval of checklists for ANSA control areas, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130930&lang=ro

⁷⁰ Law No 221/2007 on veterinary sanitary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

on the basis of veterinary sanitary certificates, which are issued by official veterinarians under the following conditions:

- strict compliance by veterinarians with ethical and professional rules;
- the inclusion in the veterinary health certificates of data which are not authenticated by the official veterinarian issuing the certificates is not permitted;
- compliance with international requirements concerning the principles for the preparation and drawing up of veterinary health certificates.

Internal movement, import, transit, export, placing on the market and trade in live animals shall be carried out on the basis of the following documents:

- the veterinary certificate;
- the movement form (F2);
- the individual passport for bovine animals;
- veterinary authorisation for means of transport (in the case of transport by means of transport).

With a view to the veterinary sanitary certification of animal movements and the application of the concept of zoning and regionalisation, the territorial subdivisions for food safety shall define or qualify the health status of animals in livestock holdings and epidemiological zones or regions in the Republic of Moldova in relation to specific animal diseases, established by ANSA on the basis of the programme of strategic actions for the surveillance, prevention and control of animal diseases, for the prevention of the transmission of diseases from animals to humans and for the protection of the environment, under the conditions laid down in the veterinary sanitary legislation and for the veterinary sanitary safety of products of animal origin.

b) Animal products;

The supervision of units producing/processing food of animal origin shall be carried out in accordance with the Annual Plan of official controls which is drawn up in accordance with Law No 50/2013 on official controls to verify compliance with feed and foodstuff legislation and animal health and welfare rules⁷¹, that partially transposed Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and foodstuff legislation, animal health and animal welfare rules and the performance of official controls is carried out under General Procedure: PG-13/02 "Preparation and performance of official controls in

⁷¹ Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

establishments producing and/or producing foodstuffs of animal origin to ensure that food business operators"⁷².

c) Certification;

Veterinary certification is carried out in accordance with Law No 221/2007 on veterinary health activity⁷³, Government Decision No 385/2009 on certain measures for the organisation and performance of veterinary certification⁷⁴ and under Specific Procedure PS/SA-PA-03/01 Certification of foodstuffs of animal origin for export⁷⁵.

The authorised veterinarian shall issue veterinary certificates for export in accordance with the specific PS/SA Procedure for the Certification of Food of Animal Origin for Export, in accordance with the Procedure, the official veterinarian/ANSA inspector shall not sign blank or incomplete veterinary certificates or veterinary certificates relating to products which he has not inspected, or which are not under his control. The consignment certification process comprises the following steps:

- Submission of application for certification and sampling
- Inspection of the lot with sampling
- Control of documents
- Identity check and physical check of the lot
- Certification decision
- Completion and issue of certificate
- Sealing of consignment

At the same time, a list of official veterinarians authorised to sign veterinary certificates for export is drawn up and approved annually by order of the Director-General of ANSA.

In accordance with ANSA Order No 158/2013⁷⁶ veterinary specialists shall have a satisfactory knowledge of veterinary health legislation in relation to the animals or

⁷² General Procedure: PG-13/02 "Preparation and performance of official controls in establishments producing and/or producing foodstuffs of animal origin to ensure that food business operators", available in Romanian at: https://www.ansa.gov.md/uploads/files/CONTROALEoficiale/2022/PG-19_02%20Pregatirea%20%C8%99i%20efectuarea%20controlului%20pe%20domeniile%20de%20competen%C8%9B%C4%83%20ANSA%20%2C%20Ordin%20%E2%84%96%20122.pdf

⁷³ Law No 221/2007 on veterinary sanitary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

⁷⁴ Government Decision No 385/2009 on certain measures for the organisation and performance of veterinary certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114296&lang=ro

⁷⁵ Specific Procedure PS/SA-PA-03/01 Certification of foodstuffs of animal origin for export, available in Romanian at: <https://www.ansa.gov.md/ro/content/import-export>

⁷⁶ ANSA Order No 158/2013 on the approval of the Regulation laying down the rules on veterinary certificates and standard forms, available in Romanian at: <http://www.ansa.gov.md/uploads/files/Ordinele%20ANSA/Ordin%20158-2013.pdf>

products to be certified, and in general be informed of the regulations to be observed when issuing certificates, and if necessary, the nature and extent of the investigations, tests and examinations carried out prior to certification. Veterinary specialists shall not include in the veterinary certificate information of which they are not personally aware or which they cannot verify.

The veterinary certificate shall be issued for goods subject to State veterinary sanitary control and supervision as follows:

- the certificate shall be drawn up in the State language using clear terminology;
- if necessary, the certificate shall be accompanied by an official translation into the language of the country of destination or transit or by certificates in accordance with the models of the countries concerned, completed in the prescribed manner.

The content of the certificate shall not include words and phrases which may be misinterpreted.

Sanitary - veterinary certificates shall be printed on standard blankets in accordance with the models established by the ANSA and shall be issued on the strict record of the territorial subdivisions for food safety. Blank usage reports are submitted monthly to the Agency. The serial number (letters) and serial number (figures) are printed on the blanks of the health certificates.

The veterinary certificate is a public document containing details of the owner, identity, origin and health of the animal and guarantees that the animals concerned have been subjected to the measures prescribed in the programme of strategic actions for the surveillance, prevention and control of animal diseases, the prevention of transmission of diseases from animals to humans and the protection of the environment, that the animals intended for slaughter have been included in the residue monitoring programme and that the withdrawal period has expired for any veterinary medicinal products administered to the animal. The territorial subdivision for food safety issues veterinary certificates for animals in its epizootiological territory only if the provisions given here and the provisions of other animal trade regulations have been met. Such certificates shall be signed by the authorised veterinarian, full name printed and stamped.

The veterinary certificate is issued for each animal individually or for several animals of the same species and category if they belong to the same owner. Quantities of animals are expressed in numbers of individual animals, except for fish, which are expressed in kilograms, and bees in numbers of hives. Such a certificate is valid for 72 hours from the day of issue.

Veterinary certificates for pet animals intended for movement out of the country are issued by official territorial veterinarians appointed by the heads of the

district/municipal food safety directorates. The movement of pets for non-commercial purposes on the territory of the Republic of Moldova is not subject to compulsory veterinary certification. Certificates shall be completed in one original copy and one copy for each commodity (economic agent, natural person) and issuing institution. The originals of the veterinary certificates shall always accompany the certified goods. The completed veterinary certificates are compulsorily kept for a period of three years in the issuing institutions.

d) Mutual assistance;

In its areas of activity, the Agency cooperates with central and local public administration authorities, competent control bodies, non-commercial organisations, and international bodies.

e) Safeguard measures;

In the process of trade, transit or import of live animals, germinating material, products and by-products of animal origin subject to veterinary supervision and control, the National Agency for Food Safety in accordance with Article 21 of Law 221/2007 on veterinary health activity has the right to order, in certain cases (outbreak of communicable diseases on the territory of the Republic of Moldova, food-borne toxicosis, non-compliant food products), to take special protective measures against any risk that may affect animal health, public health, animal protection, environmental protection and safety of animal products.

At the same time, in accordance with the provisions of Article 18 of Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules, if there is a suspicion of non-compliance with the legislation or if there are doubts as to the actual destination of the consignment or the correspondence between the consignment and the certified guarantees, the competent authority shall carry out official controls to confirm or eliminate the suspicion or doubt. The competent authority shall officially detain the consignment until the results of the official controls have been obtained”.

f) Computer system (TRACES);

Since the FBO cannot make the notification (CHED-A, CHED-P, CHED-D) in TRACESNT within 24 hours before the arrival of the shipment at the border, it is not possible to manage the traceability of the goods from the border to the final destination. It was possible to manage traceability in TRACES CLASSIC.

g) Funding of checks.

As ANSA is an authority with control attributions, in accordance with paragraph 4 of the Regulation on the organization and functioning of the National Agency for Food Safety approved by Government Decision No 600/2018⁷⁷, the financing and technical and material insurance of the Agency is made from the state budget and from other means not prohibited by law.

At the same time, the Agency's inspectors provide services against payment. Fees for services rendered are approved by Government Decision No 90/2019 on the approval of the Methodology for the calculation of fees for services rendered by the National Food Safety Agency, as well as the Nomenclature of services rendered by the National Food Safety Agency and their fees⁷⁸.

8. Please provide information on the control system for imports:

The control of the import of goods under the control of the National Food Safety Agency is carried out by the inspectors from the Border Inspection Posts.

a) Live animals:

Law No 221/2007 on sanitary-veterinary activity.⁷⁹

Law No 231/2006 on animal identification and registration.⁸⁰

Government Decision No 938/2018 for the approval of the Regulation on the way of crossing the state border of goods subject to control by the National Food Safety Agency.⁸¹

⁷⁷ Government Decision No 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

⁷⁸ Government Decision No 90/2019 regarding the approval of the Methodology for calculating the tariffs for the services provided by the National Agency for Food Safety, as well as the Nomenclature of services provided by National Agency for Food Safety and of tariffs on them, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125644&lang=ro

⁷⁹ Law No 221/2007 the veterinary health activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=

⁸⁰ Law No 231/2006 on the identification and registration of animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107354&lang=ro#

⁸¹ Government Decision No 938/2018 for the approval of the Regulation on the way of crossing the state border of goods subject to control by ANSA, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125641&lang=ro

Government Decision No 1099/2008 on animal health rules on imports of animals (harmonized with Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC, and 90/675/EEC).⁸²

In order to ensure that the imported animals are subject to veterinary checks, the National Food Safety Agency and the official veterinarians at the sanitary-veterinary checkpoints organized within the customs posts, for the monitoring of the import operation, cooperate with the other inspection services, the purpose of streamlining the supervision of animal imports.

Each consignment of imported animals shall be subject to a documentary check and an identity check by the official veterinarian at the health post organized at the customs post in order to verify the origin of the animals, their subsequent destination, the veracity of the data, contained in the sanitary-veterinary documents.

The official veterinarian of the sanitary-veterinary control post organized at the customs post shall carry out the physical inspection of the animals presented at the border, ensuring, in particular, that the biungulate animals and equidae are unloaded under his supervision.

The physical check includes, in particular, a clinical examination of the animals to ensure that they comply with the data provided in the veterinary document accompanying the group of animals and that they are clinically healthy.

All expenses related to sanitary-veterinary checks shall be borne by the consignor, the consignee, or their representative, without any compensation from the state.

The importation of animals is prohibited if:

- The animals come from the territory or from a part of the territory of a country which is not free from certain epizootic diseases set out in a list drawn up and approved by ANSA;
- Animals are sick or suspected of being sick or contaminated with a contagious disease or present a risk to public or animal health;
- The exporter did not comply with the sanitary-veterinary requirements of the Republic of Moldova;
- The animals are not fit to continue the journey;

⁸² Government Decision No 1099/2008 on the sanitary-veterinary rules on sanitary-veterinary controls on the importation of animals, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=114209&lang=ro

- The veterinary document accompanying the animals concerned shall not be drawn up in accordance with the requirements laid down.

If one of the following infectious diseases **occurs or spreads in the territory of an animal exporting country** (foot-and-mouth disease; classical swine fever; African swine fever; swine vesicular disease; Newcastle disease; bovine plague; small ruminant plague; vesicular stomatitis catarrhal fever, African horse sickness, equine viral encephalomyelitis, Teschen disease, bird flu, smallpox and goat smallpox, contagious nodular dermatosis, great rift valley fever, contagious bovine pleuropneumonia animal health or public health or, if justified by any other serious animal health reason, in particular following the findings of the official veterinarians of the veterinary control posts organized at the customs posts), ANSA takes without delay, depending on the severity of the situation, one of the following measures:

- Suspension of imports of animals from that country;
- Establish special conditions for animals from all or part of the country.

If, on the occasion of one of the veterinary checks provided for in this Veterinary Regulation, **it is found that the consignment of animals could constitute a danger to animal or public health**, ANSA shall immediately take the following measures:

A. Detention and destruction of the consignment in question;

B. Immediate information of the other sanitary-veterinary control posts organized within the customs posts about the findings made and the origin of the animals.

b) Imports of products, including food, feed, and animal by-products:

Law No 221/2007 on sanitary-veterinary activity.

Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules (transposes Titles I, II, III, V, VI (Chapter II) and VII (Chapter I) of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure verification of compliance with feed and food law and animal health and animal welfare rules.

Law No 306/2018 on food safety.⁸³

Government Decision No 938/2018 for the approval of the Regulation on the way of crossing the state border of goods subject to control by the National Food Safety Agency.

⁸³ Law No 306/2018 on food safety, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

Government Decision No 1408/2008 regarding the approval of some sanitary-veterinary norms⁸⁴ (transposes Council **Directive 2002/99/EC** of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption; **Council Directive 97/78/EC** of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries; and harmonized with: **European Commission Decision 94/360/EC** of 20 May 1994 on the reduced frequency of physical checks on certain consignments of imported products from third countries; **Regulation (EC) No 136/2004** of the European Commission of 22 January 2004 laying down the procedures for veterinary checks at Community border inspection posts on imports of products from third countries).

ANSA shall take measures to ensure that products of animal origin intended for human consumption are imported from other countries only if they comply with the requirements applicable to all stages of production, processing, and distribution of these products of animal origin, or if they offer equivalent animal health guarantees.

In order to ensure compliance with the general obligations, the list of countries and regions of the countries from which imports of products of animal origin are permitted may be established; a country should appear on such a list only if a visit of the Agency's experts takes place in that country and it is demonstrated that the competent veterinary authority of that State ensures adequate guarantees regarding the conformity of animal products with the legislation of the Republic of Moldova.

ANSA shall draw up and update the lists taking into account:

- the legislation of the country;
- the organization of the competent veterinary authority of that country and its inspection services, the competence of the services concerned, the supervision to which the services are subject and the means at their disposal, including the capacity of the staff, to enforce the law effectively;
- the current animal health requirements, which apply to the production, manufacture, handling, storage, and delivery of products of animal origin intended for the Republic of Moldova;
- assurances that may be given by the central competent authority of the country regarding compliance or equivalent with the relevant animal health conditions;
- any experience of marketing the product of animal origin originating in a country and the results of any import controls carried out;
- the results of the veterinary inspections carried out by the Agency's experts in that country;

⁸⁴ Government Decision No 1408/2008 regarding the approval of some sanitary-veterinary norms, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125561&lang=ro

- the health status of the herd, other domestic animals, and wild animals in that country, in particular in relation to exotic animal diseases and any aspect of the general health situation in the country which could pose a risk to public health or animals from the Republic of Moldova;
- the regularity, speed, and accuracy with which that country provides information on the presence of infectious and contagious diseases in its territory, in particular notifiable diseases listed by the World Organization for Animal Health (OIE) or, in the case of fish farming, notifiable listed diseases in the Aquatic Animal Health Code of the World Organization for Animal Health;
- the rules in force in this country on the prevention and control of infectious or contagious animal diseases, their implementation, including the rules on imports from other countries.

ANSA shall adopt versions of all lists updated in accordance with this point to make them available to the public; the lists drawn up may be combined with other lists drawn up for public or animal health purposes which also include models of veterinary certificates.

The import conditions for animals and products of animal origin obtained from them must be drawn up in accordance with OIE requirements, considering the epizootic situation in the country or countries concerned.

Organization and effects of controls

Each consignment shall be subject to veterinary checks at the sanitary-veterinary control post organized at the customs posts by the official veterinarians, as well as under the control of documents relating to products of animal origin to establish that the information in the veterinary certificates or documents correspond to the information previously provided.

For each consignment, the official veterinarian shall consult the database on the computerization of veterinary import procedures, ensuring that all operations necessary for updating the database are carried out.

The official veterinarian of the veterinary inspection post, organized within the customs posts, shall carry out the following checks:

- checking the identity of each consignment, in order to verify whether the products correspond to the information contained in the certificates or accompanying documents;
- the physical inspection of each consignment to check that the products of animal origin satisfy the veterinary requirements and are in a suitable condition so that they can be used for the purposes specified in the veterinary certificate or accompanying document. These checks must be

carried out in accordance with the criteria set out in Annex No 2 to this Sanitary-Veterinary Norm;

- any laboratory tests performed on the spot;
- any official sampling required for the implementation of monitoring programs.

If such checks prove that the products of animal origin do not satisfy the import conditions or if such checks reveal an irregularity, the consignor or his representative shall manage the consignment of products in accordance with point 21 (a) - b) of the Government Decision No 1243/2007 "On the approval of the Sanitary Veterinary Norm on veterinary sanitary controls applicable to trade in animals and products of animal origin"⁸⁵ and namely the destruction of products; or the use of the products for other purposes, including their return to the establishment of origin, with their placement at the respective customs destination.

Until the products of animal origin referred to in this point have been re-dispatched or until the reasons for rejection have been confirmed, the official veterinarian at the sanitary-veterinary control post, organized within the customs posts, shall store the products concerned under.

The person responsible for the load or his representative shall bear the costs of the process of repeated dispatch or destruction of the consignment or use of the product for other purposes.

c) Safeguard measures

Border inspection posts carry out a complex of measures aimed at protecting the territory of the Republic of Moldova from the entry or introduction from other states of products that do not meet sanitary-veterinary requirements, ensuring the traceability of these products, preventing the spread of infectious diseases, controlling the import of animals, products, and raw materials of animal origin as well as feed.

In accordance with Article 21 of Law No 221/2007 on sanitary veterinary activity "In the process of trade, transit or import of live animals, germinal products, products and by-products of animal origin subject to veterinary surveillance and control, the Agency shall, in certain cases, take special protection measures. against any risk likely to affect animal health, public health, animal welfare, environmental protection, and the safety of products of animal origin".

At the same time, in accordance with the provisions of Article 18 of Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules. "If there is a suspicion of non-compliance if there is any doubt as to the actual destination of the consignment or the correspondence

⁸⁵ Government Decision No 1243/2007 on the approval of the Sanitary Veterinary Norm on veterinary sanitary controls applicable to trade in animals and products of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=23470&lang=ro

between the consignment and the certified guarantees, the competent authority shall carry out official checks to confirm or remove the suspicion or doubt. The competent authority shall officially detain the consignment until the results of the official controls have been obtained."

d) Border Inspection Posts (BIPs)

The construction of border inspection posts is an important step in advancing the Republic of Moldova in carrying out the actions provided for in the Association Agreement between the Republic of Moldova and the European Union.

In the period 2016-2021, with the support of the World Bank project, 5 border inspection posts were built located in the customs posts from Tudora, Criva, Leuseni and Giurgiulesti. These border inspection posts comply with all the requirements and requirements of the European Union.

List of border inspection posts

- Leuseni – Albita border inspection post (Including Calea ferata, Ungheni);
- Giurgiulesti border inspection post (Including Galați / Port / Reni, Cahul and Calea ferata, Etulia);
- Criva – Mamaliga border inspection post (Including Valcinet Railway);
- Tudora – Starokazacie border inspection post;
- Chisinau border inspection post (Including Air Station, Railway and Post Office, Chisinau);
- Pervomaisk – Cuciurgan border inspection post (Including Railway, Cuciurgan);
- Goienii Noi – Platonovo border inspection post.

e) Computer system (TRACES)

Currently, the ANSA has access to the TRACES NT information system. Through this system, the Agency issues veterinary certificates for the export of animal products to the European Union.

The Republic of Moldova has bilaterally coordinated with the European Union 23 models of veterinary health certificates that have been integrated in TRACES NT and that are issued through the system by the competent authorities of the EU states to the Republic of Moldova.

At the same time, we inform you that currently TRACESNT is not possible to use when importing goods into the Republic of Moldova. Importing economic operators are not able to notify the Border Inspection Posts 24 hours in advance of the arrival of consignments as they did through the old system platform (TRACES CLASSIC), so they need additional efforts and resources from the Agency to

ensure the traceability of products from the state border crossing points to the place of destination.

f) Financing of controls

In accordance with point 4 of the Regulation on the organization and functioning of the National Food Safety Agency approved by Government Decision No 600/2018⁸⁶, the financing and the technical-material insurance of the Agency are carried out from the account of the state budget and of other means that are not prohibited by law.

At the same time, the Agency's inspectors provide paid services. Fees for the services provided are approved by Government Decision No 90/2019 on the approval of the Methodology for calculating tariffs for services provided by the National Food Safety Agency, as well as the Nomenclature of services provided by the National Food Safety Agency and their tariffs.⁸⁷

9. Please provide information on the identification of animals and registration of their movements:

- a) Cattle animals (including central cattle database);**
- b) Sheep and goats;**
- c) Pigs;**
- d) Equidae.**

In the Republic of Moldova, the animal identification and traceability system started in October 2007.

All animals of the cattle, sheep, goats, pigs, equine, donkey, and offspring species obtained by crossing them, all holdings (households) in which these animals are maintained or handled, whether farm, sheepfold, fair, slaughterhouse, are identified and is registered in the automated information system "State Register of Animals".

The identification, registration and traceability of animals is regulated by Law No 231/2006 on the identification and registration of animals⁸⁸ and Government Decision No 1093/2007 for the approval of the Regulation on the procedures and documents related to the Animal Identification and Traceability System⁸⁹

⁸⁶ Government Decision No 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

⁸⁷ Law No 90/2019 on the approval of the Methodology for calculated by the g tariffs for services provided ANSA, as well as the Nomenclature of services provided by the ANSA and their tariffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125644&lang=ro

⁸⁸ Law No 231/2006 on the identification and registration of animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107354&lang=ro

⁸⁹ Government Decision No 1093/2007 for the approval of the Regulation on the procedures and documents related to the Animal Identification and Traceability System, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125552&lang=ro#

harmonized with the provisions of the requirements of Article 48.4 of the Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; as well as Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97; partially transposes the provisions of Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals; and Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals.

The Automated Information System "State Register of Animals" (SIA "RSA") is a complex of elements and procedures that allow the identification and registration of animals and farms, ensuring compliance with the principle of traceability, which is managed by a single operator.

The subjects of the legal relations in the field of identification of animal registration and traceability are:

- Ministry of Agriculture and Food Industry - holder of the State Register of Animals.
- Information Technology and Cyber Security Service, through its territorial offices - the holder of the State Register of Animals, the provider of the data of the State Register of Animals, the registrar, and the sub-registrar (responsible for issuing identification and event declaration forms);
- National Food Safety Agency, through its territorial subdivisions for food safety, is the registrar and sub-registrar (responsible for issuing movement forms) and responsible for carrying out official controls on compliance with the identification, registration, and traceability of animals.

The owners of the animals have the obligation to identify the animals and to present, within 15 days from the birth, the respective information to the national operator for its inclusion in the State Register of Animals.

The owners of the animals have the obligation to declare to the territorial subdivision for food safety, within 7 days, the purchase (including import) or alienation (including export) of the animals.

The owners of the animals have the obligation to declare to the registrar, within 7 days, the death, disappearance, and slaughter of the animals.

The animals will be identified and registered within 20 days of birth, and in the case of pigs – 20 –60 days, lambs, and kids - 60 days after birth.

The animals will not leave the holding until they have been identified.

Animals shall be identified by the following means of identification:

- for cattle - two identical ear tags applied to each ear, with the free issuance by the national operator of the individual passport for cattle;
- in sheep, goats, pigs - of an ear tag;
- for horses, donkeys and their descendants obtained by crossing them - a transponder.

Imported animals shall be identified and registered within 15 days of the date of importation, but before the animals leave the holding, keeping the data of origin mentioned in the accompanying documents of the animals.

Means of identification of imported animals will be handed over to the territorial subdivision for food safety according to the national system, except for animals from countries that comply with international requirements for the identification and registration of animals.

The movement of animals on the territory of the Republic of Moldova, except for the cases of their maintenance, is carried out on the basis of the following documents:

- the sanitary-veterinary certificate;
- the movement form (F2);
- individual passport for cattle (in case of transport of cattle);
- the sanitary-veterinary authorization for the means of transport (in case of transport with a means of transport).

Equidae from the Republic of Moldova do not have a document (passport) for the identification of registered equidae that allows the reconstitution of animal origin and contains all the information on the genealogy of equidae as provided for in Commission Implementing Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae.

10. Please provide information on the animal disease control legislative framework and implementing mechanisms, including respective fields of responsibilities, organisation and powers of the competent authorities and institutions. Also please provide information on animal disease control measures:

- a) Notification of animal diseases; Foot and Mouth disease; Classical swine fever; African swine fever; African horse sickness; Avian influenza; Newcastle disease; Fish and mollusc diseases; Bluetongue disease; Transmissible Spongiform Encephalopathies; Zoonosis and other diseases;**
- b) Trade in live animals, semen, ova, and embryos;**
- c) Non-commercial movements of pet animals;**
- d) Prohibition of substances and residue monitoring;**
- e) Import requirements for live animals and animal products;**
- f) Bilateral veterinary international agreements with EU Member States, candidate countries and other third countries (if any).**

Disease control is regulated by the following regulations:

Law No 221/2007 on sanitary veterinary activity.⁹⁰

Foot-and-Mouth disease:

Government Decision No 698/2014 for the approval of the Sanitary-Veterinary Rule on measures to combat Foot-and-Mouth disease⁹¹ partially transpose Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC.

Classical swine fever/African swine fever:

Government Decision No 1368/2016 regarding the approval of some sanitary-veterinary rules⁹² transposing Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of Classical swine fever and Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending of Directive 92/119/EEC on Teschen disease and African swine fever.

Government Decision No 1374/2016 approving the Sanitary-Veterinary Rule laying down general measures for the control of animal diseases and specific measures relating to swine vesicular disease⁹³ transposing Council Directive

⁹⁰ Law No 221/2007 on sanitary veterinary activity, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125191&lang=en

⁹¹ Government Decision No 698/2014 for the approval of the Sanitary-Veterinary Rule on measures to combat Foot-and-Mouth disease, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114718&lang=ro

⁹² Government Decision No 1368/2016 regarding the approval of some sanitary-veterinary rules, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114293&lang=en

⁹³ Government Decision No 1374/2016 approving the Sanitary-Veterinary Rule laying down general measures for the control of animal diseases and specific measures relating to swine vesicular disease, available in Romanian at: https://www.legis.md/search/getResults?doc_id=111712&lang=en

92/119/EEC of 17 December 1992 laying down general Community measures for the control of animal diseases and for specific measures against swine vesicular disease.

African horse sickness:

Government Decision No 771/2012 for the approval of the Sanitary-Veterinary Rule regarding African horse sickness⁹⁴ harmonized with Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness.

African horse sickness:

Government Decision No 939/2008 for the approval of the Sanitary-Veterinary Rule regarding the measures for surveillance, control and combating of avian influenza⁹⁵ transposing Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC; European Commission Decision No 2017/263 of 14 February 2017 on risk mitigation measures, enhanced biosecurity measures and early detection systems in relation to the risks posed by wild birds of highly pathogenic avian influenza virus transmission to poultry; European Commission Decision No 2006/563/EC of 11 August 2006 concerning certain protection measures in relation to the presence of avian influenza caused by highly pathogenic strains of the H5N1 subtype in wild birds in the Community and repealing Decision No 2006/115/EC; and Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments.

Newcastle disease:

Government Decision No 1085/2017 on the establishment of measures to combat Newcastle disease⁹⁶ transposing Directive 92/66/EEC of the Council of the European Communities of 14 July 1992 laying down Community measures for the control of Newcastle disease.

Bluetongue disease:

Government Decision No 1007/2008 on the approval of Sanitary-Veterinary Rules⁹⁷ transposing Council Directive 2000/75/EC of 20 November 2000 laying

⁹⁴ Government Decision No 771/2012 for the approval of the Sanitary-Veterinary Rule regarding African horse sickness, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114387&lang=en

⁹⁵ Government Decision No 939/2008 for the approval of the Sanitary-Veterinary Rule regarding the measures for surveillance, control and combating of avian influenza, available in Romanian at: https://www.legis.md/search/getResults?doc_id=103477&lang=en

⁹⁶ Government Decision No 1085/2017 on the establishment of measures to combat Newcastle disease, available in Romanian at: https://www.legis.md/search/getResults?doc_id=102426&lang=en

⁹⁷ Government Decision No 1007/2008 on the approval of Sanitary-Veterinary Rules, available in Romanian at https://www.legis.md/search/getResults?doc_id=114206&lang=en#

down specific provisions concerning measures to control and eradicate bluetongue and Regulation No 1226/2007 of 26 October 2007 on implementing rules of Council Directive 2000/75/EC on the control, monitoring, surveillance of bluetongue and restrictions on the movement of animals of susceptible species.

Transmissible spongiform encephalopathy:

Government Decision No 404/2016 on the approval of the Sanitary-Veterinary Rule regarding the establishment of control and surveillance rules for transmissible spongiform encephalopathies⁹⁸ transposing Regulation (EC) No 999/2001 of the European Parliament and of the Council of the European Union of 22 May 2001 laying down rules for the prevention, control, and eradication of certain transmissible spongiform encephalopathies.

Zoonosis monitoring:

Government Decision No 264/2011 approving the Regulation on the monitoring of zoonoses and zoonotic agents⁹⁹ transposing Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents.

Salmonella:

Government Decision No 398/2012 for the approval of Sanitary-Veterinary Rules regarding the control and reduction of the prevalence of Salmonella in livestock¹⁰⁰ transposing Regulation (EC) No 2160/2003 of 17 November 2003 on the control of salmonella and other specific zoonotic agents present in the food web, Commission Regulation (EC) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council concerning the EU target for the reduction of the prevalence of certain salmonella serotypes in adult breeding flocks of Gallus gallus, Commission Regulation (EC) No 584/2008 of 20 June 2008 implementing Regulation (EU) No 2160/2003 of the European Parliament and of the Council on the Community target for reducing the prevalence of Salmonella Enteritidis and Salmonella Typhimurium in turkeys, Commission Regulation (EC) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council on the establishment of an EU target for the reduction of the prevalence of certain salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Regulation (EU) No Commission Regulation (EC) No 200/2010, Regulation (EC) No.1177/2006 of 1 August 2006 implementing

⁹⁸ Government Decision No 404/2016 on the approval of the Sanitary-Veterinary Rule regarding the establishment of control and surveillance rules for transmissible spongiform encephalopathies, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125705&lang=en

⁹⁹ Government Decision No 264/2011 approving the Regulation on the monitoring of zoonoses and zoonotic agents, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125617&lang=en

¹⁰⁰ Government Decision No 398/2012 for the approval of Sanitary-Veterinary Rules regarding the control and reduction of the prevalence of Salmonella in livestock, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125619&lang=ro

Regulation (EU) No 2160/2003 of the European Parliament and of the Council on requirements for the use of specific control methods in national control programs for salmonella in poultry, Commission Regulation (EC) No 200/2012 of 8 March 2012 on a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in poultry flocks, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

Fish and mollusc disease:

Government Decision No 239/2009 on the approval of the Sanitary-Veterinary Rule on the health conditions of animals and aquaculture products and measures to prevent and control certain diseases in aquatic animals¹⁰¹ transposing Council Directive 2006/88/EC of 24 October 2006 on animal health conditions applicable to animals and aquaculture products and on the prevention of certain diseases in aquatic animals and measures to combat those diseases.

The National Food Safety Agency, which implements specific control and eradication measures at the local level through Territorial (District) Subdivisions for Food Safety is responsible for the control and eradication of animal diseases.

ANSA develops and implements the Program of Strategic Actions for the Surveillance, Prophylaxis and Control of Animal Diseases, the Prevention of the Transmission of Diseases from Animals to Humans and the Protection of the Environment, which is reviewed annually and approved by Order of the Director-General.

ANSA establishes the veterinary sanitary requirements for the announcement, declaration, internal and international notification of any suspicion of illness or disease.

Cases of illness caused by the production of biopreparations or for the performance of scientific research or testing of veterinary medicinal products are exempted from the obligation to be announced and notified.

The detection of transmissible animal diseases is performed by carrying out active and passive veterinary sanitary surveillance actions in order to establish their incidence and prevalence.

In order to prevent the spread of communicable diseases through the movement of live animals, germinal products, products, and by-products of animal origin subject to veterinary health surveillance and control, the Agency shall develop veterinary health rules which shall be approved by the Government.

ANSA establishes and updates the list of communicable animal diseases that are subject to official declaration and notification, as well as those subject to

¹⁰¹ Government Decision No 239/2009 on the approval of the Sanitary-Veterinary Rule on the health conditions of animals and aquaculture products and measures to prevent and control certain diseases in aquatic animals, available in Romanian at: https://www.legis.md/search/getResults?doc_id=96390&lang=en

quarantine, differentiated according to the severity of the disease, the degree of spreadability, the particularities of the manner and routes of transmission, and economic and social implications.

Owners of animals slaughtered, killed, or otherwise affected by the outbreak of communicable diseases, outbreaks shall be compensated under conditions to be determined by Government Decision.

ANSA draws up the necessary documentation for obtaining the status of a country or free zone, or officially free, of communicable diseases and orders the application of measures to maintain this status.

ANSA carries out the division into zones and regionalization of the territory of the Republic of Moldova according to the foreseen diseases.

Prophylactic vaccinations are prohibited, except for those provided for in the Program of Strategic Actions for the Surveillance, Prophylaxis and Control of Animal Diseases, for the Prevention of the Transmission of Diseases from Animals to Humans and for the Protection of the Environment.

In the event of a special risk to animal health, ANSA shall order the carrying out of necessary vaccinations or other prophylactic vaccinations other than those presented in the program.

a) Notification of animal diseases; Foot and Mouth disease; Classical swine fever; African swine fever; African horse sickness; Avian influenza; Newcastle disease; Fish and mollusc diseases; Bluetongue disease; Transmissible Spongiform Encephalopathies; Zoonosis and other diseases;

The procedure for notifying officially notifiable diseases is as follows:

In case of suspicion of any of the officially notifiable animal diseases, the veterinarian (or owner of the animal) who detected the suspicion is obliged to immediately inform, within 24 hours the Territorial Subdivision for Food Safety, by telephone, fax, or e-mail. Subsequently, the official veterinarian of the Territorial Subdivisions for Food Safety, using the prescribed form containing data and responsible to implement all measures for the suppression of contagious diseases defined in the relevant regulations shall notify the Animal Health and Welfare Department of ANSA upon suspicion/confirmation, drawing up and implementing a plan of measures to combat the outbreak.¹⁰²

The competent laboratory shall inform ANSA and the Territorial Subdivisions for Food Safety of the results of the diagnostic investigation by telephone and fax or

¹⁰² The specific procedure for the official notification of animal diseases, available in Romanian at: https://www.ansa.gov.md/uploads/files/Sanitar-Veterinar/Proceduri/25_%20PS-SV-SA-01-01%20notificarea%20interna%20a%20bolilor%20oficial%20notificabile.pdf

e-mail. All laboratory test results are recorded in the Laboratory Management Information System (LIMS).

In the event of an officially notifiable disease being registered, ANSA provides notification in the OIE WAHIS system and in the EU ADIS system.

In cases of officially notifiable zoonotic diseases, the Ministry of Health and the Agency for Public Health shall be informed immediately.

For the rapid eradication of outbreaks of disease (bovine tuberculosis, Foot-and-Mouth disease, Rabies (in productive animals), Paratuberculosis, Classical swine fever, small ruminant plague, Avian plague (avian influenza), Vesicular stomatitis, Swine vesicular disease, and Smallpox) Goat, Bluetongue, Bovine Enzootic Leukosis, Bovine Spongiform Encephalopathy, Sheep Scrapie and African Swine Fever), which involves slaughtering or killing animals, compensations are awarded to owners for animals slaughtered, killed or otherwise affected, to animals slaughtered, killed or otherwise affected according to Government Decision No 645/2010.¹⁰³

b) Trade in live animals, semen, ova, and embryos;

Trade in live animals, semen, eggs, and embryos in the Republic of Moldova is regulated by the following regulations:

Law No 221/2007 on sanitary veterinary activity.

Government Decision No 1408/2008 on the approval of sanitary-veterinary Rules¹⁰⁴ which includes:

- The animal sanitary veterinary standard laying down the animal health requirements governing the production, processing, distribution and placing on the market of products of animal origin intended for human consumption, harmonized with the provisions of Council of Europe Directive 2002/99/EC of 16 December 2002 laying down animal health rules governing the production, processing, distribution, and introduction of products of animal origin intended for human consumption.
- The veterinary standard laying down certain basic principles governing the organization of veterinary checks on the import and marketing of products of animal origin, harmonized with the provisions of Council Directive 97/78/EC of 18 December 1997 laying down the basic principles of the

¹⁰³ Government Decision No 645/2010 for the approval of the Regulation on the calculation of compensation to owners of animals slaughtered, killed or otherwise affected as a result of the rapid elimination of outbreaks of communicable animal diseases, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=91997&lang=en

¹⁰⁴ Government Decision No 1408/2008 on the approval of sanitary-veterinary Rules, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125561&lang=en

organization of veterinary checks on products originating in third countries and introduced into the Community;

- The veterinary standard on the frequency of physical checks on certain consignments of imported animal products harmonized with the provisions of European Commission Decision 94/360/EC of 20 May 1994 on the reduced frequency of physical checks on certain consignments of animal products. imported products from third countries;
- The sanitary-veterinary standard on the establishment of procedures for carrying out sanitary-veterinary checks on the introduction for import purposes of products of animal origin through sanitary-veterinary inspection posts organized within customs posts harmonized with Regulation (EC) No 136/2004 of the European Commission of 22 January 2004 laying down the procedures for veterinary checks at Community border inspection posts on imports of products from third countries.

Government Decision No 48/2009 on the approval of the Sanitary-Veterinary Rule on animal and public health conditions and sanitary-veterinary certification for the import into the Republic of Moldova of certain live animals and of their fresh meat¹⁰⁵ transposing EC Council Decision No 542 of 21 December 1976 on the drawing up of a list of third countries or regions thereof and the establishment of animal and public health conditions and veterinary certification for the import into the Community of certain live animals and fresh meat thereof.

Government Decision No 189/2014 on animal health rules, import and transit of certain live ungulates¹⁰⁶ which partially transposes Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC and Commission Implementing Decision of 10 May 2012 amending Annex II to Council Directive 2004/68/EC as regards the basic general criteria for a territory to be considered free from bluetongue.

Government Decision No 686/2018 on animal health conditions governing intra-Community trade in ovine and caprine animals¹⁰⁷ transposing the provisions of Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals.

¹⁰⁵ Government Decision No 48/2009 on the approval of the Sanitary-Veterinary Rule on animal and public health conditions and sanitary-veterinary certification for the import into the Republic of Moldova of certain live animals and of their fresh meat, available in Romanian at: https://www.legis.md/search/getResults?doc_id=48390&lang=en

¹⁰⁶ Government Decision No 189/2014 on animal health rules, import and transit of certain live ungulates, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114425&lang=en

¹⁰⁷ Government Decision No 686/2018 on animal health conditions governing intra-Community trade in ovine and caprine animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108819&lang=ro

Government Decision No 913/2018 for the approval of the Sanitary-Veterinary Rule on animal health conditions and certification for trade (import and export) with cattle and pigs¹⁰⁸ transposing Directive 64/432/EEC of 26 June 1964 on veterinary inspection problems affecting intra-Community trade in bovine animals and swine, as last amended by Implementing Decision (EU) No 182/2011 and Commission Decision 2004/226/EC of 4 March 2004 authorizing tests for the detection of antibodies against bovine brucellosis in the framework of Council Directive 64/432/EEC.

Government Decision No 699/2018 on animal health conditions governing the movement and import of equidae¹⁰⁹ transposing the provisions of Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and import of equidae, and Commission Decision No 95/329/EC of 25 July 1995 defining the categories of male equidae to which the viral arteritis requirement laid down in Article 15 (b) (ii) of Council Directive 90/426/EEC applies.

Government Decision No 1297/2016 for the approval of some Sanitary-Veterinary Rules regarding animal health when importing reproductive material¹¹⁰ which includes:

- The Sanitary-Veterinary Rule regarding the animal health at the import of the bovine semen material, partially transposing Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species and Council Directive No 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra - Community trade in and imports of semen of domestic animals of the bovine species.
- The animal health veterinary rule on the importation of pig semen partially transposes the Council Directive of 26 June 1990 laying down animal health requirements for intra-Community trade in and imports of semen of domestic animals of the porcine species (90/429/EEC).
- The Sanitary-Veterinary on the establishment of model health certificates for imports of semen, ova and embryos of equine animals, ovine and caprine animals, as well as ova and embryos of porcine animals transposing Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova,

¹⁰⁸ Government Decision No 913/2018 for the approval of the Sanitary-Veterinary Rule on animal health conditions and certification for trade (import and export) with cattle and pigs, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125640&lang=en

¹⁰⁹ Government Decision No 699/2018 on animal health conditions governing the movement and import of equidae, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125639&lang=en

¹¹⁰ Government Decision No 1297/2016 for the approval of some Sanitary-Veterinary Rules regarding animal health when importing reproductive material, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118521&lang=ro#

and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species.

- Sanitary-veterinary standard for the establishment of health conditions governing the placing on the market and trade (import and export) of animals, semen, ova and embryos of biungulate species (Artiodactyla), mammals belonging to the orders Lagomorpha (rabbit) and Carnivora (mink, fox, dog, cat and ferret), including birds other than chickens, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges, ratites, ostriches, transposes Council Directive 92/65/EEC of 13 July 1992 laying down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos which do not comply, as regards animal health requirements, with the special Community rules referred to in Annex A (I) to Directive 90/425/EEC.

In the Republic of Moldova, the trade, import, internal circulation, transit and export of live animals and germinal products of animal origin are carried out on the basis of veterinary health certificates, which are issued by official veterinarians based on the following conditions:

- strict observance by veterinarians of ethical and professional rules;
- the non-admission of the inclusion in the veterinary sanitary certificates of some data that are not authenticated by the official veterinarian who issues the certificates;
- observance of the international requirements regarding the principles of elaboration and elaboration of the veterinary sanitary certificates.

Internal movement, import, transit, export, placing on the market and trade in live animals shall be carried out on the basis of the following documents:

- the sanitary-veterinary certificate;
- the movement form (F2);
- individual passport for cattle;
- the sanitary-veterinary authorization for the means of transport (in case of transport by means of transport).

In order to certify the veterinary sanitary certification of animal movements and to apply the concept of division by zones and regionalization, the territorial subdivisions for food safety define or qualify the health status of animals on animal farms and epidemiological areas or regions of the Republic of Moldova in relation to specific animal diseases, established by ANSA on the basis of the Program of Strategic Actions for the Surveillance, Prophylaxis and Control of Animal Diseases, for the Prevention of the Transmission of Diseases from Animals to Humans and for the Protection of the Environment, under the conditions provided by veterinary health legislation of animal origin.

The Territorial Subdivision for Food Safety shall issue veterinary certificates for animals in its epizootiological territory only if the provisions set out herein and the provisions of other regulations on trade in animals have been complied with. Such certificates shall be signed by the authorized veterinarian, the full name printed and stamped.

The veterinary certificate shall be issued for each animal individually or for several animals of the same species and category if they belong to the same owner. The quantities of animals are expressed in number of individual animals, with the exception of fish which are expressed in kilograms, and bees in number of hives. Such a certificate is valid for 72 hours from the date of issue.

ANSA shall establish the countries and units for the import into the Republic of Moldova of live animals, products, and germinal products of animal origin, depending on the epizootic situation and compliance with veterinary sanitary requirements.

The germinating material of animal origin must be produced in specialized establishments authorized by the central veterinary health authority of the country of origin.

c) Non-commercial movements of pets

The movement of pets for non-commercial purposes in the Republic of Moldova is regulated by Government Decision No 938/2009 for the approval of some sanitary-veterinary Rules regarding the non-commercial movement of pets¹¹¹ harmonized with the provisions of Regulation (EC) No 998/2003 of the European Parliament and of the Council of the European Union of 26 May 2003 on animal health requirements for the non-commercial movement of pet animals and amending Council Directive 92/65/EEC, Decision No 2004/839/EC of the European Communities of 3 December 2004 laying down the conditions applicable to non-commercial traffic, of young dogs and cats from third countries and of the Decision of the Commission of the European Communities No 2004/824/EC of 1 December 2004 establishing a model health certificate for the non-commercial movement of dogs, cats and domestic ferrets from third countries entering the Community.

Pets to be introduced to the Republic of Moldova must meet the following requirements:

- be identified by an electronic identification device (transponder) and be implanted prior to rabies vaccination.

¹¹¹ Government Decision No 938/2009 for the approval of some sanitary-veterinary Rules regarding the non-commercial movement of pets, available in Romanian at:
https://www.legis.md/search/getResults?doc_id=78000&lang=en

- be vaccinated against rabies with an inactivated vaccine produced in accordance with the OIE Manual of Standards for Diagnostic Tests and Vaccines.
- be accompanied by a veterinary certificate including the identification data of the animal concerned, the vaccination data and the serological test result for antibodies with an acceptable positive titre (equal to 0.5 IU / ml or more), performed no more than 24 months and at least 3 months before dispatch of the animal.
- be accompanied by a passport for the international movement of pets.

Dogs and cats up to three months old, unvaccinated against rabies, may be allowed on the territory of the Republic of Moldova if they are accompanied by a passport and kept in the place where they were born, without coming into contact with wild animals. likely to be exposed to infection or if they are accompanied by their mother, on whom they are still dependent.

The entry of pets into the Republic of Moldova is allowed through 7 Border Inspection Posts, where the animals are subject to checks by ANSA inspectors.

If the checks show that the animal does not comply with the requirements laid down in this Veterinary Standard, the Agency shall take measures to:

- forced return of the animal to the country of origin;
- subjecting the animal to prophylactic quarantine under official control as long as it is necessary to meet the specific sanitary-veterinary requirements, at the expense of the owner or the person accompanying the pets;
- lastly, the euthanasia of the animal, without financial compensation, in case it is not possible to carry out the forced return or its quarantine.

Likewise, according to the Government Decision No 185/2019 on the approval of the Plan of measures for surveillance, control, and eradication of rabies in foxes in the Republic of Moldova¹¹² has already initiated the procedures for drafting a Government decision that will transpose at national level Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003.

¹¹² Government Decision No 185/2019 on the approval of the Plan of measures for surveillance, control and eradication of rabies in foxes in the Republic of Moldova, available in Romanian at: https://www.legis.md/search/getResults?doc_id=113064&lang=en

d) Prohibition of substances and residue monitoring;

In accordance with Article 27 from Law No 221/2007, the National Food Safety Agency is in charge of the development and approval of the National Residue Monitoring Plan (NRMP).

The National Residue Monitoring Plan is developed and implemented in accordance with:

- Government Decision No 298/2011 for approval of the Sanitary Veterinary Rule regarding the monitoring and control of certain substances and their residues in live animals and products thereof as well as the residues of veterinary drugs in products of animal origin¹¹³ harmonized with the provisions of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC and Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products.
- Government Decision No 942/2010 for approval of the Sanitary Veterinary Rule regarding the ban on the use of certain substances with hormonal or thyreostatic action and beta-agonists in animal breeding farms¹¹⁴ transposes Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC, and 88/299/EEC);
- Government Decision No 782/2010 on approval of the Sanitary Veterinary Rule regarding the official sampling of live animals and animal origin products transposes Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products;¹¹⁵
- Government Decision No 208/2013 the sanitary veterinary Rule regarding the sampling methods for the official control of mycotoxin levels in foodstuffs of animal origin partially transposes Commission Regulation

¹¹³ Government Decision No 298/2011 for approval of the Sanitary Veterinary Rule regarding the monitoring and control of certain substances and their residues in live animals and products thereof as well as the residues of veterinary drugs in products of animal origin responses, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114327&lang=ro

¹¹⁴ Government Decision No 942/2010 for approval of the Sanitary Veterinary Rule regarding the ban on the use of certain substances with hormonal or thyreostatic action and beta-agonists in animal breeding farms, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125570&lang=en

¹¹⁵ Government Decision No 782/2010 on approval of the Sanitary Veterinary Rule regarding the official sampling of live animals and animal origin products, available in Romanian at: https://www.legis.md/search/getResults?doc_id=21212&lang=en

(EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs ;¹¹⁶

- The Government Decision No 1004/2010 on the approval of sampling methods sampling methods for the official control of pesticide residues in and on plants and products of plant and animal origin transpose Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.¹¹⁷
- Government Decision No 1191/2010 concerning the maximum permitted limits of residues of plant protection products in or on food and feed of plant and animal origin partially transposes Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC;¹¹⁸
- Government Decision No 520/2010 for approval Sanitary Regulation regarding contaminants in food partially transpose Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, transposes Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs; transposes Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food; transposes Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products; transposes Council Directive 76/621/EEC of 20 July 1976 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats;¹¹⁹
- Government Decision No 941/2010 for approval rules on the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury in foods¹²⁰ transposes Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and

¹¹⁶ Government Decision No 208/2013 the sanitary veterinary Rule regarding the sampling methods for the official control of mycotoxin levels in foodstuffs of animal origin, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=125620&lang=en

¹¹⁷ Government Decision No 1004/2010 on the approval of sampling methods sampling methods for the official control of pesticide residues in and on plants and products of plant and animal origin, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125571&lang=en

¹¹⁸ Government Decision No 1191/2010 concerning the maximum permitted limits of residues of plant protection products in or on food and feed of plant and animal origin, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114320&lang=en

¹¹⁹ Government Decision No 520/2010 for approval Sanitary Regulation regarding contaminants in food, available in Romanian at: https://www.legis.md/search/getResults?doc_id=126796&lang=en

¹²⁰ Government Decision No 941/2010 for approval rules on the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury in foods , available in Romanian at: https://www.legis.md/search/getResults?doc_id=103303&lang=en

analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.);

- National Food Safety Agency Order No 5/2021 of the on the approval of the list of active substances pharmacologically and classification depending on the maximum residual limits in food of animal origin¹²¹ transposes Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

The official sampling for implementing NRMP is carried out by the official veterinarians (inspectors) within the ANSA. Official veterinarians (inspectors) designated for sampling are continuously trained and are responsible for the collection, packaging, identification, and transport of samples to accredited national laboratories, following the procedure for implementing and monitoring the NRMP.

The list of pharmacologically active substances, authorised for food-producing animals and their classification according to maximum residue limits, is approved by Annex No 1 of ANSA Order No 5/2021.

The list of pharmacologically active substances, banned from food-producing animals, is approved by Annex No 2 of ANSA Order No 5/2021.

Both lists are identical with provisions of Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification according to maximum residue limits in foodstuffs of animal origin.

Also, according to Government Decision No 942/2010, it is forbidden placing on the market/use of: thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, estradiol 17- β and esterified derivatives thereof, of β -agonist substances, androgenic, gestagenic and estrogenic substances (with some exceptions).

e) Import requirements for live animals and animal products;

In accordance with Law No 221/2007 regarding the sanitary veterinary activity, the requirements for the export, import and transport of live animals and animal products are developed by the Ministry of Agriculture and Food Industry and are proposed for approval by the Government.

¹²¹ ANSA Order No 5/2021 of the on the approval of the list of active substances pharmacologically and classification depending on the maximum residual limits in food of animal origin, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125380&lang=en

The specific requirements for the import of live animals and animal products in relation to public health, animal health and welfare are set by ANSA in veterinary certificates and in accordance with the requirements and standards of the EU and the World Organization for Animal Health (OIE). Veterinary health certificates are initiated with each country individually, based on the request of the exporting country to ANSA.

In addition, according to Article 31 of Law No 221/2007 regarding the sanitary veterinary activity animals from importation (except for immediate slaughter) must be subjected to prophylactic quarantine for a period of 30 days, in isolated and specially arranged places, authorized by the territorial subdivisions for food safety, which allow the introduction of animals into these places only after verification of compliance with specific veterinary health requirements. During the quarantine period, the animals are subjected to clinical and immunological examinations, pathological and laboratory tests, as well as other measures aimed at the prevention and eradication of contagious diseases. All measures to be taken while the animals are in quarantine are defined by ANSA in the Program of Strategic Actions for Surveillance, Prophylaxis and Control of Animal Diseases,

ANSA shall establish the countries and units for the importation into the Republic of Moldova of live animals, products, and germinal products of animal origin, depending on the epizootic situation and compliance with veterinary sanitary requirements. The Agency shall establish, by Order of the Director-General, the list of countries and enterprises in those countries or parts thereof from which the importation of products and animal by-products intended for human consumption into the territory of the Republic of Moldova is authorized.

According to the provisions of Article 21 of Law No 221/2007 regarding the sanitary veterinary activity In the case of trade in, transit through, or importation of, live animals, germinal products, products and by-products of animal origin subject to veterinary surveillance and control, the Agency ANSA shall, in certain cases, take special measures to protect against any risk of animal health public health, animal protection, environmental protection and the safety of products of animal origin.

According to Article 29 of Law No 221/2007 regarding the sanitary veterinary activity the Ministry of Agriculture and Food Industry elaborates and presents for approval to the Government Ruleative regulations regarding the protection measures against the outbreak of diseases on the territory of some countries with which the Republic of Moldova carries out trade in live animals, products, and by-products subject to veterinary surveillance and control. An imminent risk to animal or human health, as well as the protection measures of the countries - trading partners of the Republic of Moldova, when on their territory is declared an animal disease that poses a risk to trade in live animals, germinal material of animal origin, products and by - products subject to veterinary supervision and control.

The regulatory framework for establishing import requirements for live animals and products of animal origin is as follows:

- Government Decision No 189/2014 on animal health rules, import and transit of certain live ungulates, which partially transposes Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC and Commission Decision of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2002) 1043).¹²²
- Government Decision No 357/2012 for the approval of the Sanitary-Veterinary Rule on the sale and import of poultry and eggs for hatching¹²³ transposes Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs and Commission Regulation (EC) No 617/2008 of 27 June 2008 laying down detailed rules for implementing Regulation (EC) No 1234/2007 as regards marketing standards for eggs for hatching and farmyard poultry chicks.
- Government Decision No 103/2011 for the approval of the Sanitary-Veterinary Rule regarding the requirements for the import and placing on the market of some aquaculture products¹²⁴ harmonized with the provisions of Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products , Council Regulation (EC) No 2578/2000 of 17 November 2000 amending Regulation (EC) No 2406/96 laying down common marketing standards for certain fishery products and Commission Regulation (EC) No 790/2005 of 25 May 2005 amending Council Regulation (EC) No 2406/96 laying down common marketing standards for certain fishery products.
- Government Decision No 1113/2010 approving the Sanitary-Veterinary Regulation laying down requirements for the veterinary certification for the import and placing on the market of live aquaculture animals and products obtained from them¹²⁵ transposes Commission Regulation (EC)

¹²² Government Decision No 189/2014 on animal health rules, import and transit of certain live ungulates, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114425&lang=en

¹²³ Government Decision No 357/2012 for the approval of the Sanitary-Veterinary Rule on the sale and import of poultry and eggs for hatching, available in Romanian at: https://www.legis.md/search/getResults?doc_id=48276&lang=en

¹²⁴ Government Decision No 103/2011 for the approval of the Sanitary-Veterinary Rule regarding the requirements for the import and placing on the market of some aquaculture products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=13386&lang=ro

¹²⁵ Government Decision No 1113/2010 approving the Sanitary-Veterinary Regulation laying down requirements for the veterinary certification for the import and placing on the market of live aquaculture animals and products obtained from them, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125574&lang=ro

No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species and Commission Regulation (EU) No 346/2010 of 15 April 2010 amending Regulation (EC) No 1251/2008 as regards the placing on the market and import requirements for consignments of aquaculture animals intended for Member States or parts thereof with national measures approved by Decision 2010/221/EU.

- Government Decision No 967/2010 on some veterinary certification measures for the import of feed products¹²⁶ transposes Commission Regulation (EC) No 68/98 of 9 January 1998 fixing the maximum export refund on wholly milled medium grain and long grain A rice in connection with the invitation to tender issued in Regulation (EC) No 2095/97.
- Government Decision No 838/2009 regarding some conditions regarding the authorization of the import or transit of intestines of animal origin¹²⁷ transposes Commission Decision 2003/779/EC of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries.
- Government Decision No 175/2009 on the approval of the Sanitary-Veterinary Regulation on animal health conditions and veterinary certification on imports of equidae for slaughter¹²⁸ transposes Commission Decision 93/196/EEC of 5 February 1993 on animal health conditions and veterinary certification for imports of equidae for slaughter.
- Government Decision No 137/2009 transposes Commission Decision 93/197/EEC of 5 February 1993 on animal health conditions and veterinary certification for imports of registered equidae and equidae for breeding and production¹²⁹
- Government Decision No 48/2009 harmonized with the provisions of Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries from which the Member States authorize imports of bovine animals, swine, and fresh meat¹³⁰

¹²⁶ Government Decision No 967/2010 on some veterinary certification measures for the import of feed products, available in Romanian at: https://www.legis.md/search/getResults?doc_id=12628&lang=en

¹²⁷ Government Decision No 838/2009 regarding some conditions regarding the authorization of the import or transit of intestines of animal origin, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=114299&lang=en

¹²⁸ Government Decision No 175/2009 on the approval of the Sanitary-Veterinary Regulation on animal health conditions and veterinary certification on imports of equidae for slaughter, available in Romanian at: https://www.legis.md/search/getResults?doc_id=21411&lang=en

¹²⁹ Government Decision No 137/2009 on the approval of the Sanitary-Veterinary Regulation on animal health conditions and veterinary certification on imports of registered equidae and equidae for breeding and production, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=23723&lang=ro

¹³⁰ Government Decision No 48/2009 on the approval of the Sanitary-Veterinary Rule on animal and public health conditions and sanitary-veterinary certification for the import into the Republic of Moldova of certain live animals and of their fresh meat, available in Romanian at: https://www.legis.md/search/getResults?doc_id=48390&lang=en

- Government Decision No 711/2014 partially transposes Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption.¹³¹
- Government Decision No 1099/2008 transposes Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC.¹³²
- Government Decision No 882/2015 for the approval of the Sanitary-Veterinary Rule on health requirements and the veterinary certification for the temporary admission of registered horses transposes Commission Decision 92/260/EEC of 10 April 1992 on animal health conditions and veterinary certification for temporary admission of registered horses¹³³
- Government Decision No 229/2017 on the approval of the Sanitary-Veterinary Rule regarding the import and transit of poultry and poultry products, as well as the sanitary-veterinary certification requirements transposes Regulation (EC) No Commission Regulation (EC) No 798/2008 of 8 August 2008 establishing a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community, as well as health certification requirements.¹³⁴
- Government Decision No 67/2018 on the approval of the Sanitary-Veterinary Rule on the establishment of animal health conditions for imports of certain birds transposes Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof¹³⁵
- Government Decision No 913/2018 on the approval of the Sanitary-Veterinary Regulation on animal health conditions and certification in trade (import and export) with bovine animals and swine transposes

¹³¹ Government Decision No 711/2014 for the approval of the Sanitary-Veterinary Norm on the establishment of animal and public health conditions and of the sanitary-veterinary certification of imports of raw milk, dairy products, colostrum and colostrum products intended for human consumption , available in Romanian at: https://www.legis.md/search/getResults?doc_id=18555&lang=en

¹³² Government Decision No 1099/2008 on sanitary-veterinary rules on sanitary-veterinary controls on the importation of animals, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114209&lang=en

¹³³ Government Decision No 882/2015 for the approval of the Sanitary-Veterinary Rule on health requirements and the veterinary certification for the temporary admission of registered horses, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114818&lang=en

¹³⁴ Government Decision No 229/2017 on the approval of the Sanitary-Veterinary Rule regarding the import and transit of poultry and poultry products, as well as the sanitary-veterinary certification requirements, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125634&lang=ro

¹³⁵ Government Decision No 67/2018 on the approval of the Sanitary-Veterinary Rule on the establishment of animal health conditions for imports of certain birds, available in Romanian at: https://www.legis.md/search/getResults?doc_id=102099&lang=en

Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine.¹³⁶

- Government Decision No 438/2009 for the approval of the Sanitary-Veterinary Rule regarding the animal health conditions and sanitary-veterinary certification in case of import of bees and bumblebees transposes Commission Decision No 2003/881/EC of 11 December 2003 concerning the animal health and certification conditions for imports of bees (*Apis mellifera* and *Bombus* spp.) from certain third countries and repealing Decision 2000/462/EC.¹³⁷
- Government Decision No 664/2012 approving the Sanitary-Veterinary Rule on health requirements for the movement of circus animals partially transposes Commission Regulation (EC) No 1739/2005 of 21 October 2005 laying down animal health requirements for the movement of circus animals between Member States.¹³⁸

f) Bilateral international veterinary agreements with EU Member States, candidate countries and other third countries (if any).

The following international agreements have been concluded in the veterinary field:

- Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Azerbaijan, signed on April 21, 2005, in Chisinau.¹³⁹
- Agreement between the Government of the Republic of Moldova and the Council of Ministers of the Republic of Albania on cooperation in the veterinary field, signed in Chisinau on November 1, 2004.¹⁴⁰
- Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Hungary¹⁴¹

¹³⁶ Government Decision No 913/2018 on the approval of the Sanitary-Veterinary Regulation on animal health conditions and certification in trade (import and export) with bovine animals and swine, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125640&lang=en

¹³⁷ Government Decision No 438/2009 for the approval of the Sanitary-Veterinary Rule regarding the animal health conditions and sanitary-veterinary certification in case of import of bees and bumblebees, available in Romanian at: https://www.legis.md/search/getResults?doc_id=24192&lang=en

¹³⁸ Government Decision No 664/2012 approving the Sanitary-Veterinary Rule on health requirements for the movement of circus animals, available in Romanian at: https://www.legis.md/search/getResults?doc_id=114385&lang=en

¹³⁹ Government Decision No 511/2006 on the approval of the Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Azerbaijan, available in Romanian at: https://www.legis.md/search/getResults?doc_id=26431&lang=en

¹⁴⁰ Government Decision No 323/2005 for the approval of the Agreement between the Government of the Republic of Moldova and the Council of Ministers of the Republic of Albania on cooperation in the veterinary field, available in Romanian at: https://www.legis.md/search/getResults?doc_id=26959&lang=en

¹⁴¹ Government Decision No 761/2003 on the approval of the Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Hungary, available in Romanian at: https://www.legis.md/search/getResults?doc_id=29568&lang=en

- Convention between the Government of the Republic of Moldova and the Government of the Republic of Uzbekistan on Cooperation in the Sanitary-Veterinary Field.¹⁴²
- Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Italian Republic.¹⁴³
- Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Bulgaria.¹⁴⁴
- Commonwealth of Independent States Agreement on cooperation in veterinary medicine.¹⁴⁵
- Agreement No 956/2003 on the collaboration in the field of veterinary medicine between the Government of the Republic of Moldova and the Government of the Republic of Turkey.¹⁴⁶
- Agreement between the Government of the Republic of Moldova and the Government of the Republic of Belarus on cooperation in the veterinary field of 29.06.2000.¹⁴⁷
- Agreement on the application of Rules, rules and technical, medical, pharmaceutical, sanitary, veterinary, and phytosanitary requirements to goods imported into the member countries of the Commonwealth of Independent States.¹⁴⁸
- Veterinary Sanitary Convention between the Government of the Republic of Moldova and the Cabinet of Ministers of Ukraine.¹⁴⁹
- Agreement between the National Food Safety Agency of the Republic of Moldova and the National Sanitary Veterinary and Food Safety Authority of Romania on the granting of non-reimbursable financial assistance for the surveillance, control and eradication of rabies in the buffer-area

¹⁴² Government Decision No 89/2001 for approval of the Convention between the Government of the Republic of Moldova and the Government of the Republic of Uzbekistan on cooperation in the field of veterinary medicine, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=48635&lang=en

¹⁴³ Government Decision No 282/1998 on the approval of the Veterinary Convention between the Government of the Republic of Moldova and the Government of the Italian Republic, available in Romanian at: https://www.legis.md/search/getResults?doc_id=44312&lang=en

¹⁴⁴ Sanitary-veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Bulgaria, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=115892&lang=en

¹⁴⁵ Commonwealth of Independent States Agreement on cooperation in veterinary medicine, available in Romanian at: https://www.legis.md/search/getResults?doc_id=118129&lang=en

¹⁴⁶ Agreement No 956 of 04-08-2003 on the collaboration in the field of veterinary medicine between the Government of the Republic of Moldova and the Government of the Republic of Turkey, available in Romanian at: https://www.legis.md/search/getResults?doc_id=28057&lang=en

¹⁴⁷ Agreement between the Government of the Republic of Moldova and the Government of the Republic of Belarus on cooperation in the veterinary field of 29.06.2000, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=47543&lang=en

¹⁴⁸ Agreement on the application of Rules, rules and technical, medical, pharmaceutical, sanitary, veterinary and phytosanitary requirements to goods imported into the member countries of the Commonwealth of Independent States, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=31671&lang=en

¹⁴⁹ Veterinary Sanitary Convention between the Government of the Republic of Moldova and the Cabinet of Ministers of Ukraine, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=46396&lang=en

established on the territory of the Republic of Moldova (no exit 25464 of 15.04.2019, Government of Romania, National Sanitary Veterinary and Food Safety Authority of Romania, entry number 584 of 23.04.2019 National Food Safety Agency of the Republic of Moldova);

- Agreement between the National Food Safety Agency and DG SANTE “Supporting Protection Measures Against African Swine Fever in the Republic of Moldova 2022.
- At the same time, negotiations were initiated on the following draft agreements:
- Sanitary-veterinary agreement between the Government of the Republic of Moldova and the Government of the Republic of Estonia;¹⁵⁰
- Convention between the Government of the Republic of Moldova and the Government of Norway on cooperation in the sanitary-veterinary field;¹⁵¹
- Agreement between the Government of the Republic of Moldova and the Government of the Czech Republic on cooperation in the sanitary-veterinary field;¹⁵²
- - Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Federal Ministry of Food, Agriculture and Forestry of the Federal Republic of Germany on cooperation in the veterinary sector;¹⁵³
- -Agreement on cooperation in the veterinary field;¹⁵⁴
- - Convention between the Government of the Republic of Moldova and the Government of Romania on cooperation in the sanitary-veterinary field;¹⁵⁵
- - Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Council of Ministers of Serbia and Montenegro;¹⁵⁶

¹⁵⁰ Sanitary-veterinary agreement between the Government of the Republic of Moldova and the Government of the Republic of Estonia, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=71605&lang=en

¹⁵¹ Convention between the Government of the Republic of Moldova and the Government of the Kingdom of Norway on cooperation in the sanitary-veterinary field, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=71532&lang=en

¹⁵² Agreement between the Government of the Republic of Moldova and the Government of the Czech Republic on cooperation in the sanitary-veterinary field, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=74543&lang=en

¹⁵³ Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Federal Ministry of Food, Agriculture and Forestry of the Federal Republic of Germany on cooperation in the veterinary sector, available in Romanian at: https://www.legis.md/search/getResults?doc_id=73380&lang=en

¹⁵⁴ Agreement on cooperation in the veterinary field, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=98499&lang=en

¹⁵⁵ Convention between the Government of the Republic of Moldova and the Government of Romania on cooperation in the sanitary-veterinary field, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=116415&lang=en

¹⁵⁶ Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Council of Ministers of Serbia and Montenegro, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=70886&lang=en

- Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Nord Macedonia;¹⁵⁷
- Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture and Rural Development of the Republic of Poland on cooperation in the field of veterinary medicine;¹⁵⁸
- Agreement between the Government of the Republic of Moldova and the Government of the Slovak Republic on cooperation in the field of veterinary medicine.¹⁵⁹

11. Please provide information on the animal welfare legislation:

a) Farm animals, laying hens, including information on production conditions, chickens raised for the production of meat, calves, pigs;

Animal welfare of the laying hens farm is governed by the following acts:

Law No 221/2007 on sanitary veterinary activity¹⁶⁰ which establishes that owners or caregivers of animals have the obligation to comply with and apply the sanitary veterinary requirements and other rules on the housing and care of animals on farms, gardens, zoos and reservations or from temporary agglomerations of animals or during grazing, in order to comply with their physiological and behavioural requirements, according to the sanitary veterinary requirements in the field of protection and ensuring **animal welfare**. ANSA verifies compliance with sanitary veterinary requirements regarding the protection and welfare of domestic and wild animals.

Government Decision No 1275/2008 on the approval of the sanitary-veterinary norm on the protection of farm animals, transposes Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes. and lays down the veterinary requirements for the protection of farm animals.¹⁶¹

¹⁵⁷ Sanitary Veterinary Convention between the Government of the Republic of Moldova and the Government of the Republic of Nord Macedonia, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=71138&lang=en

¹⁵⁸ Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture and Rural Development of the Republic of Poland on cooperation in the field of veterinary medicine, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=72432&lang=en

¹⁵⁹ Agreement between the Government of the Republic of Moldova and the Government of the Slovak Republic on cooperation in the field of veterinary medicine, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=75662&lang=en

¹⁶⁰ Law No 221/2007 on sanitary veterinary activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

¹⁶¹ Government Decision No 1275/2008 on the approval of the sanitary-veterinary norm on the protection of farm animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114276&lang=ro

Government Decision No 677/2008 for the approval of the sanitary-veterinary norm regarding the protection of laying hens), transposes Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens and lays down minimum requirements for laying hen rearing systems, improved and unimproved cage rearing systems, alternative free access between levels or with access to outdoor spaces. In the Republic of Moldova, growth in unenriched cages was allowed only until January 1, 2012, but due to insufficient financial resources for an adequate subsidy of farmers, this method of growth is still allowed.¹⁶²

Government Decision No 942/2008 for the approval of the Regulation on the registration and of breeding units for laying hens, transposes Commission Directive 2002/4/EC of 30 January 2002 on the registration of establishments keeping laying hens, covered by Council Directive 1999/74/EC and lays down the method of registration and evidence of laying hen breeding units for sanitary-veterinary supervision.¹⁶³

Government Decision No 773/2013 on the approval of the sanitary-veterinary norm for establishing the requirements for the commercialization of poultry meat, transposes Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultry meat and laying down requirements and standards for the commercialization of poultry meat, the mandatory conditions to be met by poultry meat, health control, post-slaughter veterinary examination, marking and labelling.¹⁶⁴

Government Decision No 415/2009 for the approval of the sanitary-veterinary norm regarding the protection of the chickens intended for meat production transposes the Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production and lays down requirements for intensive rearing systems for chickens of Gallus species intended for meat production, maintenance conditions and parameters as well as regulations on population density which must not exceed 33 kg/m². If the farmer intends to obtain the right for a population with a higher density, he must obtain an additional authorization from ANSA.¹⁶⁵

¹⁶² Government Decision No 677/2008 for the approval of the sanitary-veterinary norm regarding the protection of laying hens, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=21937&lang=ro

¹⁶³ Government Decision No 942/2008 for the approval of the Regulation on the registration and of breeding units for laying hens, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125558&lang=ro

¹⁶⁴ Government Decision No 773/2013 on the approval of the sanitary-veterinary norm for establishing the requirements for the commercialization of poultry meat, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130549&lang=ro

¹⁶⁵ Government Decision No 415/2009 for the approval of the sanitary-veterinary norm regarding the protection of the chickens intended for meat production, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=114297&lang=en

Government Decision No 859/2008 on the approval of the sanitary-veterinary norm regarding the minimum criteria for the protection of pigs intended for rearing and fattening, transposes the Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs and establishes minimum requirements for the protection of pigs at stages of the production cycle.¹⁶⁶

Government Decision No 1325/2008 on the approval of the sanitary-veterinary norm regarding the establishing minimum requirements for the protection of calves for the purpose of rearing and fattening transposes Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves.¹⁶⁷

Law No 211/2017 on the protection of animals used for experimental or other scientific purposes transposes Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.¹⁶⁸

b) Animals during transportation:

Government Decision No 793/2012 for the approval of the sanitary-veterinary norm on protection and animal welfare during transportation¹⁶⁹ partially transposes Council Regulation (EC) 1/2005 of 22 December 2004 on the protection of animals during transportation and related operations and amending of Directives 64/432 EEC and 93/119/EC and Regulation (EC) No 1255/97 on the transportation of all live animals with the exception of the transportation of animals by farmers using their own agricultural vehicles or means of transport, the transportation of certain categories of animals for seasonal transhumance, the transportation by farmers of their own animals, with their own means of transport, less than 50 kilometres from their holding, the transportation of animals directly to or from veterinary offices or clinics and lays down general and special requirements for all types of transportation of animals, the duties and obligations of the competent authorities in relation to the authorization of means of transport for live animals, emergency measures and penalties for non-compliance by carriers.

¹⁶⁶ Government Decision No 859/2008 on the approval of the sanitary-veterinary norm regarding the minimum criteria for the protection of pigs intended for rearing and fattening, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110353&lang=ro

¹⁶⁷ Government Decision No 1325/2008 on the approval of the sanitary-veterinary norm regarding the establishing minimum requirements for the protection of calves for the purpose of rearing and fattening, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110453&lang=ro

¹⁶⁸ Law No 211/2017 on the protection of animals used for experimental or other scientific purposes, available in Romanian at: https://www.legis.md/search/getResults?doc_id=105612&lang=en

¹⁶⁹ Government Decision No 793/2012 for the approval of the sanitary-veterinary norm on protection and animal welfare during transportation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114388&lang=ro

c) Animals at the time of slaughter or killing:

Government Decision No 369/2015 for the approval of the sanitary-veterinary norm on the protection of animals at the time of killing¹⁷⁰ transposes Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing

12. Please provide information on the zootechnical legislation.

1. Law No 412/1999 on animal breeding¹⁷¹

The aim of the Law is to create the conditions for increasing the quality and growth of livestock production. The normative Act lays down the legal and economic bases for the organisation of animal breeding, as well as the relations between the State and livestock keepers. It regulates the main rights and obligations of livestock keepers, breed improvement and animal breeding, feed resources, scientific activity in animal breeding and the financing of the livestock sector.

Harmonisation. Does not transpose European Union legislation.

2. Law No 371/1995 on Selection and Breeding in Animal Breeding¹⁷²

The purpose of the Law is firstly to create the economic premises for increasing the quality and the growth of the global animal production on the basis of the improvement of existing breeds, the creation and implementation in production of new breeds, types, lines, crosses and hybrids of animals with a high productive and adaptive potential, the protection of the achievements of selection, and secondly the protection of the rights of natural and legal persons, who have the conditions for obtaining, breeding, reproduction, use and marketing of livestock resources in order to increase animal production.

The Law establishes the legal and economic bases for the organisation of breeding and reproduction in the livestock sector of the Republic of Moldova and regulates the relations between the State, owners, holders, and beneficiaries of livestock resources.

¹⁷⁰ Government Decision No 369/2015 for the approval of the sanitary-veterinary norm on the protection of animals at the time of killing, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=114805&lang=en

¹⁷¹ Law No 412/1999 on animal breeding, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108551&lang=ro

¹⁷² Law No 371/1995 on Selection and Breeding in Animal Breeding, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=109449&lang=ro

Harmonisation. Does not transpose European Union legislation.

Note. On 27 April 2022, the Government of the Republic of Moldova approved the Government Decision for the approval of the draft new Law on Animal Breeding (Government Decision No 274/2022¹⁷³), which was transmitted to the Parliament for adoption, and which will repeal the Law on Animal Breeding No 412/1999 and the Law No 371/1995 on Selection and Reproduction in Animal Breeding. The mentioned draft law will transpose into the national legislation of the Republic of Moldova the Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding (Animal Breeding Regulation).

3. Law No 70/2006 on beekeeping.¹⁷⁴

The aim of the Law is to create conditions for increasing the quantity and improving the quality of beekeeping production.

The purpose of the Law is to regulate relations in beekeeping, to protect the rights of beekeepers and to create conditions for the protection and rational use of honeybees in the production of bee products and the pollination of entomophilous flora.

Harmonisation. Does not transpose European Union legislation.

4. Law No 149/2006 on fish stocks, fisheries, and fish farming¹⁷⁵

The law establishes the legal framework in the field of fish stocks, fisheries, and fish farming. It regulates the manner and conditions for the creation and protection of fish stocks, the reproduction, growth, and acquisition of hydrobionts, the improvement of aquatic fishery objectives and the development of fish farming, and establishes the principles of activity of the public authorities responsible for the management of aquatic biological resources

¹⁷³ Government Decision No 274/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=131062&lang=ro
the text of the draft law and Table of concordance are available in Romanian at: <https://www.parlament.md/ProcesulLegislativ/Proiectedeactelegislative/tabid/61/LegislativId/5986/language/ro-RO/Default.aspx>

¹⁷⁴ Law No 70/2006 on beekeeping, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107261&lang=ro

¹⁷⁵ Law No 149/2006 on fish stocks, fisheries, and fish farming, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130542&lang=ro

Harmonisation. Does not transpose European Union legislation.

5. Law No 27/2017 on the classification of cattle, pig, and sheep carcasses¹⁷⁶

The law lays down the legal and economic grounds for the national system for the classification of cattle, pig, and sheep carcasses, as well as the relations between state institutions and economic agents involved in animal breeding and slaughter activities.

The purpose of the Law is to ensure transparent activity of the parties involved in the rearing and slaughtering of farm animals, to increase the quality and added value of cattle, pig and sheep carcasses obtained in authorised meat production establishments in the Republic of Moldova, and to provide fair remuneration to livestock farmers who supply live animals for slaughter.

This law does not apply to carcasses obtained in individual households for the purpose of personal consumption, provided that they are not exposed to trade, and to establishments slaughtering less than 20 head of adult bovine animals and/or 20 head of sheep, and/or 50 head of pigs per week, according to the results of the previous year.

Harmonisation. This law is compatible with the provisions of Article 2 para. (3), Article 3, Article 6 para. (1) and (2), Article 7 para. (1), Article 8, Article 13 para. (1)-(3), Article 14 para. (1), Article 21 para. (2), Article 22 para. (1), Article 26 para. (2), Article 28, 29, Article 30 para. (1) and (2), Article 33 para. (1), Annexes 1, 3, 6, 7 and partly compatible with Article 1, Article 2 para. (1), (2) and (4), Article 5, Article 6 para. (3), Article 7 para. (2), Article 11 para. (1) and (2), Article 12, Article 13 para. (5), Article 15 para. (1), Article 16 para. (1), Article 20, Article 21 para. (3), Article 22 para. (2), Article 23 para. (1), Article 24 para. (1) and (2), Article 25 para. (2), Article 30 para. (3), Article 31, 32, Article 33 para. (2) and 36 of Commission Regulation (EC) No 1249/2008 of 10 December 2008 laying down detailed rules for the application of the Community scales for the classification of beef, pig and sheep carcasses and the reporting of prices thereof, is also compatible with Annex IV to Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003.

The regulatory framework for the implementation of livestock legislation consists of the following normative acts:

¹⁷⁶ Law No 27/2017 on the classification of cattle, pig, and sheep carcasses, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=98613&lang=ro

- **Government Decision No 306/2011** approving the zootechnical standard on the bonification of bee families, breeding, and certification of beekeeping genetic material¹⁷⁷

The purpose of the act is to improve the genetics and increase the productivity of bee families for the benefit of mass beekeepers, users of bee brood genetic material.

Harmonisation. Does not transpose European Union legislation.

- **Government Decision No 1203/2003 on the import and export of breeding resources.**¹⁷⁸

The normative act lays down the conditions and modalities for the export and import of breeding resources, in order to protect the domestic market from the invasion of non-valuable genetic material and breeding resources not approved in the Republic, as well as to protect the copyrights of domestic breeders - authors of breeds, types, lines and breeds of animals

Harmonisation. Does not transpose European Union legislation.

- **Order of the Ministry of Agriculture, Regional Development and Environment No 31/2017** on the approval of the Regulation on state certification of livestock farms for breeding animals;¹⁷⁹

State certification in the breeding category is a measure of commissioned assessment of livestock farms based on unique regulatory requirements, in order to verify the compliance of the genetic and productive value of animals with breed standards, to accelerate the process of genetic improvement of livestock, to make rational use of breeding resources and to increase the efficiency of selection and breeding activity. The normative act provides for the organisation and conduct of the certification procedure, as well as the requirements for breeding farms, which are developed according to the breed standard and biological peculiarities of each animal species in the conditions of the Republic of Moldova.

Harmonisation. Does not transpose European Union legislation.

- **Order of the Ministry of Agriculture and Food Industry No 32/2022 on the approval of the Instructions for the bonification**¹⁸⁰

Instructions for the bonification of Karakul Moldovenesc sheep are a sectoral normative act, drawn up in accordance with the provisions of Article 10 of Law No 371/1995 on selection and reproduction in animal husbandry, and Article 6 of the Animal Husbandry Law No 412/1999. The Instructions contain technical and methodological concepts for assessing

¹⁷⁷Government Decision No 306/2011 approving the zootechnical standard on the bonification of bee families, breeding, and certification of beekeeping genetic material, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114328&lang=ro

¹⁷⁸ Government Decision No 1203/2003 on the import and export of breeding resources, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=14086&lang=ro

¹⁷⁹ Order of the Ministry of Agriculture, Regional Development and Environment No 31/2017 on the approval of the Regulation on state certification of livestock farms for breeding animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128221&lang=ro

¹⁸⁰ Order of the Ministry of Agriculture and Food Industry No 32/2022 on the approval of the Instructions for the bonification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130083&lang=ro

the morpho-productive performance and complex breeding value of Karakul Moldovenesc sheep, as well as for carrying out important selection work, which can be applied by zootechnical specialists with special methodological professional knowledge described in the relevant methodological and scientific literature.

13. Please provide information on the expenditure in the veterinary field.

For the purpose of coherent implementation of the State's veterinary policies, as estimated in the Med-Term Budgetary Expenditure, financial resources are allocated as follows:

- Implementation of the programme of strategic actions for the surveillance, prevention and control of animal diseases, prevention of the transmission of diseases from animals to humans and protection of the environment, as well as to ensure the identification and free registration of animals on non-professional holdings – 33 812 700 MDL;
- For the compensation of owners of animals affected or killed in the framework of disease eradication programmes, according to the provisions of Government Decision 645/2012 approving the Regulation on the calculation of compensation to owners of animals slaughtered, killed, or otherwise affected as a result of the rapid liquidation of outbreaks of transmissible animal diseases¹⁸¹ financial resources amounting to 500 000 MDL are required.
- Implementation of the fox rabies eradication programme (EU co-financed) - 24 789 800 MDL;
- Monitoring of compliance with rules on microbiological criteria and other pathogens for food products - 2 392 900 MDL;
- Implementation of the monitoring plan for residues in animal products - 3 277 000 MDL;
- Implementation of raw milk monitoring programme - 1 169 000 MDL;
- Implementation of the National Fodder Monitoring Programme - 465 000 MDL;
- Implementation of the programme for monitoring the quality of veterinary medicinal products - 110 300 MDL;
- Expenditure related to the functioning and development of ANSA - 163 250 100 MDL.

¹⁸¹ Government Decision 645/2012 approving the Regulation on the calculation of compensation to owners of animals slaughtered, killed or otherwise affected as a result of the rapid liquidation of outbreaks of transmissible animal diseases, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=91997&lang=ro#

III. PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS

14. Please provide information on the legislative framework on the placing on the market of food, feed, and animal by-products

In the Republic of Moldova, placement of foodstuffs on the market is regulated by the following normative framework:

Law No 306/2018 on food safety¹⁸² aims to achieve a high level of protection of human health and consumer interests in relation to food safety, considering the diversity of food supply, including traditional products by ensuring efficient functioning of the national market and provides the following:

- general food safety requirements,
- the responsibilities of competent authorities,
- traceability, labelling of foodstuffs,
- safety requirements for the organization of the production, authorization, and registration process,
- food safety supervision and control procedures, subsequent responsibilities and dispute resolution arising between food/feed operators and state control and supervision bodies as a result of control and supervision activities.

The law transposes the following provisions into the national legislation:

- Regulation (EC) No 178/2002 of the European Parliament and of the EU Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; and
- Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin.

Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules¹⁸³ establishes the following:

¹⁸² Law No 306/2018 on food safety, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

¹⁸³ Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

- obligations and powers of competent authorities on the exercise of official controls;
- sampling and analysis methods used in official controls;
- contingency plans drawn up by the relevant directorates of the competent Crisis Management Authority;
- the organisation of official controls by the competent authority on the import of feed and foodstuffs, as well as the procedure for registration and authorisation of food and veterinary economic operators.

It also sets the general rules on the exercise of official controls in order to verify compliance with the rules relating to:

- prevention, elimination, or reduction to permissible levels of risks to human and animal health, either directly or through environmental conditions;
- ensuring fair practices in trade in feed and food and protecting the interests of consumers, including labelling of feed and food and other forms of consumer awareness.

The exercise of official controls under this law is without prejudice to the primary legal responsibility of feed and food operators to ensure the safety of feed and food in accordance with relevant legislation or to any civil or criminal liability arising from non-compliance with their obligations.

The law does not regulate feed used in auxiliary households.

This law provides for the transposition of Titles I, II, III, V, VI (Chapter II) and VII (Chapter I) of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Law No 279/2017 on informing of consumers on food products¹⁸⁴ sets the mandatory food information to ensure a high level of consumer protection, taking into account their differences in perception and their need for information, while ensuring proper functioning of the market of the Republic of Moldova, including the general objectives and categories of food information, the general requirements for food Information and the responsibilities of food operators, as well as the content of the nutrition declaration.

The law defines the general requirements and responsibilities governing food information, in particular food labelling. It lays down the means for guaranteeing

¹⁸⁴ Law No 279/2017 on informing of consumers on food products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105652&lang=ro

the consumers' right to information and the procedures for providing food information, considering the need to provide for sufficient flexibility to be able to respond to future developments and new information requirements.

It applies to food business operators at all stages of the food chain, where their activities relate to informing consumers about food, as well as all foodstuffs intended for the final consumer, including those delivered by public catering establishments, and to foodstuffs intended to be supplied to them. This law applies to public catering services provided by transport companies.

The rules on nutrition and health claims on foodstuffs, the rules on the labelling of food supplements, as well as the rules on the labelling of foodstuffs for special nutritional purposes shall be approved by the Government.

This law partially transposes the following EU legal acts:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004;
- Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs.

Law No 296/2017 on general hygienic requirements for foodstuffs¹⁸⁵ establishes general foodstuffs hygienic requirements for food operators, considering the following regulatory aspects:

- ensuring food safety throughout the food chain;
- general implementation of procedures based on the principles of Hazard Analysis and Critical Control Points (hereinafter referred to as *HACCP*), while applying good hygiene practices;
- development and compliance with the national and international guidelines of good practice at all stages of the food chain, in accordance with food hygienic requirements and with application of *HACCP* principles;
- verification of compliance of imported foodstuffs with the hygiene requirements for national foodstuffs, equivalent to those of the European Union;

¹⁸⁵ Law No 296/2017 on general hygienic requirements for foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105658&lang=ro

- ensuring food safety accountability of food business operators.

The provisions of this law apply to all stages of production, processing, and distribution of foodstuffs, as well as export activities.

The provisions of this law do not apply to the following:

- primary production for private household consumption;
- domestic preparation, handling and/or storage of foodstuffs intended for private household consumption;
- collection centres and tanneries falling within the definition of food-related activities only because they handle the raw material for the production of gelatine or collagen.

This law sets the following:

- the responsibilities of food operators regarding food hygiene
- the preparation and use of national best practice guidelines
- general hygiene requirements for primary production, including hygiene requirements applicable to foodstuffs

This law:

- transposes Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
- transposes Article 3 (2) and Article 6 of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin;
- transposes Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004;
- partially transposes Commission Regulation (EU) No 579/2014 of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea “published in the Official Journal of the European Union L 160 of 29 May 2014, as last amended by Commission Regulation (EU) 2019/978 of 14 June 2019”.

Law No 129/2019 on animal by-products and derived products that are not intended for human consumption¹⁸⁶ transposes the provisions of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).and lays down:

- classification of animal by-products and derived products
- disposal of and restrictions in the use of animal by-products and derived products,
- collection, transport, and traceability procedures
- authorisation of establishments and facilities
- placing on the market, import, transit and export, official controls

Law No 221/2007 on sanitary veterinary activity¹⁸⁷ establishes the main sanitary and veterinary rules and requirements in the Republic of Moldova, the rights and obligations of the state, natural and legal persons in the process of production, processing, storage, transportation and marketing of live animals and products of animal origin.

The purpose of the law is to ensure animal health, prevent transmission of diseases from animals to humans, to ensure the safety of animal products intended for human consumption, sanitation and quality of feed, testing and authorization of veterinary drugs and substances used in veterinary diagnostic activities, protection of the country's territory from infectious diseases by organizing veterinary and sanitary activity.

The procedure for requesting, granting, suspending, and withdrawing the veterinary permissive acts for economic agents under this law is established by Law No 160/2011 on the regulation by authorization of entrepreneurial activity where such is not regulated by this law. This law does not transpose any European acts.

Law No 231/2010 on internal trade.¹⁸⁸ The purpose of this Law is to create a relevant legal framework for trade by developing a marketing network for commercial products and services while ensuring free competition, protection of life, health, safety and economic interests of consumers and it establishes the general principles for trade in the territory of the Republic of Moldova.

¹⁸⁶ Law No 129/2019 on animal by-products and derived products that are not intended for human consumption, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118406&lang=ro

¹⁸⁷ Law No 221/2007 on sanitary veterinary activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

¹⁸⁸ Law No 231/2010 on internal trade, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=127948&lang=ro

This law aims to achieve the following objectives:

- encouraging the marketing of products and services;
- encouraging free enterprise, ensure fair competition and free movement of commercial products and services;
- maximum satisfaction of consumer needs in various products and services, ensuring food and consumer safety;
- stimulating the development of small and medium-sized enterprises;
- improvement of the institutional framework for the regulation of trade activities;
- establish a framework for interaction between central and local public administration authorities in the field of trade;
- modernization and development of forms of distribution of goods and provision of commercial services;
- simplification of trade launching procedures;
- coordination of the trade supervision functions of competent state institutions.

Law No 129/2019 on animal by-products and derived products not intended for human consumption¹⁸⁹. The law establishes the following:

- classification of animal by-products and derived products;
- elimination and restriction of the use of animal by-products and derived products;
- collection, transport, and traceability procedures;
- authorisation of establishments and installations;
- placing on the market, import, transit, and export, subsequently the organization of official controls.

This law transposes the provisions of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

Government Decision No 208/2013 on the approval of sampling methods for determining the level of mycotoxins in foodstuffs¹⁹⁰ partially transposes the provisions of Commission Regulation No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the level of

¹⁸⁹ Law No 129/2019 on animal by-products and derived products not intended for human consumption, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118406&lang=ro

¹⁹⁰ Government Decision No 208/2013 on the approval of sampling methods for determining the level of mycotoxins in foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125620&lang=ro

mycotoxins in foodstuffs and lays down the procedure for sampling, method of sampling by product and method of analysis.

Government Decision No 925 of 31 December 2009 adopting the Sanitary Regulation on Government Decision No 221 of 16 March 2009 on the approval of rules on microbiological criteria for foodstuffs.¹⁹¹ The Decision transposes Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

Government Decision No 11/2022 on the approval of the sanitary and veterinary rule on animal by-products and derived products not intended for human consumption.¹⁹² This Decision transposes Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive and laying down the procedure for the disposal and use of animal by-products and derived products, restrictions on the use of animal by-products, elimination, recovery and use of animal by-products as fuel, processing requirements, including the processing of animal by-products and derived products into biogas and compost, special rules on research, feeding of animals, collection and disposal of animal by-products, in addition the application of alternative methods of use or disposal of animal by-products or derived products, requirements for collection, transport, placing on the market of animal by-products and derived products.

Government Decision No 686 of 13 September 2012 on the approval of methods of analysis for feed control.¹⁹³ It transposes the provisions of Regulation No 152/2009/EC of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed and sets out the sampling methods for the official control of feed for the determination of constituents, including materials containing, consisting of or produced from genetically modified organisms, feed additives, undesirable substances and pesticide residues, methods for preparing samples for analysis and expressing the results, methods for the analysis on the control of the composition of raw material for feed and compound feed, methods of analysis for the control of the admissible level of additives in feed, methods of analysis for the control of undesirable substances in feed, methods of analysis for the determination of constituents of animal origin for the official control of feed and the methods for determining the energy value of compound feed for poultry.

¹⁹¹ Government Decision No 221 of 16 March 2009 on the approval of rules on microbiological criteria for foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130511&lang=ro

¹⁹² Government Decision No 11/2022 on the approval of the sanitary and veterinary rule on animal by-products and derived products not intended for human consumption, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130906&lang=ro

¹⁹³ Government Decision No 686 of 13 September 2012 on the approval of methods of analysis for feed control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103175&lang=ro

Government Decision No 196/2011 on the approval of the Health Regulation on nutrition and health claims on foodstuffs.¹⁹⁴ This Decision transposes Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs, Commission Regulation No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 on nutrition and health claims and Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation No 1924/2006 of the European Parliament and of the Council, and lays down the general/specific principles and conditions of use for nutrition and health claims, the requirements for health endorsement of health claims and the mandatory information to accompany health claims, including data protection.

Government Decision No 941 of 11 October 2010 on the approval of Rules on methods of sampling and analysis of samples for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs.¹⁹⁵

These rules transpose the provisions of Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs.

Government Decision No 1150/2017 on the approval of the Food Safety Strategy for 2018-2022.¹⁹⁶

The Food Safety Strategy for 2018-2022 is a development of the provisions of the Food Safety Strategy for 2011-2015, approved by Government Decision No 747/2011¹⁹⁷ and is fully in line with the National Agricultural and Rural Development Strategy for 2014-2020, approved by Government Decision No 409/2014, the National Public Health Strategy for 2014-2020, approved by Government Decision No 1032/2013¹⁹⁸, with the main objective of achieving a high level of food safety and consumer protection, taking into account the diversity

¹⁹⁴ Government Decision No 196/2011 on the approval of the Health Regulation on nutrition and health claims on foodstuffs, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=109690&lang=ro

¹⁹⁵ Government Decision No 941 of 11 October 2010 on the approval of Rules on methods of sampling and analysis of samples for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=103303&lang=ro

¹⁹⁶ Government Decision No 1150/2017 on the approval of the Food Safety Strategy for 2018-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=111638&lang=ro

¹⁹⁷ Government Decision No 747/2011 the Food Safety Strategy for 2011-2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=22092&lang=ro#

¹⁹⁸ Government Decision No 1032/2013 on the approval of the National Public Health Strategy for the years 2014-2020, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103097&lang=ro

of food supply, accession to external markets and ensuring close and balanced cooperation between central public authorities.

The main principle of the food safety policies, set out in Law No 113/2012¹⁹⁹ establishing the general principles and requirements of food safety legislation, is the application of the “Farm to Fork” principle, which includes all stages of the food chain, including production of feed for animals; plant health; animal health, animal protection and welfare; primary production; food processing, storage, transportation, marketing, import and export. In this integrated approach, the primary responsibility for the production of safe food as well as for the application of related legislation lies with the operators of the food business. However, other stakeholders, both competent authorities and consumers, also play an important role. In the management of food controls, it is important to ensure risk-based scientific research.

The strategy describes the situation in the food safety and food control sector in the Republic of Moldova, it identifies the advantages, disadvantages, opportunities, and risks through a SWOT analysis, defines the general objective and specific objectives, the problems requiring Government intervention and identifies the necessary measures within each field, clearly stipulating the responsibilities and deadlines for implementation.

The responsibility of regulation of the food safety policy is with the Ministry of Agriculture and Food Industry, partially shared with the Ministry of Health. The related implementation duties are included in the competence of the National Food Safety Agency, the National Agency for Public Health, and other central public authorities.

Monitoring, surveillance, and control activities are carried out under Laws and Government Decisions. In general, these normative acts are harmonized with EU legislation, in particular with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law and animal health and animal welfare rules, and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Within the National Food Safety Agency, official control plans are developed centrally under Law No 131/2012²⁰⁰ on state control over entrepreneurial activity and Law No 50/2013²⁰¹ on official controls to verify compliance with feed and

¹⁹⁹ Law No 113/2012 on the establishment of general principles and requirements of food safety legislation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112774&lang=ro

²⁰⁰ Law No 131/2012 on state control over entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=96045&lang=ro

²⁰¹ Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and animal welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

food law and animal health and animal welfare rules, while their implementation is ensured by territorial subdivisions. Moreover, at the central level, ANSA develops procedures and instructions, develops and monitors the implementation of national residue monitoring plans, manages the activity of territorial subdivisions in relation to the safety of food products of animal and plant origin; analyses and processes monthly, quarterly, semi-annual and annual data and reports sent by territorial subdivisions; ensures permanent communication with DG SANTE to obtain and maintain the status of country approved for the export of food products of animal origin to the EU market.

The monitoring and supervision of food business operators is carried out through a number of methods and programs, including monitoring activities of established indicators, surveillance, documentary checks, on-site inspections, sampling, and testing of samples.

The manner of performing official controls and supervision of products of animal and non-animal origin, retail and public catering establishments, pharmaceutical products for veterinary use, feed are set out in the ANSA National Multiannual Control Plan. Annual residue monitoring plans for red meat, meat products, eggs, natural honey, and fish are also being developed.

In accordance with national regulatory requirements, the official control of the establishments must be carried out in accordance with risk analysis. However, surveillance programmes for the safety of foodstuffs of animal and non-animal origin show that the frequency of checks in production, processing, storage, or retail establishments does not meet the level of identified risk.

The National Agency for Public Health carries out state supervision of public health in the field of food safety in accordance with the provisions of Law No 10/2009²⁰² on state supervision of public health and in accordance with the areas of competence indicated in Article 25 of Law No 306/2018²⁰³ establishing the general principles and requirements of the food safety legislation. For all fields of activity and groups of products that fall within its competence in the field of food safety, sanitary regulations are developed harmonized with national and international requirements and approved by the Government.

Government Decision No 435/2010 approving specific hygiene rules for foodstuffs of animal origin.²⁰⁴

These rules lay down specific hygiene rules for processed or unprocessed foodstuffs of animal origin for food business operators. These specific rules complement the general food hygiene rules and provide for the obligations of food

²⁰² Law No 10/2009 on state supervision of public health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125959&lang=ro

²⁰³ Law No 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

²⁰⁴ Government Decision No 435/2010 approving specific hygiene rules for foodstuffs of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125564&lang=ro

business operators and the conditions for the import of food products of animal origin.

These rules shall not apply to foodstuffs containing both products of plant origin and processed products of animal origin, unless otherwise expressly indicated. At the same time processed foodstuffs of animal origin used for the preparation of such foodstuffs must be obtained and handled in accordance with these Rules.

These rules do not apply to the following:

- primary production intended for private household use;
- production, handling, and storage of foodstuffs for own consumption;
- the direct sale by the producer of small quantities of primary products to final consumers or to a local retail enterprise which supplies the final consumer directly;
- d) direct sale by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to a local retail undertaking which supplies such meat directly to the final consumer as fresh meat;
- e) hunters who sell small quantities of wild game or wild game meat directly to the final consumer or to a local retail enterprise supplying the final consumer directly.

These rules shall apply in retail trade in the case of operations carried out with a view to the sale of foodstuffs of animal origin to another undertaking, except where:

- operations are limited to the storage or transport, but in this case the specific temperature requirements laid down in Chapters IV to XVI of these Rules shall apply;
- the sale of foodstuffs of animal origin from retail undertakings is intended for other retail undertakings and in the case of localized and restricted activity.

These specific Rules for the hygiene of products of animal origin transposes Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, Annexes II to IV and VI to Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.

Government Decision No 1112/2010 approving the sanitary veterinary norm for the organization of specific official controls on foodstuffs of animal origin.²⁰⁵

The sanitary-veterinary rule for the organisation of specific official controls on foodstuffs of animal origin establishes the organization and performance of official controls on foodstuffs of animal origin and checking the compliance with the requirements for feed and food of animal origin, animal health and welfare at food economic operators. It applies without prejudice to the primary responsibilities of food economic operators working with food products of animal origin, as set out in Law No 306/2018 on food safety.

The provisions of this rule transposes Regulation (EC) No 854/2004/EC of 29 April 2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, Commission Regulation (EC) No 2074/2005 of 5 December 2005, Commission Regulation (EC) No 1663/2006 of 6 November 2006, Council Regulation (EC) No 1791/2006 of 20 November 2006, Commission Regulation (EC) No 1021/2008 of 17 October 2008, Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 and Commission Regulation (EU) No 2285/2015 of 8 December 2015.

Government Decision No 59/2017 approving the implementing measures for the Rapid alert system for food and feed at the national level.²⁰⁶

These measures are necessary for the application and operation of the Rapid alert system for food and feed at national level. The Ministry of Agriculture and Food Industry ensures the development and submission for approval, in accordance with the legislative provisions, of the Technical concept of the automated information system for transmitting, receiving and recording alerts for food and feed and provide for the rights and obligations of members of the alert network, alert notifications, exchange of information with other states and establishing the rights and obligations of the members of the Alert Network, the notification procedure, as well as the exchange of information with other states.

The implementing measures for the rapid alert system for food and feed at the national level transposes Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed.

²⁰⁵ Government Decision No 1112/2010 approving the sanitary veterinary norm for the organization of specific official controls on foodstuffs of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125573&lang=ro

²⁰⁶ Government Decision No 59/2017 approving the implementing measures for the Rapid alert system for food and feed at the national level, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125631&lang=ro

Government Decision No 657 of 18 August 2014 approving maximum limits for coccidiostats or histomonostats in food following the inevitable transfer of these substances into feeding stuffs.²⁰⁷

This Decision transposes the provisions of Commission Regulation No 124/2009/EC of the European Communities of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed and establishes that in case where food contains a contaminant that exceeds the allowable limits, it will not be placed on the market and if a significant amount of residues is found below the established level, the National Food Safety Agency will carry out investigations to confirm that residues are present as a result of the inevitable transfer into food, but not as a result of illegal administration of coccidiostats or histomonostats. At the same time, foodstuffs complying with the established limits shall not be mixed with foodstuffs exceeding these limits.

Government Decision No 806 of 16 October 2013 approving the Rule on quick-frozen foods intended for human consumption.²⁰⁸

Transposes Directive No 89/108/EEC of the Council of the European Communities of 21 December 1988 on the approximation of the laws of the member states relating to quick-frozen foodstuffs intended for human consumption and provides the general requirements for the manufacture, transport, storage and placing on the market of quick-frozen products and the official control of quick-frozen foodstuffs

Government Decision No 910 of 16 December 2020 approving veterinary requirements for animal feed.²⁰⁹

The mentioned act partially transposes Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene, Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials, Commission Regulation (EU) 2015/786 of 19 May 2015 defining the acceptability criteria for detoxification processes applied to products intended for

²⁰⁷ Government Decision No 657 of 18 August 2014 approving maximum limits for coccidiostats or histomonostats in food following the inevitable transfer of these substances into feeding stuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=19116&lang=ro

²⁰⁸ Government Decision No 806 of 16 October 2013 approving the Rule on quick-frozen foods intended for human consumption, https://www.legis.md/cautare/getResults?doc_id=125621&lang=ro

²⁰⁹ Government Decision No 910 of 16 December 2020 approving veterinary requirements for animal feed, available in Romanian at: [https://www.legis.md/cautareavailable in Romanian at:/getResults?doc_id=125591&lang=ro](https://www.legis.md/cautareavailable%20in%20Romanian%20at%3A%2FgetResults%3Fdoc_id%3D125591%26lang%3Dro)

animal feed, as provided for in Directive 2002/32/EC of the European Parliament and of the Council, Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC, Commission Directive 82/475/EEC of 23 June 1982 laying down the categories of feed materials which may be used for the purposes of labelling of compound feedingstuffs for pet animals, Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed, p.1.1, para. 3-5 and 8; p. 1.2.1, para 3 of the Annex to Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products, and veterinary medicinal products. The Decision is laying down feed safety requirements, the list of feed materials used, including those prohibited for use, feed hygiene requirements, import, export of feed, and good practices applied in animal feeding, including requirements applied to feed undertakings that carry out primary production activities.

Government Decision No 311 of 21 May 2012 approving the Regulation laying down the conditions governing the preparation, placing on the market and use of feed containing medicinal products²¹⁰ transposes the provisions of Council Directive No 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the community and lays down the conditions for the preparation, placing on the market and use of medicated feedingstuffs.

The aim of the competent authorities in **Government Decision No 680/2018 approving the General plan for crisis management in the food and feed sector**²¹¹ invested with responsibilities in the field of food safety is to make the Republic of Moldova a healthier and safer place where consumers can trust that their interests are protected 2004 and establishes the General crisis management plan in the food and feed sector.

Crises in the food and feed sector have highlighted the urgent need to develop and implement a crisis management plan. It will incorporate actions and procedures tailored to reality and aimed at regulating the management and ensuring a rapid and coordinated response of the competent authorities in the field of crisis management. Those organisational procedures make it possible to better coordinate efforts, identify and apply the most effective measures, based on quality scientific information.

²¹⁰ Government Decision No 311/2012 approving the Regulation laying down the conditions governing the preparation, placing on the market and use of feed containing medicinal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114649&lang=ro

²¹¹ Government Decision No 680/2018 approving the General plan for crisis management in the food and feed sector, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125704&lang=ro

The National Agricultural and Rural Development Strategy for 2014-2020 approved by Government Decision No 409 of 4 June 2014²¹² and the Food Safety Strategy for 2018-2022 approved by Government Decision No 1150 of 20 December 2017²¹³, their main objective is to ensure a fair standard of living for farmers, and a safe supply of harmless food at affordable prices for consumers.

Currently the competent authorities invested with the responsibilities in the field of food safety are the following: the Ministry of Agriculture and Food Industry, the Ministry of Health, through the National Agency for Public Health, the Ministry of Internal Affairs, the Ministry of Defence, the Ministry of Finance, through the Customs Service and the National Food Safety, which has the role of coordinating the authorities in the field of food safety.

This General plan for crisis management in the food and feed sector transposes Commission Decision 2004/478/EC of 29 April 2004 on the adoption of a general plan for food/feed crisis management.

Government Decision No 931/2011 on retail trade.²¹⁴

The specific rules for retail trade regulate the activities in retail trade exercised in the territory of the Republic of Moldova by natural and legal persons, regardless of their legal form of organization and type of ownership, establish requirements for these traders and define the types of trade establishments. This Decision does not transpose any European acts.

Government Decision No 1209/2007 on the provision of public catering services.²¹⁵

These rules establish the basic requirements for the activity of all economic operators providing public catering services in the territory of the Republic of Moldova, regardless of the form of ownership and subordination and regulate the relations between economic operators and consumers in the provision of these services.

The economic operator carries out activities in the field of public catering according to the notification submitted to the local public administration authority, specifying the location and type of public catering establishment. Not harmonized with the European Union acts.

²¹² Government Decision No 409/2014 approved by The National Agricultural and Rural Development Strategy for 2014-2020, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110039&lang=ro

²¹³ Government Decision No 1150/2017 approved the Food Safety Strategy for 2018-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=111638&lang=ro

²¹⁴ Government Decision No 931/2011 on retail trade, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130545&lang=ro

²¹⁵ Government Decision No 1209/2007 on the provision of public catering services, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130479&lang=ro

Government Decision No 221/2009 on the approval of rules for microbiological criteria for foodstuffs.²¹⁶

These rules lay down microbiological criteria for certain micro-organisms and the mechanisms of application which food business operators must comply with when implementing general and special hygiene measures.

The rules on microbiological criteria for foodstuffs transposes Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

These rules do not contradict other sanitary and veterinary and sanitary-epidemiological rules and norms related to carrying out other sampling and analysis for the detection and quantitative determination of microorganisms, toxins, or metabolites both in food products suspected of being dangerous and in a risk analysis.

15. Please provide information on the respective fields of responsibilities, organisation and powers of the competent institutions and authorities.

ANSA has the mission to ensure the implementation of state policies in areas aimed at ensuring food safety and food quality, including alcohol, alcohol production, wine and beer, maintenance of a system public measures to ensure animal health and plant protection, the safety of food and raw materials, and the protection of consumers in the food area.

ANSA operates on the basis of Government Decision No 600/2018 on the organization and functioning of the National Food Safety Agency,²¹⁷ Law No 50/2013 on official controls for compliance with feed and food law and detailed rules on animal health and welfare, which transpose Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004²¹⁸, Law No 306/2018 on food safety²¹⁹ harmonized with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 and Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011

²¹⁶ Government Decision No 221/2009 on the approval of rules for microbiological criteria for foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130511&lang=ro

²¹⁷ Government Decision No 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro#

²¹⁸ Law No 50/2013 on official controls for compliance with feed and food law and detailed rules on animal health and welfare, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

²¹⁹ Law No 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

and Law No 221/2007 regarding the sanitary-veterinary activity²²⁰

The main areas of competence of ANSA with regard to the placing on the market of food, feed, and animal by-products:

- biological, chemical, and physical safety of food of animal and plant origin;
- supervision and control of food manufacturing, hygiene at food enterprises, including food units in medical institutions, health resorts, pre-school, primary, secondary, special, extracurricular education institutions, educational alternatives, and children's camps;
- the supervision and control of the production of animal feed and medicated feed, of the hygiene at the feed producing enterprises;
- surveillance and control over the use of genetically modified organisms (GMOs);
- monitoring the quality of primary products, the quality of food and feed;
- authorization and / or registration of food business operators, according to the provisions of Law No 231/2010 on internal trade;²²¹
- certification of food safety for export/re-export, according to the provisions of Law No 160/2011²²² regarding the regulation by authorization of the entrepreneurial activity;
- supervision and control of the labelling of foodstuffs throughout the food chain, including baby foodstuffs, including starting and continuing formulas, cereal-based preparations, foodstuffs intended for special medical purposes and substitutes for a total diet for weight control, in accordance with food regulations;
- monitoring the quality of drinking water used by food businesses at all stages of the food chain, market surveillance of drinking water and mineral water, including bottled water;
- protection of consumers of food products and services at all stages of the food chain;
- identification, assessment, management, and communication of risks in the field of food and feed safety;
- verification of the records in the individual medical records of the employees of the food enterprises and verification of their training in the field of hygiene.

²²⁰ Law No 221/2007 regarding the sanitary-veterinary activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

²²¹ Law No 231/2010 on internal trade, available in Romanian

https://www.legis.md/cautare/getResults?doc_id=127948&lang=ro

²²² Law No 160/2011 regarding the regulation by authorization of the entrepreneurial activity, available in Romanian at: [/www.legis.md/cautare/getResults?doc_id=130022&lang=ro](https://www.legis.md/cautare/getResults?doc_id=130022&lang=ro)

ANSA:

- promote the coordination of activities carried out by international governmental and non-governmental organizations in order to comply with food and feed safety standards;
- contribute to the development of agreements on the recognition of the equivalence of specific food and feed safety measures;
- promotes coherence between international technical standards and food regulations.

16. Hygiene rules: Please provide information on:

a) Specific rules concerning products of animal origin, including information on the situation of agri-food establishments and the microbiological quality of raw milk.

b) Control rules, including the implementation of HACCP (Hazard Analysis and Critical Control Points) by food business operators. Please also provide statistics on the number of units (by activity) that apply HACCP.

c) Specific control rules for products of animal origin.

d) Rules for animal origin by-products, including information on the system for collecting carcasses and materials and the situation of the units.

a) Specific rules for products of animal origin, including information on the situation of agri-food establishments and the microbiological quality of raw milk.

The basic rules of sanitary-veterinary requirements and food safety are regulated by Law No 296/2017 on general food hygiene requirements²²³(transposes: Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004, Article 3 (2) and Article 6 of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004, Commission Regulation (EC) No 2074/2005 of 5 December 2005; and partially transposes: Commission Regulation (EU) No 579/2014 of 28 May 2014), Law No 221/2007 regarding the sanitary-veterinary activity²²⁴, Law No 50/2013²²⁵ on official controls for compliance with feed and food law and animal health and welfare rules (transposed Titles I, II, III, V, VI (Chapter II) and VII (Chapter I) of the Regulation (EC) No 882/2004 of 29 April 2004 on official controls performed to ensure compliance with feed and food law and animal health and animal welfare rules).

The sanitary-veterinary rule for organizing the official specific control of food products of animal origin is regulated by Government Decision No 1112/2010²²⁶ transposes Regulation (EC) No 854/2004 of the European Parliament and of the

²²³ Law No 296/2017 on general food hygiene requirements, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122836&lang=ro#

²²⁴ Law No 221/2007 regarding the sanitary-veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

²²⁵ Law No 50/2013 on official controls for compliance with feed and food law and detailed rules on animal health and welfare, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

²²⁶ Government Decision No 1112/2010 for the approval of the Veterinary Sanitary Norm for the organization of the official specific control of foodstuffs of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125573&lang=ro

Council of 29 April 2004, and stipulates that food business operators must ensure that all stages of food production, processing and distribution, which are under their supervision, meet the hygiene requirements of the provisions of this Regulation and in accordance with Government Decision No 435/2010²²⁷ on the approval of specific rules for the hygiene of foodstuffs of animal origin transposes Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004. The authorization/approval of the establishments is done according to Law No 221/2007 on the sanitary-veterinary activity (Article 18), as well as in accordance with the specific procedure PS (04/1)-1/01 “Authorization and listing of establishments in the field of products of animal origin intended for human consumption”.

Milk production/processing units according to Government Decision No 435/2010 on the approval of specific rules for the hygiene of foodstuffs of animal origin²¹⁴ food business operators must implement procedures to ensure that raw milk meets the criteria in accordance with the legislation in force.

The criteria for raw milk and colostrum are implemented by the food business operator, according to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004, Chapter III, section IX, Annex II transposed in the legislation of the Republic of Moldova.

Thus, the surveillance of the food sector that produces milk is carried out:

- by the food business operator producing the milk;
- by the food business operator collecting or processing the milk;
- by the National Food Safety Agency to supervise the safety criteria in order to comply with the criteria in accordance with the legislation in force:

Germ content at 30 ° C (per ml)	≤ 100,000(1)
Somatic cell content (per ml)	≤ 400,000(2)
^(*1) Variable geometric mean over a period of two months, with at least two samplings per month. ^(*2) Variable geometric mean over a period of three months, with at least one sampling per month, except for the case when the competent authority defines another methodology to consider seasonal variations in production levels.	

b) Control rules, including the implementation of HACCP (Hazard Analysis and Critical Control Points) by food business operators. Please also provide statistics on the number of units (by activity) that apply HACCP

According to Law No 296/2017 on general food hygiene requirements, FBOs should implement and maintain permanent procedures based on HACCP principles. Thus, ANSA in accordance with specific procedure "Audit of the HACCP system in the establishment of FBO", performs audits of verification of

²²⁷ Government Decision No 435/2010 on the approval of specific rules for the hygiene of foodstuffs of animal origin, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125564&lang=en

actions based on HACCP principles in the establishments of processing products of animal origin. Delegated inspector fills-in the checklist approved by the specific procedure. Further, according to provisions of the Government Decision No 221/2009 (harmonized with Commission Regulation (EC) No 2073/2005 of 15 November 2005), FBO shall perform tests based on the microbiological criteria set out in Annex 1 of the Government Decision.

During official control in FBO, ANSA staff evaluate the implementation of procedures based on HACCP basic principles and good hygiene practice, apply appropriate sampling frequencies, assess the decisions of the FBO in the context of procedures based on HACCP principles, check the results of the FBO self-control programs and makes recommendations on implementation of the non-conformities identified during the Audit of the HACCP principles applied.

The situation on implementation of HACCP system is the following:

FBO of animal origin: slaughterhouses -25; FBO for milk and dairy products – 15; FBO for the production of meat and meat products – 19; FBO for the production of fish and fishery products – 4; FBO for honey and bee products – 4; egg collection and packaging centres – 7.

FBO of non-animal origin: 79 non-animal FBO implemented the HACCP system, of which 38 are exporting to the EU. 35 establishments producing alcohol, wine products, beer and alcohol production implementing the HACCP system, of which 28 export to the EU.

c) Specific control rules for products of animal origin.

The organization of official controls along the production chain is carried out in accordance with Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules²²⁸ and on the basis of Law No 131/2012 on entrepreneurial activity.²²⁹ Annually, ANSA elaborates, approves and includes in the State Register of Controls (here and after RSC - the electronic system of the State Chancellery) the Plan of official controls for all areas of competence for the following year. The frequency of controls is based on the risk analysis, in line with the Methodology on state control over entrepreneurial activity based on the risk criteria related to the areas of competence of ANSA, approved by Government Decision No 1280/2018. In 2021 there were included in the system all the planned and unannounced official controls that refer to the entrepreneurial activity. At the central level of ANSA, the Strategic Planning and Quality Management, Risk Analysis and Assessment and Control Planning

²²⁸ Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=122829&lang=en

²²⁹ Law No 131/2012 on entrepreneurial activity, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=68955&lang=en

Department is designated for the purpose of monitoring the fulfilment of official controls, which prepares the monthly/quarterly/half-yearly/annual report on official controls. Official controls are carried out at any stage of production, processing, distribution of food, depending on the risks, the background of food business operators, or any information that could indicate non-conformities. At the end of each year, ANSA is preparing the Annual Report.

ANSA has the following procedures for carrying out official controls:

- General Procedure PG-19/01 "Preparation and performance of official control over the areas of competence of ANSA";
- General Procedure PG-13/02 "Preparation and conduct of official controls on food safety holdings";
- Specific procedure PS/SA-MSD-02/01 „Audit of the HACCP system in food business units”;
- General procedure PG-08/01: Sampling of foodstuffs';
- Specific procedure PS/SA-MSD-01/01 „Verification of Food Traceability”;
- Specific procedure PS/SA-PA-03/01 „Certification of foodstuffs of animal origin for export”;
- General procedure PG-12/01„Actions taken in the case of non-compliant foodstuffs”.

At the same time, the Animal Origin Products Safety and Quality and Sanitary-Veterinary Department, carries out unannounced checks in case of complaints of citizens or food business operators or any non-compliance detected during official inspections by official veterinarians (inspectors). In case of non-conformities in the activity of STSA inspectors, the Department informs through the informative note the ANSA Director-General who in turn conveys the information to the disciplinary commission that operates based on Law No 158/2008 on the civil service and the status of civil servants. The Disciplinary Board may impose any sanctions on inspections.²³⁰

d) Rules for animal by-products, including information on the system of collection of carcasses and materials and the situation of the units.

In accordance with Article 18 of Law No 221/2007, any economic activity related to animal by-products not intended for human consumption (collection, transport,

²³⁰ Law No 158/2008 on the civil service and the status of civil servants, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130341&lang=ro#

handling, treatment, processing, storage, placing on the market, distribution, use and disposal) must be authorized by the National Food Safety Agency.²³¹

In accordance with Article 6 (2) of Law No 129/2019 on animal by-products and derived products not intended for human consumption, operators of animal by-products not intended for human consumption must ensure that all stages of collection, transport, handling, treatment, processing, storage, placing on the market, distribution, use and disposal within the units under their control correspond to requirements established by law.²³²

Depending on the level of risk presented, Law No 129/2019 on animal by-products and derived products not intended for human consumption lays down principles for the classification of animal by-products (materials of categories I, II and III) and possible methods of disposal and use of the by-products. The law is harmonized with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products and derived products not intended for human consumption.²³³

In accordance with that law, operators must ensure compliance with hygiene requirements, traceability of by-products, and that they are accompanied by a veterinary health certificate during transport.

Government Decision No 11/2022 on the approval of the Sanitary-Veterinary Rule on animal by-products and derived products not intended for human consumption.²³⁴

In accordance with Law No 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, all units operating with by-products shall be regularly subject to official controls by the Agency. There are a number of product processing units (Cat. III) that are authorized in the Republic of Moldova (biogas plants, incineration plants, pet food production units using by-products, units for burying animals). However, a national system for the collection of by-products (including animal carcasses) is being developed. For information, the Government of Moldova contracted the services of the International Finance Corporation (IFC), part of the World Bank Group, to conduct the feasibility study, construction of the unit (for products of category I, II and III).²³⁵

²³¹ Law No 221/2007 regarding the sanitary-veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

²³² Law No 129/2019 on animal by-products and derived products not intended for human consumption, available in Romanian at: https://www.legis.md/search/getResults?doc_id=118406&lang=en

²³³ Law No 129/2019 on animal by-products and derived products not intended for human consumption, available in Romanian at: https://www.legis.md/search/getResults?doc_id=118406&lang=en

²³⁴ Government Decision No 11/2022 on the approval of the Sanitary-Veterinary Rule on animal by-products and derived products not intended for human consumption, available in Romanian at: https://www.legis.md/search/getResults?doc_id=130906&lang=en

²³⁵ Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules, available in Romanian at: https://www.legis.md/search/getResults?doc_id=122829&lang=en

17. Funding of checks: Please provide information on specific rules for feed hygiene, including information on the applicable legislation and procedures for approval/registration of feed establishments.

The official controls carried out by the National Food Safety Agency are funded within the limits of the budgetary allocations provided for this purpose for the competent authority according to Article 24 of the Law No 50/2013 on official controls aimed at checking compliance with the feed and food legislation and animal health and welfare rules.²³⁶

The economic operators carrying out activities related to animal feed are subject to the sanitary veterinary authorization/registration procedure, in accordance with Article 18 of the Law No 221/2007 on the sanitary veterinary activity.²³⁷

According to the plan of official controls in establishments subject to supervision by areas of competence, approved by the Director of the Agency, feed business operators shall be subject to official control. The frequency of controls is assessed following the risk assessment, a procedure approved by Government Decision No 1280/2018.²³⁸

Official controls at the said economic operators are performed using the checklists developed in accordance with the legislation applicable to the controlled activity (approved by Order of the Ministry of Agriculture, Regional Development and Environment No 79/2019 on the approval of checklists for the areas under the control of the National Food Safety Agency²³⁹).

During the official controls, the Agency verifies whether/to what extent the rules on feed hygiene are complied with, in order to ensure the safety of feed throughout the food chain, from the primary production of feed to the feeding of animals from which foodstuffs are obtained; with the exception of private domestic feed production from the obtaining of food for private domestic consumption.

The requirements regarding feed hygiene are provided for in Government Decision No 910/2020 approving the sanitary-veterinary requirements for feed.²⁴⁰ Feed is not allowed to be placed on the market and is not allowed to be obtained from

²³⁶ Law No 50/2013 on official controls aimed at checking compliance with the feed and food legislation and animal health and welfare rules, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

²³⁷ Law No 221/2007 regarding the sanitary-veterinary activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro#

²³⁸ Government Decision No 1280/2018 approving the methodology for State control of business activity on the basis of the risk analysis relating to the areas of competence of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127585&lang=ro#

²³⁹ Order of the Ministry of Agriculture, Regional Development and Environment No 79/2019 on the approval of checklists for the areas under the control of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130930&lang=ro#

²⁴⁰ Government Decision No 910/2020 approving the sanitary-veterinary requirements for feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130574&lang=ro

food-producing animals if it is unsafe, i.e., if it has a negative impact on animal or human health, and the food obtained from animals becomes a risk factor for human consumption;

Feed business operators are required to carry out preventive activities, eliminating the feed safety risks. The operators must perform risk control:

- by detecting the presence of pathogenic micro-organisms and other prohibited contaminants in the feed,
- by taking measures to control any dangerous contamination, such as from air, soil, water, fertilizers, plant protection products, biocides, veterinary medicinal products, as well as the handling and disposal of waste;
- by taking measures relating to plant health, animal health and the environment.
- by taking technical or organizational measures to prevent or limit cross-contamination and errors.

Government Decision No 910/2020²⁴¹ also defines the general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP), which, together with the application of good hygiene practices, expand the responsibility of feed business operators.

The National Food Safety Agency has developed checklists for the control of each type of feed activity (including feed hygiene). These checklists, together with others, are approved by the Order of the Ministry of Agriculture and Food Industry No 79/2019.²⁴²

²⁴¹ Government Decision No 910/2020 on the approval of the Sanitary-Veterinary Requirements compared to feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130574&lang=ro#

²⁴² Order of the Ministry of Agriculture, Regional Development and Environment No 79/2019 on the approval of checklists for the areas under the control of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130930&lang=ro#

IV. FOOD SAFETY RULES

18. Please provide information on the legislative framework on food safety rules;

In the Republic of Moldova, food safety is regulated by the following normative and legislative acts:

Law No 306/2018 on food safety²⁴³ The Law aims to achieve a high level of protection of human health and consumer interests in relation to food safety, taking into account the diversity of food supply, including traditional products, ensuring efficient functioning of the national market and lays down general requirements for food safety, the responsibilities of competent authorities, traceability, labelling of foodstuffs, safety requirements for the organisation of the process of production, authorisation, registration, food safety supervision and control procedures, subsequent responsibilities and resolution of disputes arising between food/feed operators and state control and supervisory bodies as a result of control and supervisory activities.

The law transposes the following provisions into the national legislation:

- Regulation (EC) No 178/2002 of the European Parliament and of the EU Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements for food of animal origin set by Regulation (EC) No 178/2002 of the European Parliament and of the Council.

Law No 50/2013 on official controls to verify compliance with the legislation on animal feed and food and with animal health and welfare rules²⁴⁴. This law lays down the general rules on the performance of official controls in order to verify compliance with the rules relating to the prevention, elimination or reduction to permissible levels of risks to human and animal health, either directly or through environmental conditions; guarantee fair practices in trade in feed and food and protection of consumer interests, including the labelling of feed and food and other forms of consumer information, and provide for the powers and duties of competent authorities in carrying out official controls, methods of sampling and analysis used in official controls, contingency plans drawn up by relevant departments of the crisis management competent authority, organisation of official controls by the competent authority on the import of feed and food, and the

²⁴³ Law No 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

²⁴⁴ Law No 50/2013 on official controls to verify compliance with feed and food legislation and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

procedure for the registration and authorisation of food and veterinary economic operators.

The exercise of official controls under this law is without prejudice to the primary legal responsibility of feed and food operators to ensure the safety of feed and food in accordance with relevant legislation or to any civil or criminal liability arising from non-compliance with their obligations.

The law does not regulate feed used in auxiliary households.

This law provides for the transposition of Titles I, II, III, V, VI (Chapter II) and VII (Chapter I) of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Law No 119/2004 on plant protection products and fertilisers.²⁴⁵ The law establishes a legal framework and state policy in the sphere of phytosanitary products and fertilizers, regulates the conditions of their research, testing, experimentation and state approval, manufacturing, import, transportation, storage, marketing and harmless use for humans, animals and the environment, the relations related to state supervision and control over compliance with the current legislation, determines the rights and obligations of enterprises, institutions, organizations and citizens, the powers of relevant competent authorities, acts that constitute violations, as well as the liability for their commission.

The fundamental principles of the state policy in the field of phytosanitary products and fertilizers are the following:

- the priority of protecting human health and the environment as regards economic efficiency of the use of plant protection products and fertilizers;
- state supervision over their approval, manufacture, import, transportation, storage, marketing, and use;
- scientific and practical justification of the application of phytosanitary products and fertilizers by land beneficiaries of any type of ownership;
- optimising the use of plant protection products and fertilizers by extending the application of biological methods of plant protection and other environmentally harmless processes;
- harmlessness of plant protection products and fertilizers for humans, animals, and the environment in the case of their manufacture, research-testing-experimentation, and application, subject to compliance with the requirements established by national standards, phytosanitary regulations, and other normative acts;

²⁴⁵ Law No 119/2004 on plant protection products and fertilisers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

- promotion of an integrated state policy in the field.

For the purpose of transposing the provisions of Ar. 1 and 3 of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides and Article 3 and 59 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Government Decision No 115/2013 on the control of nitrates in foods of plant origin²⁴⁶.

The maximum nitrate limits are valid for food products of plant origin that are placed on the market of the Republic of Moldova, and the nitrate content shall not exceed the maximum limits set in the table in the Annex to the Decision.

Maximum nitrate limits shall apply to the edible part of food of plant origin in the form in which it is marketed. Does not apply to fresh spinach to be processed and transported directly in bulk from the field to the processing plant.

The purpose of the sampling procedures is to obtain a representative sample from a batch intended for analysis in order to verify compliance with the maximum nitrate limits in foodstuffs of plant origin.

Compliance with the maximum nitrate limits in foodstuffs of plant origin is established based on the contents determined in laboratory samples.

The sampling shall be carried out by a trained specialist designated by the competent authority.

Food business operators, natural or legal persons, shall allow the agent to take samples of food products of plant origin to check compliance with the maximum nitrate limits, established by this Decision.

The rules on the control of nitrates in foodstuffs of plant origin transpose point 1 of the Annex to Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.

Methods of sampling for the official control of the content of nitrates in food products of plant origin are implementing the requirements of Article 8 of

²⁴⁶ Government Decision No 115/2013 on the control of nitrates in foods of plant origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123312&lang=ro

Commission Regulation (EC) No 1881/2006/EC of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and the provisions of Commission Regulation (EC) No 1882/2006/EC of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.

Government Decision No 1191/2010 approving the sanitary regulation on maximum permissible residue limits in plant protection products in or on food and feed of plant and animal origin for animals.²⁴⁷

That Regulation is particularly concerning public health and establishes the need to ensure a high level of consumer protection, includes harmonised provisions on the maximum permissible residue limits of plant protection products in or on food and feed of plant and animal origin for animals and lays down the groups of products subject to harmonised MALs and active substances that do not require MALs, MALs applicable to products of plant and animal origin, MALs allowed for processed and/or composite products, and the procedure for organisation of official controls, sampling and methods of analysis.

This Regulation shall apply to products of plant and animal origin or certain parts of those products and intended for use as food or feed and shall be binding on all economic operators.

The Regulation shall not apply to products listed in Annex 1, specifically setting out the intention for:

- manufacture of products other than food and feed;
- sowing or planting;
- activities authorized by law for testing for active substances.

The MALs in plant protection products established in accordance with this Regulation shall not apply to products listed in Annex 1 which are intended for export to third countries and are treated before export, should it be satisfactorily demonstrated that the country of destination claims or accepts the treatment in question, to prevent the introduction of harmful organisms into its territory.

This sanitary regulation on maximum allowable residue limits in plant protection products in or on food and feed of plant and animal origin partially transposes Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414/EEC and sets the normative framework in the said field.

²⁴⁷ Government Decision No 1191/2010 approving the sanitary regulation on maximum permissible residue limits in plant protection products in or on food and feed of plant and animal origin for animals, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114320&lang=ro

Government Decision No 1004/2010 approving the sampling methods for the official control of pesticide residues on and from plants and products of plant and animal origin.²⁴⁸

The purpose of the sampling procedures is to obtain a representative sample from a batch intended for analysis to verify compliance with the maximum residue pesticide limits. Where the maximum residue limit for a given product is missing, the limits laid down by the Codex Alimentarius Commission shall be taken into account. The methods and procedures defined include methods and procedures recommended by the Codex Alimentarius Commission.

Samples shall be taken by an inspector appointed, as appropriate, by the National Food Safety Agency and/or by the competent authority for public health surveillance for the purpose of identifying, assessing risks to human health, mitigating their negative impact on health, and justifying the MALs of harmful substances in soil, water, air, and foodstuffs.

Producers and traders of agricultural products, natural or legal persons, shall allow the designated inspector to take samples of fresh, dried, processed or included in complex foodstuffs and of products of animal origin intended for import, export, or domestic consumption.

The methods transpose Commission Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues on and in products of plant and animal origin and repealing Directive 79/700/EEC.

Government Decision No. 1045/2005 approving the Regulation on the import, storage, marketing and use of plant protection products and fertilizers.²⁴⁹

This regulation lays down the conditions and way of importing, storing, marketing and use of plant protection products and fertilizers with the aim of suppressing their illicit import, ensuring the protection of vital interests and the security of citizens, in accordance with requirements of the legislation in force.

On the territory of the Republic of Moldova it is allowed to import, manufacture, transport, store, trade and use only phytosanitary products and fertilizers, approved by the State Center for Attestation and Approval of phytosanitary products and included in the State Register of phytosanitary Products and Fertilizers, allowed for use in the Republic of Moldova.

²⁴⁸ Government Decision No 1004/2010 approving the sampling methods for the official control of pesticide residues on and from plants and products of plant and animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125571&lang=ro

²⁴⁹ Government Decision No. 1045/2005 approving the Regulation on the import, storage, marketing and use of plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113258&lang=ro

Government Decision No. 1307/2005 on the approval of the Regulation on attestation and state approval of plant protection products and fertilizers for use in agriculture and forestry.²⁵⁰

On the territory of the Republic of Moldova it is allowed to import, manufacture, transport, store, trade and use only phytosanitary products and fertilizers, approved by the State Center for Attestation and Approval of phytosanitary products and included in the State Register of phytosanitary Products and Fertilizers, allowed for use in the Republic of Moldova.

Government Decision No. 520/2010 on the approval of the sanitary regulation on contaminants in foodstuffs.²⁵¹

This regulation governs contaminants contained or likely to be present in foodstuffs and the maximum levels of some contaminants in foodstuffs and aims to protect public health.

For the purposes of this regulation, the terms set out in Law No. 306/2018 on food safety²⁵² shall apply.

This Regulation shall not apply to:

- contaminants that have significance only for the quality of food products, but are not significant for Public Health; alien bodies, such as insect fragments, animal hair and others;
- microbial toxins, such as botulinum toxin and staphylococcal enterotoxin, as well as microorganisms;
- technological assistants;
- other contaminants that are subject to specific normative acts.
- Foodstuffs placed on the market must not contain contaminants in quantities exceeding the maximum levels laid down in this regulation.
- Maximum levels specified in Annex 1 to this Regulation shall apply to the edible part of the foodstuffs concerned.

This sanitary Regulation on contaminants in foodstuffs transposes Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food and transposes Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs; Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in

²⁵⁰ Government Decision No. 1307/2005 on the approval of the Regulation on attestation and state approval of plant protection products and fertilizers for use in agriculture and forestry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125303&lang=ro

²⁵¹ Government Decision No. 520/2010 on the approval of the sanitary regulation on contaminants in foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=126796&lang=ro

²⁵² Law No. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

feed and food Commission recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxins in cereals and cereal-based products, Council Directive 76/621/EEC of 20 July 1976 setting the maximum level of erucic acid in oils and fats intended for human consumption as such and in foods containing added oils and fats.

Government Decision No. 42/2020 for the approval of the Requirements for the sustainable use of plant protection products.²⁵³

Requirements for the sustainable use of plant protection products are hereby laid down to reduce risks and their effects on human health and the environment by promoting integrated pest management and alternative techniques such as non-chemical methods for plant protection. It applies to plant protection products as defined in art. 3 of Law no. 119/2004²⁵⁴ plant protection products and fertilisers.

The decision transposes Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community Action for the sustainable use of pesticides.

Regulation No. 231/2003 on the management of plant protection products and fertilizers in the national economy.²⁵⁵

The Regulation on the management of plant protection products and fertilizers in the national economy is intended for specialists in the field of plant protection, environment, hygienists, specialists in labor protection, institutions for designing agricultural objectives, other specialists in the national economy, engaged in the work with plant protection products and fertilizers.

This Regulation is developed for the purpose of ensuring safety at the management of plant protection products in agriculture, establishes the requirements for protection and hygiene of labor, fire safety, environmental protection, based on the Law on plant protection and phytosanitary quarantine No. 228/2010²⁵⁶, The Law on the regime of harmful products and substances No. 1236/1997²⁵⁷, Government Decision no. 599/2000 on the approval of the regulation on the import, marketing and use of chemical and biological preparations for the protection and stimulation of plant growth²⁵⁸ and other legislative and normative acts in the field of plant

²⁵³ Government Decision No. 42/2020 for the approval of the Requirements for the sustainable use of plant protection products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=120320&lang=ro

²⁵⁴ Law No. 119/2004 plant protection products and fertilisers, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

²⁵⁵ Regulation No. 231/2003 on the management of plant protection products and fertilizers in the national economy, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=37349&lang=ro

²⁵⁶ Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

²⁵⁷ Law No. 1236/1997 on the regime of harmful products and substances, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=113322&lang=ro

²⁵⁸ Government Decision No. 599/2000 on the approval of the regulation on the import, marketing and use of chemical and biological preparations for the protection and stimulation of plant growth, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=47675&lang=ro

protection, labor and sanitary hygiene, environmental protection. The Regulation has outdated provisions and should be adapted to all normative acts related to the field.

The sanitary, environmental and hygienic requirements of this Regulation extend to the production facilities, processes and equipment regarding the management of plant protection products and fertilizers and are mandatory for execution by natural and legal persons, regardless of departmental affiliation and form of ownership, whose activity belongs to the field of plant protection, as well as those who import and sell plant protection products and fertilizers, build and operate production facilities, means of transport, technical-sanitary equipment, intended for works with pesticides and fertilizers, including neutralization and deactivation equipment.

Law No. 279/2017 on consumer information on foodstuffs.²⁵⁹

The law establishes mandatory information on foodstuffs in order to ensure a high level of consumer protection, taking into account their differences in perception and need for information, while ensuring proper functioning of the market of the Republic of Moldova and establishes the general objectives and categories on foodstuff information, general requirements on foodstuff information and responsibilities of food operators, as well as the content of the nutrition declaration.

This law defines the general requirements and responsibilities governing food information, in particular food labelling. It lays down the means for guaranteeing consumers ' right to information and procedures for providing food information, taking into account the need to provide for sufficient flexibility to be able to respond to future developments and new information requirements.

This applies to food business operators at all stages of the food chain, where their activities relate to informing consumers about foodstuffs, as well as all foodstuffs intended for the final consumer, including those delivered by catering establishments, and foodstuffs intended to be supplied to them. This law applies to public catering services provided by transport companies.

The rules on nutrition and health records on foodstuffs, the rules on the labelling of food supplements, as well as the rules on the labelling of foodstuffs for special nutritional purposes shall be approved by the government.

This law transposes:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing

²⁵⁹ Law No. 279/2017 on consumer information on foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122833&lang=ro

Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004;

- Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs.

Law No. 296/2017 on general food hygiene requirements²⁶⁰

This law lays down the general food hygiene requirements for food business operators and establishes the responsibilities of food business operators regarding food hygiene, the procedure for drawing up and using national best practice guidelines, the general hygiene requirements for primary production, including hygiene requirements applicable to food, taking into account the following regulations:

- ensuring food safety throughout the food chain;
- general implementation of procedures based on the principles of Hazard Analysis and Critical Control Points (hereinafter referred to as Hazard Analysis and Critical Control Points – *HACCP*), together with the application of good hygiene practices;
- development and compliance with national and international guidelines of good practice at all stages of the food chain, in accordance with food hygiene requirements and the application of HACCP principles;
- verification of compliance of imported foodstuffs with the hygiene requirements of national foodstuffs, equivalent to those of the European Union;
- making food business operators responsible for food safety.

The provisions of this law apply to all stages of production, processing and distribution of food products, as well as export activities.

The provisions of this law do not apply:

- primary production for private household consumption;
- domestic preparation, handling and / or storage of foodstuffs intended for private domestic consumption;
- collection centres and tanneries falling within the definition of food-related activities only because they handle the raw material for the production of gelatin or collagen.

²⁶⁰ Law No. 296/2017 on general food hygiene requirements, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122836&lang=ro

Given law:

- transposes Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
- transposes Art. 3 Para. (2) and Art. 6 of Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin;
- transposes Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 ;
- partially transposes Commission Regulation (EU) No 579/2014 of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea .

Law No. 221/2007 on the sanitary veterinary activity²⁶¹

This law establishes main sanitary veterinary norms and requirements in the Republic of Moldova, the rights and obligations of the state, natural and legal persons in the process of production, processing, storage, transportation and marketing of live animals and products of animal origin.

The purpose of the law is to ensure the health of animals, preventing the transmission of diseases from animals to humans, to ensure the safety of animal products intended for human consumption, sanitation and quality of feed, testing and authorization of veterinary drugs and substances used in veterinary diagnostic activities, protection of country's territory from infectious diseases by organizing veterinary sanitary activity.

Likewise, it provides for the organization and functioning of veterinary sanitary services, veterinary sanitary activity, obligations and responsibilities of natural and legal persons in the veterinary sanitary field, procedure for issuing veterinary authorization, veterinary sanitary requirements on animal health and germinal products of animal origin, veterinary sanitary requirements on the movement of products and by-products of animal origin, veterinary sanitary requirements on the protection of public veterinary health, procedure for import, transit and export of goods subject to state veterinary control, veterinary sanitary requirements on the protection and welfare of animals, State Veterinary sanitary activities, delimitation

²⁶¹ Law No. 221/2007 on the sanitary veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

of functions between authorities with supervisory and control duties in the field of animal products flow.

The procedure for requesting, granting, suspending and withdrawing the permissive acts in the veterinary field provided by this law for economic agents is established by Law No. 160/2011²⁶² on the regulation by authorization of entrepreneurial activity in the part where it is not regulated by this law.

This law does not transpose European acts.

Law No. 182/2019 on drinking water quality²⁶³

This law establishes the legal framework on the quality of drinking water, as well as measures on the part of authorities responsible for ensuring compliance with the quality of drinking water, procedure for supervision and monitoring, information, reporting and ensuring the quality of drinking water.

The purpose of this law is to ensure sustainable compliance with drinking water quality by creating a flexible and transparent legal framework, as well as by promoting adequate risk management.

This law aims to protect human health from the adverse effects of drinking water contamination by ensuring its harmlessness and purity.

This law transposes Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and partially transposes Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the public with regard to radioactive substances in water intended for human consumption.

Government decision No. 1150/2017 on the approval of Food Safety Strategy for the years 2018-2022²⁶⁴

The Food Safety Strategy for 2018-2022 represents a development of provisions of Food Safety Strategy for 2011-2015, approved by Government Decision No. 747/2011²⁶⁵ and it is fully in line with the National Agricultural and Rural Development Strategy for 2014-2020, approved by Government Decision No. 409/2014²⁶⁶, The National Public Health Strategy for 2014-2020, approved by

²⁶² Law No. 160/2011 on the regulation by authorization of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro

²⁶³ Law No. 182/2019 on drinking water quality, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119769&lang=ro

²⁶⁴ Government decision No. 1150/2017 on the approval of Food Safety Strategy for the years 2018-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=111638&lang=ro

²⁶⁵ Government Decision No. 747/2011 approved by The Food Safety Strategy for 2018-2022 represents a development of provisions of Food Safety Strategy for 2011-2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103235&lang=ro

²⁶⁶ Government Decision No. 409/2014 approved by National Agricultural and Rural Development Strategy for 2014-2020, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110039&lang=ro

Government Decision No. 1032/2013²⁶⁷ with the main objective of achieving a high level of food safety and consumer protection, taking into account the diversity of food supply, access to external markets and ensuring close and harmonious cooperation between central public authorities.

The basic principle of food safety policies, stipulated in Law No. 306/2018 on food safety²⁶⁸, is the application of the principle of “from farm to fork”, which includes all stages of the food chain, including: the production of animal feed; plant health; animal health, protection and welfare; primary production; food processing, their storage, transportation, marketing, import and export. In this integrated approach, the primary responsibility for the production of safe food as well as for the application of related legislation lies with the operators of the food business. However, other stakeholders, both competent authorities and consumers, also play an important role. In the management of food controls important scientific research based on the level of scientific risk are based on the level of risk.

Respective present Strategy describe the current situation in the food safety and Food control Sector in the Republic of Moldova identifies advantages, disadvantages, opportunities and risks through a SWOT analysis, defines the general objective and specific objectives, the problems that require government intervention and identifies the necessary measures within each field, clearly stipulating the responsibilities and deadlines for execution.

The responsibility for regulating food safety policy is borne by the Ministry of Agriculture and Food Industry and is partially shared with the Ministry of Health. The implementation tasks in the field are placed in the competence of the National Food Safety Agency, the National Agency for Public Health or other central public authorities.

Monitoring, surveillance and control activities are carried out under laws and government decisions. In general, these normative acts are harmonized with EU legislation: Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Within the National Food Safety Agency, official control plans are developed centrally under Law No.131/2012 on state control over entrepreneurial activity and Law No.50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, and their implementation is carried out by territorial subdivisions. Also, at central level, the National Food Safety Agency

²⁶⁷ Government Decision No. 1032/2013 on the approval of the National Public Health Strategy for the years 2014-2020, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103097&lang=ro

²⁶⁸ Law No. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

develops procedures and instructions, develops and monitors the implementation of national residue monitoring plans, manages the activity of territorial subdivisions in relation to the safety of food products of animal and plant origin; analyzes and processes monthly, quarterly, semi-annual and annual data and reports sent by territorial subdivisions; communicates permanently with DG SANTE in order to obtain and maintain the status of an approved country for the export of food products of animal origin to the EU market.

The monitoring and supervision of food business operators is carried out through a number of methods and programs, which include monitoring activities for established indices, documentary surveillance, on-site inspections, sampling and testing of samples.

The manner of carrying out official controls and supervision of products of animal and non-animal origin, retail and public catering establishments, pharmaceutical products for veterinary use, feed are provided in the National Multiannual Control Plan of the National Food Safety Agency. Annual residue monitoring plans for red meat, meat products, eggs, natural honey and fish are also being developed.

In accordance with national regulatory requirements, the official control of the units must be carried out in conjunction with risk analysis. However, surveillance programmes for the safety of foodstuffs of animal and non-animal origin show that the frequency of checks in production, processing, storage or retail establishments is not correlated with the level of risk assigned.

The National Agency for Public Health carries out state supervision of Public Health in the field of food safety in accordance with the provisions of Law No. 10/2009 on state surveillance of Public Health²⁶⁹ and in accordance with the areas of competence indicated in Law No.306/2018²⁷⁰. For all fields of activity and groups of products that fall within its competence in the field of food safety, sanitary regulations are developed harmonized with national and international rigors and approved by the government.

Government Decision No. 435/2010 on the approval of specific hygiene rules for foodstuffs of animal origin.²⁷¹

These rules lay down specific hygiene rules for processed or unprocessed foodstuffs of animal origin for food business operators. These specific rules complement the general Rules on food hygiene and provide for the obligations of food business operators and the conditions for the importation of food products of animal origin.

²⁶⁹ Law No. 10/2009 on state surveillance of Public Health, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125959&lang=ro

²⁷⁰ Law no. 306/2018 on food safety, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=112711&lang=ro

²⁷¹ Government Decision No. 435/2010 on the approval of specific hygiene rules for foodstuffs of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125564&lang=ro

These rules shall not apply to foodstuffs containing both products of plant origin and processed products of animal origin, unless expressly indicated otherwise. At the same time processed foodstuffs of animal origin used for the preparation of such foodstuffs must be obtained and handled in accordance with these rules.

These Rules do not apply to:

- primary production intended for private household use;
- production, handling and storage of foodstuffs for own consumption;
- direct sale by the producer of small quantities of primary products to the final consumer or to a local retail enterprise which supplies the final consumer directly;
- the direct sale by the producer of small quantities of meat from poultry and lagomorphic animals slaughtered on the farm to the final consumer or to a local retail undertaking which supplies such meat directly to the final consumer as fresh meat;
- hunters who sell small quantities of wild game or wild game meat directly to the final consumer or to a local retail enterprise supplying the final consumer directly.

The rules shall apply in retail trade in case of operations carried out with a view to the sale of foodstuffs of animal origin to another undertaking, except where:

- Operations are limited to storage or transport, but in this case the specific temperature requirements laid down in Chapters IV to XVI of these rules must be complied with;
- the sale of foodstuffs of animal origin from the retail undertaking is intended for other retail undertakings also in the case of a localized and restricted activity.

These specific rules for the hygiene of products of animal origin transpose Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin,, Annexes II to IV and VI to Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products covered by Regulation (EC) No 853/2004 of the European Parliament and of the Council and the organisation of official controls provided for in Regulation (EC) No. 854/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending regulations (EC) No. 853/2004 and (EC) no 854/200.

Government Decision No. 1112/2010 for the approval of the sanitary-veterinary norm for the organization of the official control of foodstuffs of animal origin.²⁷²

The sanitary-veterinary rule for organizing the official specific control of foodstuffs of animal origin establishes the way of organizing and performing the official control of foodstuffs of animal origin and checking compliance with the requirements for feed and foodstuffs of animal origin, animal health and welfare at economic agents active in the food sector. It applies without prejudice to the primary responsibility of economic agents active in the field of food products of animal origin, stipulated in law no. 306/2018 on food safety.

The provisions of this rule transposes the provisions of Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Government Decision No. 59/2017 on the approval of measures implementing the rapid alert system for food and feed at national level²⁷³.

These measures are necessary for the application and operation of the rapid alert system for food and feed at national level and provide for the rights and obligations of members of the alert network, alert notifications, information exchange with other states. Ministry of Agriculture and Food Industry ensures the elaboration and submission for approval, in accordance with the provisions of the legislation, of the technical concept of the automated information system for transmitting, receiving and recording alerts for food and feed.

The measures implementing the rapid alert system for food and feed at national level transpose Regulation (EU) No. 16/2011 of 10 January 2011 laying down implementing measures for the rapid alert system for food and feed.

Government Decision No. 680/2018 approving the general plan for crisis management in the food and feed sector²⁷⁴.

The goal of the competent authorities with responsibilities in the field of food safety is to make the Republic of Moldova a healthier and safer place, where consumers can trust that their interests are protected.

Crises in the food and feed sector have highlighted the urgent need to develop and implement a crisis management plan. It will contain actions and procedures

²⁷² Government Decision No. 1112/2010 for the approval of the sanitary-veterinary norm for the organization of the official control of foodstuffs of animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125573&lang=ro

²⁷³ Government Decision No. 59/2017 on the approval of measures implementing the rapid alert system for food and feed at national level, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125631&lang=ro

²⁷⁴ Government Decision No. 680/2018 approving the general plan for crisis management in the food and feed sector, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125704&lang=ro

adapted to reality aimed at regulating management and ensuring a rapid and coordinated response of the authorities with responsibilities in the field of crisis management. Those organisational procedures make it possible to better coordinate efforts, identify and apply the most effective measures, based on quality scientific information.

The national Strategy for agricultural and Rural Development for 2014-2020, approved by Government Decision No. 409 of June 4, 2014 and the Food Safety Strategy for 2018-2022, approved by Government Decision No. 1150 of December 20, 2017, have as main objective ensuring a fair standard of living for farmers, stable supply of harmless food at affordable prices for consumers.

Currently the competent authorities with responsibilities in the field of food safety are: the Ministry of Agriculture and Food Industry, Ministry of Health, through the National Agency for Public Health, Ministry of Internal Affairs, Ministry of Defense, Ministry of Finance, through the Customs Service and National Food Safety Agency which has the role of coordinator of authorities in the field of food safety.

This General Plan for Crisis Management in the food and feed sector transposes Commission Decision 2004/478/EC of 29 April 2004 on the adoption of a general plan for Crisis Management in the food and feed sector.

Government Decision No. 931/2011 on the conduct of retail trade.²⁷⁵

The specific rules for the conduct of retail trade regulate the activities in retail trade practiced on the territory of the Republic of Moldova by natural and legal persons, regardless of their legal form of organization and type of ownership, establish requirements towards these traders and define the typology of trade units.

This General Plan for Crisis Management in the food and feed sector transposes Commission Decision 2004/478/EC of 29 April 2004 on the adoption of a general plan for Crisis Management in the food and feed sector.

Government Decision No. 1209/2007 on the provision of public catering services²⁷⁶

The given rules establish the basic requirements for the activity of all economic agents providing public catering services on the territory of the Republic of Moldova, regardless of the form of ownership and subordination, and regulate the relations between economic agents and consumers in the provision of these services, establish the specific rules for the provision of public catering services, the type-nomenclature of public catering establishments, the sanitary regulation

²⁷⁵ Government Decision No. 931/2011 on the conduct of retail trade, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130545&lang=ro

²⁷⁶ Government Decision No. 1209/2007 on the provision of public catering services, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130479&lang=ro

for public catering establishments, as well as the technical requirements for public catering establishments, equipment, inventory and installations, including professional requirements for personnel employed in public catering establishments.

The economic agent carries out activities in the field of public catering according to the notification submitted to the local public administration authority, in which the location and type of public catering unit is indicated.

It is not harmonized with the documents of the European Union.

Government Decision No. 221/2009 on the approval of rules on Microbiological Criteria for foodstuffs.²⁷⁷

These rules lay down microbiological criteria for certain micro-organisms and application mechanisms which food business operators must comply with when implementing general and special hygiene measures and provide for general and special testing and sampling procedures, the analytical method applied, guidelines for sampling, including sampling rules for germs.

The rules on Microbiological Criteria for foodstuffs transpose Regulation (EC) No. 2073/2005 of 15 November 2005 on Microbiological Criteria for foodstuffs. These rules do not contradict other sanitary-veterinary and sanitary-epidemiological rules and norms related to carrying out other sampling and analysis for the detection and quantitative determination of microorganisms, toxins or metabolites both in food products suspected of being dangerous and in a risk analysis.

Government Decision No. 229/2013 for the approval of the sanitary regulation on food additives.²⁷⁸

This Regulation lays down rules on food additives used in foodstuffs with a view to ensuring the efficient functioning of the internal market, a high level of protection of the health of the population and a high level of consumer protection, including the protection of consumer interests and fair practices in trade in foodstuffs, taking into account, where appropriate, the protection of the environment.

The regulation provides:

- the national list of food additives authorised for use in foodstuffs and the conditions of use, according to Annex no. 1 of the Regulation; the list of food additives, including carriers, authorised in food additives, food enzymes, food flavourings and nutrients and their conditions of use, as set out in Annex no. 2 of the Regulation; the list of food colouring agents

²⁷⁷ Government Decision No. 221/2009 on the approval of rules on Microbiological Criteria for foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130511&lang=ro#

²⁷⁸ Government Decision No. 229/2013 for the approval of the sanitary regulation on food additives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109707&lang=ro#

referred to in point 54 of this Regulation for which food labels include additional information;

- conditions of use of food additives in foodstuffs, including food additives, food enzymes and food flavourings;
- rules on the labelling of food additives marketed as such.

The sanitary regulation on food additives lays down transpose Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives..

19. Please provide information on the respective areas of responsibilities, organisation and competences of institutions and competent authorities.

The authorities responsible for the development and implementation of the food safety regulatory framework in the Republic of Moldova are:

1. Ministry of Agriculture and Food Industry

Government Decision No. 695/2017 on the organisation and functioning of the Ministry of Agriculture and Food Industry²⁷⁹

The Regulation on the organisation and functioning of the Ministry of Agriculture and Food Industry governs its mission, functions, fields of activity and rights, as well as the organisation of the activity, which is the central specialised body of the public administration responsible for the implementation of government policy in the fields of activity entrusted to it.

The Ministry's task is to analyse the situation and problems in its fields of activity, to develop effective public policies in the areas referred to in point 6, to monitor the quality of policies and legislative acts, and to propose justified State interventions that will provide effective solutions in the fields of competence, ensuring the best relationship between expected results and expected costs.

The Ministry shall carry out the functions established by this Regulation in the following areas:

- production of products of plant and animal origin;
- processing of products of plant and animal origin;
- wine and alcoholic beverages;
- plant protection and phytosanitary quarantine;
- organic production and products with designation of origin;

²⁷⁹ Government Decision No. 695/2017 on the organisation and functioning of the Ministry of Agriculture and Food Industry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro

- veterinary medicine;
- selection and breeding in animal husbandry;
- food safety;
- the development and organisation of the markets in agricultural and agri-food products;
- rural development programmes;
- consultancy in agriculture;
- land improvements and land fund.

2. National Food Safety Agency

Government Decision No. 600/2018 on the organisation and functioning of the National Food Safety Agency.²⁸⁰

The National Food Safety Agency (hereinafter — the Agency) has the task of ensuring the implementation of state policies in the areas aimed at guaranteeing food safety and food quality, including ethyl alcohol, alcoholic production, wine products and beer, maintaining a system of public measures to ensure animal health and plant protection, the harmfulness of food and raw materials, and the protection of consumers in the food sector.

The Regulation on the organisation and functioning of the National Food Safety Agency governs the mission, areas of activity, functions and rights of the National Food Safety Agency and the organisation of its work. The Agency is the central administrative authority attached to the Government which implements State policy in the fields of activity entrusted to it. In its work, the Agency shall be governed by the Constitution of the Republic of Moldova,²⁸¹ Law No. 136/2017 on the Government,²⁸² Law No. 221/2007 on veterinary activity,²⁸³ Law No. 306/2018 on food safety,²⁸⁴ Law No. 228 /2010 on plant protection and phytosanitary quarantine²⁸⁵ and other legislative acts, decrees of the President of the Republic of Moldova, ordinances, decisions and provisions of the Government, and this Regulation.

²⁸⁰ Government Decision No. 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

²⁸¹ Constitution of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128016&lang=ro

²⁸² Law No. 136/2017 on the Government, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125861&lang=ro

²⁸³ Law No. 221/2007 on veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

²⁸⁴ Law No. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

²⁸⁵ Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

In its fields of activity, the Agency works with central and local public administration authorities as well as with international bodies.

The main areas of competence of the Agency in relation to food safety are:

- the biological, chemical and physical safety of food of animal and plant origin;
- supervision and control of food production, hygiene in food businesses, including food establishments in healthcare establishments, spa establishments, pre-school establishments, pre-primary, primary, secondary, special, extracurricular establishments, educational alternatives and children's camps;
- supervision and control of the production of feed and medicated feedingstuffs, hygiene in feed businesses;
- supervision and control of the use of genetically modified organisms (GMOs);
- supervision of the quality of primary products, food and feed quality;
- the authorisation and/or registration of food business operators, in accordance with Law No. 231/2010 on internal trade²⁸⁶;
- certification of the harmfulness of food products for export/re-export, in accordance with Law No. 160/2011 regulating the activity of entrepreneurs by authorisation²⁸⁷;
- supervision and control of food labelling throughout the food chain, including baby foods, including infant formula and follow-on formula, processed cereal-based food, food for special medical purposes and total diet replacement for weight control, in accordance with food regulations;
- monitoring the quality of drinking water used by food businesses at all stages of the food chain, market surveillance of drinking water and mineral waters, including bottled waters;
- the protection of consumers of food products and services at all stages of the food chain;
- identification, assessment, management and communication of risks in the area of food and feed harmfulness;
- checking records in the individual health records of food business employees and checking their hygiene training.

The Agency shall:

²⁸⁶ Law No. 231/2010 on internal trade, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=127948&lang=ro

²⁸⁷ Law No. 160/2011 regulating the activity of entrepreneurs by authorisation, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=130022&lang=ro#

- promote the coordination of work on compliance with food and feed safety standards carried out by international governmental and non-governmental organisations;
- contribute to the development of agreements on the recognition of equivalence of specific food and feed safety measures;
- promote consistency between international technical standards and food regulations.

3. Republican Veterinary Diagnostic Centre

Government Decision No. 1211/2018 approving the Statute of the Public Institution ‘Republican Centre of Veterinary Diagnostic’²⁸⁸

These Regulations govern the mission, areas of competence, functions and rights of the Public Institution “Republican Centre of Veterinary Diagnostic” and the organisation of its activities. The Centre is a public institution in which the National Food Safety Agency acts as founder. It is a self-managed public institution and is the National Reference Laboratory performing laboratory test on official control on animal health and food safety.

The areas of competence of the Centre shall be as follows:

- laboratory investigations in the field of animal health, food and feed safety and quality;
- laboratory investigations to verify safety and hygiene criteria in food chain operators;
- laboratory investigations in the field of quality and safety verification of veterinary medicinal products;
- risk assessment and scientific research in the fields of activity.

Republican Center for Veterinary Diagnosis includes at regional level:

- Food Safety laboratories (Center and North)
- Animal Health laboratories (Center, North and South).

4. Central Phytosanitary Laboratory

Government Decision No. 1209/2018 approving the Statute of the Public Institution “Central Phytosanitary Laboratory”²⁸⁹

²⁸⁸ Government Decision No. 1211/2018 approving the Statute of the Public Institution Republican Centre of Veterinary Diagnostic, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128878&lang=ro

²⁸⁹ Government Decision No. 1209/2018 approving the Statute of the Public Institution “Central Phytosanitary Laboratory”, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128880&lang=ro

This Regulations govern the mission, areas of competence, functions and rights of the Public Institution ‘Central Phytosanitary Laboratory’ and the organisation of its work.

The areas of competence:

- verification and identification of plant health, plant protection and nutrition, soil fertility;
- checking the quality of plant protection products, pesticide residues in plants and plant products;
- checking the quality of the seed and propagating material, the quality of agri-food products and products involved in organic farming;
- the provision of testing services related to the harmfulness of products in the areas of competence set out in point. 1) to 3) of the present judgment.

5. Central Laboratory for the testing of alcoholic/non-alcoholic beverages and preserved products

Government Decision No. 1210/2018 approving the Statute of the Public Institution ‘Central Laboratory for the testing of alcoholic/non-alcoholic beverages and preserved products’.²⁹⁰

This Statutes govern the mission, areas of competence, functions and rights of the Public Institution “Central Laboratory for the testing of alcoholic/non-alcoholic beverages and preserved products” and the organisation of its work.

The areas of competence of the Laboratory shall be as follows:

- provision of analysis services on the safety and quality of food, raw materials and alcoholic production;
- organisation of laboratory and sensory analyses for alcoholic production and foodstuffs;
- provision of conformity assessment services for alcoholic production and foodstuffs.

6. Ministry of Health

Government Decision No. 148/2021 on the organisation and functioning of the Ministry of Health.²⁹¹

²⁹⁰ Government Decision No. 1210/2018 approving the Statute of the Public Institution Central Laboratory for the testing of alcoholic/non-alcoholic beverages and preserved products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128879&lang=ro

²⁹¹ Government Decision No. 148/2021 on the organisation and functioning of the Ministry of Health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130828&lang=ro

The Regulation on the organisation and functioning of the Ministry of Health governs its mission, functions, field of activity, rights and organisation of its work.

The Ministry of Health is the central specialised body of the public administration which ensures the implementation of government policy in the field of activity entrusted to it.

In its work, the Ministry shall be governed by the Constitution of the Republic of Moldova, Law No. 136/2017 on the Government and other legislative acts, decrees of the President of the Republic of Moldova, Government ordinances, decisions and provisions, and this Regulation.

The Ministry's mission is to analyse the situation and problems in the field of activity managed, to develop effective public policies in the field of health care, to monitor the quality of policies and legislation, and to propose justified State interventions that will provide effective solutions in the areas of competence, ensuring the best relationship between expected results and expected costs.

The competences of the Ministry of Health regarding state supervision of public health in the field of food safety are carried out by the National Agency for Public Health.

According to Article 25 of Law No. 306/2018 on food safety,²⁹² the areas of competence of the Ministry of Health on State supervision of public health in the field of food safety are:

- identification, assessment, management and communication of risks to the health and nutrition of the population;
- recording outbreaks of food-related diseases and epidemiological research of these cases with the National Food Safety Agency;
- approving and controlling the quality of drinking water in the public water supply network;
- providing hygiene training and organising the medical examination of employees of undertakings producing, processing, storing, transporting and marketing food or catering services;
- the health authorisation of food additives, food supplements, novel foods, fortified foods, foods treated with ionising radiation, foods with added vitamins and minerals, foods for special medical purposes, total diet replacement for weight control, nutrition and health claims made on foods, and food contact materials;
- monitoring compliance with the rules on nutrition and health claims for infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes, total diet replacement for weight control and mineral waters, which are marketed in pharmacies;

²⁹² Law No. 306/2018 on food safety, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

- the supervision and control of foodstuffs for infants and young children, as well as of products intended for particular nutritional uses, which are marketed in pharmacies;
- authorisation of natural mineral water sources;
- market surveillance of food contact materials placed on the market, with the exception of food contact materials in use at all stages of the food chain;
- preparing and submitting proposals to the Government for the approval of regulations in the field of food additives, food supplements, novel foods, fortified foods, foods treated with ionising radiation, foods with added vitamins and minerals, infant formulae and follow-on formulae, processed cereal-based foods and baby foods, foods for special medical purposes, total diet replacement for weight control, mineral and potable waters and their sources, food contact materials and nutrition and health claims made on foods;
- establishment of microbiological and physico-chemical parameters, levels of pesticide residues and contaminants in foodstuffs having an impact on public health.

7. National Agency for Public Health

Government Decision No. 1090/2017 on the organisation and functioning of the National Agency for Public Health²⁹³

The Regulation on the organisation and functioning of the National Agency for Public Health sets out the mission, areas of activity, functions and rights of the National Agency for Public Health (hereinafter — the Agency) and the way in which its work is organised.

The Agency is an administrative authority attached to the Ministry of Health, with territorial subdivisions — public health centres, responsible for implementing State policy in the fields of activity entrusted to it.

In its work, the Agency shall be governed by the Constitution and laws of the Republic of Moldova, the decrees of the President of the Republic of Moldova, the orders, decisions and provisions of the Government, other legislative acts, international treaties to which the Republic of Moldova is a party, orders and provisions of the Minister of Health and this Regulation.

The task of the Agency is to ensure the implementation of State policy in the areas of competence, in the manner and within the limits assigned by the regulatory framework.

²⁹³ Government Decision No. 1090/2017 on the organisation and functioning of the National Agency for Public Health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129690&lang=ro

The Agency shall carry out the functions established by this Regulation for the food safety segment, including in State control (inspection).

8. Environment Agency

Government Decision No. 549/2018 on the establishment, organisation and functioning of the Environment Agency²⁹⁴

The Regulation on the organisation and functioning of the Environment Agency governs its legal status, mission, areas of activity, core functions, main tasks and rights, and the organisation of its work.

The Environment Agency is the administrative authority attached to the Ministry of the Environment, responsible for implementing State policy in the fields of activity entrusted to it.

In its work, the Agency shall be governed by the Constitution and laws of the Republic of Moldova, the decrees of the President of the Republic of Moldova, the orders, decisions and provisions of the Government, other legislative acts, international treaties to which the Republic of Moldova is a party, orders and provisions of the Minister of the Environment, and by this Regulation.

The Agency's task is to ensure the implementation of the environmental protection policy by achieving the best relationship between the expected results and the budgetary allocations approved by the annual budget law.

The Agency shall carry out the functions set out in this Regulation in the following areas of activity:

- prevention of environmental pollution;
- air protection and climate change;
- protection and regulation of the use of water resources;
- protection and regulation of the use of animal and plant kingdom and aquatic biological resources;
- biodiversity conservation and management of State-protected natural areas;
- waste management;
- biosecurity.

The core functions of the Agency shall be:

- ensure the implementation of public policy documents and environmental legislation at national, local and local level;

²⁹⁴Government Decision No. 549/2018 on the establishment, organisation and functioning of the Environment Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127927&lang=ro

- providing technical support to the Ministry for substantiating draft public policy documents and legislative acts in the field of environmental protection;
- the regulation and authorisation of activities having an impact on the quality of the environment, issuing to natural and legal persons permissions for the practice of the activities of an entrepreneur with an environmental impact (permits, environmental agreements, permits, certificates, notifications, opinions and coordination), as provided for in the schedule of permissions, approved by Law No. 160 of 22 July 2011 regulating the activity of entrepreneurs by authorisation;²⁹⁵
- carrying out the monitoring of the quality of environmental factors (monitoring of water, air, soil quality, forestry and natural areas protected by the State, maintenance of the status and use of water and soil resources, plantation of plant and animal regulation, fisheries monitoring, monitoring of subsoil status, air pollution monitoring, geological monitoring, monitoring of environmental pollution) in order to provide natural and legal persons with information on the quality of the environment, to develop the system of statistical indicators on environmental protection, and to draw up and publish the National Report on the State of the Environment in the Republic of Moldova;
- setting up and managing special registers and registers, managing the information and data system for its areas of activity and ensuring public access to environmental information.

The Agency shall have the following main tasks:

in the field of protection and regulation of the use of water resources:

- participate in the implementation of national legislation on the quality and protection of surface and groundwater resources, submit proposals to amend and supplement that legislation;
- participate in the process of gradual harmonisation of national legislation with Community environmental legislation in the field of water quality;
- participate in the implementation of the provisions of policy documents and international environmental treaties to which the Republic of Moldova is a party in the field of water quality and protection;
- set limit values for emissions of pollutants to surface waters based on existing pollution levels and their measurement methods;
- issue to natural and legal persons an environmental permit for the special use of water, suspend, withdraw or extend its validity;
- set up and ensure the functioning of the system for monitoring the quality of surface water and groundwater;

²⁹⁵Law No. 160 of 22 July 2011 regulating the activity of entrepreneurs by authorisation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro

- ensure the functioning of the water quality laboratory and carry out measurements, analyses and environmental investigations of surface and groundwater;
- provide technical support to the Ministry in drawing up programmes for monitoring the status and use of surface water and groundwater and ensure their implementation;
- administer state resources and information systems in the field of water, within the limits of the competence established by legislation;

in the field of biosecurity:

- ensure the implementation of national legislation on genetically modified organisms, regularly monitor and report to the Ministry on the state of play of its implementation, submit proposals to amend and supplement that legislation;
- participate in the process of harmonising national legislation with Community environmental legislation on genetically modified organisms and subsequently ensure the implementation of the adopted legislation;
- implement the provisions of the policy documents and international biosecurity treaties to which the Republic of Moldova is a party, prepare and submit to the Ministry information on their implementation;
- participate in the work of the National Commission for Biological Security;
- regulate activities in the field of genetically modified organisms;
- receive, manage and evaluate the technical content of the dossiers for the notification and authorisation of genetically modified organisms;
- issue authorisation for the import of living genetically modified organisms for scientific use and/or release into the environment to natural and legal persons, suspend, withdraw or prolong its validity;
- collaborate with the notifier, the Ministry, the Commission on Biological Safety and the relevant authorities, in the event of emergencies and accidents in the field of genetically modified organisms, in order to minimise the risk to the environment and human health or to implement the safeguard clause.

20. Please provide information for each item listed below:

- a) Labelling, presentation and advertising of foodstuffs including nutrition and health claims and nutritional labelling;**
- b) Additives authorised and purity criteria;**
- c) Food enzymes and food colours;**
- d) Extraction solvents;**
- e) Flavourings;**
- f) Food contact materials;**
- g) Food supplements;**

- h) Food for particular nutritional uses;**
- i) Quick-frozen Foodstuffs;**
- j) Contaminants;**
- k) Novel foods;**
- l) Ionising radiation;**
- m) Mineral waters and spring waters.**

a) Labelling, presentation and advertising of foodstuffs including nutrition and health claims and nutritional labelling;

Law No. 279/2017 on food information to consumers²⁹⁶

Pursuant to the provisions of the Law No. 279/2017 on food information to consumers, food business operators ensure that all foods intended for the final consumer or mass caterer is accompanied with the mandatory food information, which includes: the name of the food, list of ingredients, allergens, quantity of certain ingredients or categories of ingredients, the net quantity of the food, information on durable life period, special storage conditions and/or conditions of use, the name and address of the responsible business operator, the country of origin or the place of provenance, instructions for use, acquired alcoholic strength for beverages containing more than 1.2% by volume of alcohol, nutritional declaration, and batch identification. Additional mandatory particularities for certain types or categories of food are also provided in the abovementioned law.

According to the Law No. 306/2018 on food safety,²⁹⁷ the labelling, advertising and presentation of foodstuffs must not mislead the consumer, and information provided through food labelling should be sufficient, accurate and easy-to-compare to enable consumers to choose the food that meets their requirements, as well as to inform on the potential risks they may be exposed.

With regard to nutrition and health claims, the national authority in charge with their regulation and control is National Agency for Public Health under the Ministry of Health, as stipulated in the Art. 8, para. 7 of the Law No. 306/2018 on food safety.

The Government Decision No. 196/2011 approving the Sanitary Regulation on nutrition and health claims made on foodstuffs,²⁹⁸ transposes Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, Commission Regulation (EC) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims and Commission Implementing Decision

²⁹⁶ Law No. 279/2017 on food information to consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122833&lang=ro

²⁹⁷ Law No. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

²⁹⁸ Government Decision No. 196/2011 approving the Sanitary Regulation on nutrition and health claims made on foodstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109690&lang=ro

2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.

The Regulation lays down general principles and conditions for the use of nutrition and health claims, as well as requirements for the health endorsement of health claims. The list of health claims allowed to be made on foodstuffs other than those relating to the reduction of the risk of disease and the development and health of children shall be approved by the Government. The entity responsible for issuing the health endorsement for health claims is the National Agency for Public Health.

The Law no. 279/2017²⁹⁹ additionally defines the general requirements and responsibilities governing food information, especially food labelling. It provides for the means to guarantee consumers' right to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to be able to respond to future developments and new information requirements.

This applies to food business operators at all stages of the food chain, where their activities relate to informing consumers about food, as well as all food intended for the final consumer, including those delivered by public catering establishments, and foodstuffs intended to be supplied to them. This law applies to catering services provided by transport companies.

The rules on nutrition and health claims on foodstuffs, the rules on the labelling of food supplements, and the rules on the labelling of foodstuffs for special nutritional purposes are approved by the Government.

b) Additives authorised and purity criteria

Government Decision No. 229/2013 approving the Sanitary Regulation on food additives³⁰⁰ lays down rules on food additives used in foodstuffs to ensure the efficient functioning of the domestic market, a high level of protection of public health and a high level of consumer protection, including the protection of consumers' interests and fair food trade practices, taking account of environmental protection issues, where appropriate.

The regulation provides:

- the national list of food additives authorized for use in foodstuffs and the conditions of use, in accordance with Annex 1 to this Regulation; the list of food additives, including carrier substances, authorized in food

²⁹⁹ Law No. 279/2017 on food information to consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122833&lang=ro

³⁰⁰ Government Decision No. 229/2013 approving the Sanitary Regulation on food additives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103124&lang=ro

additives, food enzymes, food flavourings and nutrients and their conditions of use, in accordance with Annex no. 2 to this Regulation; the list of food colours referred to in point 54 of this Regulation for which food labels shall include additional information;

- the conditions of use of food additives in foodstuffs, including food additives, food enzymes and food flavourings;
- the rules on the labelling of food additives marketed as such.

The Sanitary Regulation on Food Additives is harmonised with Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

c) Food enzymes and food colours;

Government Decision No. 1056/2016 approving the Sanitary Regulation on food enzymes³⁰¹

The Regulation lays down rules on food enzymes used in foodstuffs, including such enzymes used as processing aids, to ensure the efficient functioning of the domestic market, a high level of protection of public health and a high level of consumer protection, including the protection of consumers' interests and fair food trade practices, taking account of environmental protection issues, where appropriate.

To this end, this Regulation provides for the national list of authorized food enzymes; conditions for the use of food enzymes in foodstuffs; labelling rules for food enzymes marketed as such.

This Regulation applies to food enzymes and does not apply to food enzymes where they are used in the manufacture of the following:

- food additives falling under the Sanitary Regulation on food additives, approved by Government Decision No. 229 of 29 March 2013³⁰²
- processing aids.

This Regulation shall apply without prejudice to specific rules on the use of food enzymes:

- in specific food products;
- for purposes other than those provided for by this Regulation.

³⁰¹ Government Decision No. 1056/2016 approving the Sanitary Regulation on food enzymes, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102595&lang=ro

³⁰² Government Decision No. 229 /2013 approved by the Sanitary Regulation on food additives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109707&lang=ro

It does not apply to microbial cultures that are traditionally used in food production and may incidentally produce enzymes, but which are not specifically used to make them.

Government Decision No. 1056/2016 transposes Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

d) Extraction solvents;

Government Decision No. 671/2020 approving the Sanitary Regulation on extraction solvents used in the production of foodstuffs and food ingredients³⁰³

This Regulation applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients, as well as to all extraction solvents used or intended for use in the production of food and food ingredients imported into the country.

It does not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives unless these food additives, vitamins or nutritional additives are included in the Annex; nor to extraction solvents or foods for export.

Food business operators shall ensure that the use of food additives, vitamins and other nutritional additives does not result in the presence of extraction solvents in foodstuffs in residual quantities which are hazardous to human health.

The Sanitary Regulation on extraction solvents used in the production of foodstuffs and food ingredients transposes Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

e) Flavourings;

Government Decision No. 1245/2018 approving the sanitary regulations on flavourings and certain food ingredients with flavouring properties intended

³⁰³ Government Decision No. 671/2020 approving the Sanitary Regulation on extraction solvents used in the production of foodstuffs and food ingredients, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123054&lang=ro

for use in and on foodstuffs and on smoke flavourings used or intended for use in or on foodstuffs³⁰⁴

This Regulation lays down rules on flavourings and certain food ingredients with flavouring properties used in foodstuffs and transitional measures concerning the list of flavourings and raw materials in order to ensure the effective functioning of the domestic market, a high level of protection of public health and consumer protection, including the protection of consumer interests and certain fair practices in food trade, taking into account, where appropriate, the environmental protection.

The regulation lays down:

- the national list of food flavourings and raw materials approved for use in and on foodstuffs;
- the conditions of use of flavourings and food ingredients with flavouring properties in and on foodstuffs;
- rules on flavour labelling.

The sanitary regulation on flavourings and certain food ingredients with flavouring properties intended for use in or on foods and establishing transitory measures on the list of flavourings and raw materials transposes Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties intended for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No. 2232/96 and (EC) 110/2008 and Directive 2000/13/EC; Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC; Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council.

f) Food contact materials;

Government Decision No. 308/2011 approving the Sanitary Regulation on materials and articles intended to come into contact with food products³⁰⁵ which transposes the provisions of the Regulation of the European Parliament and

³⁰⁴ Government Decision No. 1245/2018 approving the sanitary regulations on flavourings and certain food ingredients with flavouring properties intended for use in and on foodstuffs and on smoke flavourings used or intended for use in or on foodstuffs, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=112688&lang=ro

³⁰⁵ Government Decision No. 308/2011 approving the Sanitary Regulation on materials and articles intended to come into contact with food products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=114330&lang=ro

of the Council No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food.

The goal of this Regulation is to ensure the efficient functioning of the domestic market as regards the placing on the market of materials and articles intended to come into contact with foodstuffs and to provide, at the same time, a basis for ensuring a high level of protection of human health and consumer interests.

Government Decision No. 278/2013³⁰⁶ transposes the provisions of Regulation (EU) No. 10/2011 of the European Commission of 14 January 2011 on plastic materials and articles.

This Regulation defines specific requirements for the manufacture and placing on the market of plastic materials and articles intended to come into contact with food, which are already in contact with food, which may reasonably come into contact with food. This Regulation applies to materials and objects placed on the market of the Republic of Moldova which fall into the following categories:

- materials, objects and parts thereof which are made exclusively of plastic;
- materials and objects made of several layers of plastic glued with adhesives or by other means;
- materials and objects referred to under letters a) or b) point 1 of this Regulation printed and/or covered with a coating;
- plastic layers and plastic covers forming cover fittings and closing devices which, together with the respective covers and closing devices, make up a set of two or more layers of different types of materials;
- plastic layers in multimaterial multilayer materials and articles.

The sanitary regulation regarding the good manufacturing practice of the materials and articles intended to come into contact with food products, approved by Government Decision No. 594/2014³⁰⁷ transposes Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The purpose of this Regulation is to lay down rules on good manufacturing practice for groups of materials and articles intended to come into contact with foods.

The sanitary regulation on recycled plastic materials and articles intended to come into contact with foodstuffs, approved by Government Decision No.

³⁰⁶ Government Decision No. 278/2013 approved by the sanitary regulation on plastic materials and articles intended to come into contact with the food products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103122&lang=ro

³⁰⁷ The sanitary regulation regarding the good manufacturing practice of the materials and articles intended to come into contact with food products, approved by Government Decision No. 594/2014, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102933&lang=ro

492/2015³⁰⁸ transposes Commission Regulation (EC) No. 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006.

The Regulation applies to plastic materials and articles and their components which are intended to come into contact with foodstuffs, as set out in the Sanitary Regulations on plastic materials and articles intended to come into contact with foodstuffs.

The sanitary regulation regarding the ceramic, glass, porcelain, faience, enamelled and vitrified articles that come in contact with foodstuffs, approved by Government Decision No. 493/2015³⁰⁹ transposes Council Directive of 15 October 1984 No. 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

The Regulation applies to plastic materials and articles and their components which are intended to come into contact with foodstuffs, as set out in the Sanitary Regulation on plastic materials and articles intended to come into contact with foodstuffs.

The Sanitary regulation regarding the ceramic, glass, porcelain, faience, enamelled and vitrified articles that come in contact with foods, approved by Government Decision no. 493/2015 transposes the provisions of the Council Directive of 15 October 1984 No. 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

This Regulation regulates the possible migration of lead and cadmium from ceramic, glass, porcelain, earthenware, enamelled and glazed objects which, in the finished product stage, come or are in contact with foodstuffs.

The sanitary regulation regarding the materials and articles that contain the vinyl chloride monomer and that come into contact with foods, approved by Government Decision 580/2017³¹⁰ transposes Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs and Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control

³⁰⁸ The sanitary regulation on recycled plastic materials and articles intended to come into contact with foodstuffs, approved by Government Decision No. 492/2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102858&lang=ro

³⁰⁹ The sanitary regulation regarding the ceramic, glass, porcelain, faience, enamelled and vitrified articles that come in contact with foodstuffs, approved by Government Decision No. 493/2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102859&lang=ro

³¹⁰ The sanitary regulation regarding the materials and articles that contain the vinyl chloride monomer and that come into contact with foods, approved by Government Decision 580/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=101165&lang=ro

of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs.

This Regulation governs the presence of vinyl chloride monomer and the limit of its migration from materials and articles made of polymers or copolymers of vinyl chloride, which, as finished products, come into contact with food or are intended to come into contact with food, and the method for determining the vinyl chloride monomer content in materials and articles.

Sanitary regulation on limiting the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs approved by Government Decision no. 548/2017³¹¹ transposes Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

This Regulation applies to materials and articles intended to come into contact with foodstuffs, as referred to in the Sanitary Regulation on materials and foodstuffs intended to come into contact with foodstuffs, which are manufactured from substances or contain one or more of the substances listed in the Regulation.

Sanitary Regulation laying down specific conditions and detailed procedures for the placing on the market of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and the Hong Kong Special Administrative Region of the People's Republic of China, approved by Government Decision No. 968/2017³¹² transposes the provisions of Commission Regulation (EC) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China.

The purpose of the Regulation is to establish the necessary legal framework, specific conditions and detailed procedures for the placing on the market of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and the Hong Kong Special Administrative Region of the People's Republic of China.

Sanitary regulation on active and intelligent materials and articles intended to come into contact with foodstuffs, approved by Government Decision No.

³¹¹ Sanitary regulation on limiting the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs approved by Government Decision no. 548/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100964&lang=ro

³¹² Sanitary Regulation laying down specific conditions and detailed procedures for the placing on the market of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and the Hong Kong Special Administrative Region of the People's Republic of China, approved by Government Decision No. 968/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=60293&lang=ro

945/2018³¹³ transposes Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.

The Regulation applies to active and intelligent materials and objects intended to come into contact with foodstuffs, referred to in the Sanitary Regulation on materials and articles intended to come into contact with foods, which are manufactured and placed on the market of the Republic of Moldova.

g) Food supplements;

Government Decision No. 538/2009 approving the Sanitary Regulation regarding food supplements³¹⁴

This Regulation applies to foodstuffs placed on the market as foodstuffs and presented as such, without prejudice to the provisions of national legislation on novel foods. Food supplements are placed on the market only in pre-packaged form by the manufacturer.

This Regulation does not apply to medicinal products, as defined in Law No. 1409/1997 on medicinal products.³¹⁵

The Sanitary Regulation on food supplements transposes Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements².

h) Food for particular nutritional uses;

Government Decision No. 179/2018 approving the sanitary regulations on foods for infants and young children, foods intended for special medical purposes and total diet replacement for weight control³¹⁶ transposes Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC,

³¹³ Sanitary regulation on active and intelligent materials and articles intended to come into contact with foodstuffs, approved by Government Decision no. 945/2018, available in Romanian at https://www.legis.md/cautare/getResults?doc_id=109123&lang=ro

³¹⁴ Government Decision No. 538/2009 approving the Sanitary Regulation regarding food supplements, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110115&lang=ro

³¹⁵ Law No. 1409/1997 on medicinal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=115116&lang=ro

³¹⁶ Government Decision No. 179/2018 approving the sanitary regulations on foods for infants and young children, foods intended for special medical purposes and total diet replacement for weight control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102137&lang=ro

2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

The Regulation lays down the composition and information requirements for the following categories of foods:

- beginning formulas and continuation formulas;
- cereal-based preparations and baby food;
- foodstuffs intended for special medical purposes;
- substitutes for a total weight control diet.

The Regulation also establishes a list of substances that may be added to one or more categories of foods and lays down rules for the updating of this list.

i) Quick-frozen foodstuffs;

Government Decision No. 806/2013 approving the Standard for quick-frozen foodstuffs, intended for human consumption³¹⁷

This Standard applies to quick-frozen products intended for human consumption.

Ice cream and other edible ice, with or without cocoa, domestically produced, are not considered quick-frozen foods.

There are general requirements for the manufacture, transport, storage and placing on the market of quick-frozen foods as well as the procedure for sampling quick-frozen foods and temperature measurement methods.

Entities producing quick-frozen foodstuffs must comply with the requirements of general hygiene and food safety legislation. They shall be subject to veterinary authorization for foodstuffs of animal origin or officially registered in the field of food safety for those of non-animal origin.

For the purposes of this Standard, 'quick-frozen foodstuffs' means foodstuffs

- which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18 °C or lower at all points, and

³¹⁷ Government Decision No. 806/2013 approving the Standard for quick-frozen foodstuffs, intended for human consumption, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=125621&lang=ro

- which are marketed in such a way as to indicate that they possess the characteristic described in letter a).

measurement of the temperature of quick-frozen food - recording the temperature of the quick-frozen product using the instruments specified in point 2 of Annex no. 2 to this Standard.

This Regulation applies to the agri-food and fisheries sector, as well as to food hygiene.

The Standard on quick-frozen foods for human consumption transposes Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption.

Government Decision No. 1402/2007 approving the Technical Regulation “Quick-frozen fruits, berries and vegetables”³¹⁸

The minimum quality and food safety requirements to be met by quick-frozen fruits, berries and vegetables are set out in Government Decision No. 1402/2007 approving the Technical Regulation “Quick-frozen fruits, berries and vegetables.

The inspectors from the National Food Safety Agency verify, during the official control actions, the temperature of the quick frozen foods according to the provisions of the Law No. 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules.³¹⁹

j) Contaminants;

Government Decision No. 520/2010 approving the Sanitary Regulation on food contaminants³²⁰

This document regulates contaminants that are or may be present in foodstuffs and the maximum levels of certain contaminants in foodstuffs and aims at protecting public health. For the purpose of this Regulation, the terms provided in Law No. 306/2018 on food safety³²¹ apply.

The sanitary regulation on food contaminants is harmonised with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in

³¹⁸ Government Decision No. 1402/2007 approving the Technical Regulation “Quick-frozen fruits, berries and vegetables”, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=22860&lang=ro

³¹⁹ Law No. 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

³²⁰ Government Decision No. 520/2010 approving the Sanitary Regulation on food contaminants, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=126796&lang=ro

³²¹ Law no. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

foodstuffs, Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food, Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products, and Council Directive 76/621/EEC of 20 July 1976 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats.

Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin³²²

Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin transposes point 1 of the Annex to the Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs and Regulation (EC) No 1882/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs.

The Regulation sets the maximum nitrate levels for foodstuffs of plant origin marketed in the Republic of Moldova, applicable to the edible part of foodstuffs of plant origin in the form in which they are sold.

In the Republic of Moldova, the maximum allowable levels for the following contaminants are established:

- Nitrates in foodstuffs of plant origin
- Mycotoxins;
- Heavy metals (lead, cadmium, mercury, inorganic tin, arsenic);
- 3-monochloropropane-1,2-diol (3-MCPD);
- Dioxins and polychlorinated biphenyls (PCBs);
- Polycyclic aromatic hydrocarbons;
- Melamine;
- Inherent plant toxins
- Dioxins, furans and polychlorinated biphenyls;
- T-2 and HT-2 toxin in cereals and cereal products;

The Regulation does not apply to:

- contaminants that are only significant for food quality, but they are not significant for public health; physical contaminants, such as fragments of insects, animal hair and others;

³²² Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123312&lang=ro

- microbial toxins, like botulinum toxin and staphylococcal enterotoxin, as well as micro-organisms;
- processing aids;
- other contaminants that are subject of specific regulations.

The methods of sampling as well as the measures taken in case of exceeding the maximum levels are also specified.

Control Rules:

As part of the food safety monitoring and surveillance, the National Food Safety Agency takes samples in order to monitor the content of contaminants in raw materials and food. If products with excess contaminants are detected, trade is prohibited and withdrawal from the market is ordered. The following prohibitions on use, mixing and detoxification also apply:

Foods that do not meet the prescribed maximum levels are not used as food ingredients.

Foods that meet the maximum levels of contaminants shall not be mixed with foods that exceed these levels.

Foods to be sorted or to be subjected to other physical treatments in order to reduce levels of contamination shall not be mixed with foodstuffs intended for human consumption or with foodstuffs intended for use as food ingredients.

Foods containing Mycotoxins shall not be deliberately detoxified by chemical treatments.

The National Food Safety Agency is also implementing a program to monitor the nitrate content of plant-based foods. The methods of sampling, preparation of samples and analysis for the official control of nitrate levels in foodstuffs is carried out in accordance with the methods set out in Annex no. 2 and no. 3 to the Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin.³²³ The samples are analysed at an ISO 17025 accredited laboratory and shall not exceed the limits laid down in Annex no. 1 to Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin.

If products with excess nitrate content are detected, the laboratory shall immediately inform ANSA, which in turn shall take all necessary measures to prevent the placing of non-compliant products on the market.

³²³ Government Decision No. 115/2013 on the control of nitrates in foodstuffs of plant origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123312&lang=ro

k) Novel food;

Government Decision No. 925/2009 approving the Sanitary Regulation on novel foods³²⁴

The Sanitary Regulation on novel food was approved by Government Decision No. 925/2009 is harmonised with Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients and Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, as well as Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Regulation lays down the rules for the introduction of novel food on the market of the Republic of Moldova, to guarantee a high level of protection of human health and the interests of consumers, at the same time ensuring the efficient functioning of the domestic market.

l) Ionising radiation;

Government Decision No. 867/2012 approving the Regulation on the treatment with ionising radiation of products of different origin³²⁵

The Regulation aims at establishing specific basic requirements for the treatment of foodstuffs and food ingredients with ionising radiation, as well as to ensure their harmlessness.

It contains the general principles and procedures required for carrying out the ionising radiation treatment of foodstuffs and food ingredients.

The Regulation applies to the processes of manufacture, labelling, trade, import and export of foodstuffs and food ingredients, which are treated with ionising radiation.

The process of treating the products with ionising radiation must be carried out in hygienic and technological conditions allowing the following objectives to be achieved: prevention, reduction, quantitative destruction of micro-organisms that cause alteration of products, extension of product life, control of maturation.

³²⁴ Government Decision No. 925/2009 approving the Sanitary Regulation on novel foods, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103376&lang=ro

³²⁵ Government Decision No. 867/2012 approving the Regulation on the treatment with ionising radiation of products of different origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=10181&lang=ro.

Foods that are subject to radiation must be in good health and in good condition. These products, as well as the packaging thereof, must be compatible with the radiation process.

Foods can be treated with ionising radiation only if there is a need for it with respect to food hygiene, this treatment is technologically necessary and is for the benefit of the consumer.

Ionising radiation treatment should not be used as a substitute for hygiene or health measures or good manufacturing practice.

This Regulation extends to the ionising radiation treatment of foods and food ingredients, included in the lists approved by the Government.

This Regulation is enforceable for all operators of ionising radiation sources used for these purposes, regardless of their form of ownership and departmental subordination.

The regulation on ionising radiation treatment of products of different origins partially transposes the Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member states concerning foods and food ingredients treated with the ionising radiation and transposes the Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation.

m) Mineral and spring waters.

At national level the requirements for mineral waters and spring waters are laid down in the **Government Decision No. 57/2019 approving the sanitary regulations for the exploitation and trade of natural mineral waters**³²⁶.

The Regulation applies to water extracted from the territory of the Republic of Moldova and/or imported, all mineral waters or spring waters, bottled and intended for selling for human consumption, which are recognized as such. The Regulation also lays down the requirements for the labelling of mineral waters and spring waters.

The Regulation transposes the following European Union Regulations:

- Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters;

³²⁶ Government Decision No. 57/2019 approving the sanitary regulations for the exploitation and trade of natural mineral waters, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=112872&lang=ro

- Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters;
- Commission Regulation (EU) No 115/2010 of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

The monitoring and control of the quality of mineral and spring water is performed by the following authorities:

The National Agency for Public Health ensures control at the source, so that any water recognized as natural mineral water corresponds to this definition and so that the source from which it is obtained is exploited.

The National Food Safety Agency carries out market surveillance of drinking water and mineral water, including bottled water.

Government Decision No. 934/2007 establishing the Automated Information System "State Register of Natural, Drinking Mineral Waters and Bottled Non-Alcoholic Beverages"³²⁷

In order to intensify the control over the quality of natural, drinking mineral waters and bottled non-alcoholic beverages, the Government:

- Developed the Automated Information System "State Register of Natural, Drinking Mineral Waters and Bottled Non-Alcoholic Beverages"
- The beneficiary of the Automated Information System "State Register of Natural, Drinking Mineral Waters and Bottled Non-Alcoholic Beverages" is the Ministry of Health, through its subordinate institution - the National Agency for Public Health.
- Approved the Sanitary Standards regarding the use and marketing of natural mineral waters; Sanitary Norms regarding the quality of drinking water; Regulation on the non-alcoholic beverages; Regulation on medicinal mineral waters; Regulation on the marking with the "State Trademark" of natural, drinking mineral waters and bottled non-alcoholic beverages; Form submitting information on the circulation of natural, drinking mineral water and bottled non-alcoholic beverages, produced or imported.

³²⁷ Government Decision No. 934/2007 establishing the Automated Information System "State Register of Natural, Drinking Mineral Waters and Bottled Non-Alcoholic Beverages", available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113742&lang=ro

21. Please provide information on bilateral international agreements on food safety rules with EU Member States, candidate countries and other third countries (if any).

In the field of food safety, the Republic of Moldova has signed the following International Agreements:

- Memorandum of Understanding between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture of the Czech Republic on the cooperation in the field of agriculture (Signed in Chisinau on 25.05.2010. In force since 25.05.2010). No term;
- Memorandum of Understanding between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Rural Development of Hungary on cooperation in the areas of food safety, animal health, phytosanitary and plant protection (Signed in Budapest on 05.12.2016.). The Memorandum is concluded for a period of 5 years, after which the period of validity will be extended for further consecutive periods of 5 years;
- Memorandum of Understanding between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture and Rural Development of the State of Israel on cooperation in the field of agriculture (Signed in Chisinau on 23.07.2014. In force since 07.10.2014). The Memorandum is valid for a period of 5 years with automatic extension for consecutive periods of 5 years;
- Memorandum of Understanding between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture of the Hashemite Kingdom of Jordan on cooperation in the field of agriculture and food industry (Signed in Amman, 08.09.2016. In force from 22.12.2017). The Memorandum is valid for a period of 5 years with automatic extension for consecutive periods of 5 years;
- Memorandum between Federal Service for Veterinary and Phytosanitary Surveillance and the Ministry of Agriculture and Food Industry of the Republic of Moldova on products of plant origin supplied from the Republic of Moldova to the Russian Federation (as regards pesticides, nitrates and nitrites), signed on 2 October 2008. The Memorandum is valid for a period of 5 years with automatic extension for consecutive periods of 5 years;
- Government Decision No 427/2014 approving the Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture and Food of the Republic of Belarus on economic and scientific-technical cooperation, signed in Minsk on 6 June 2011;³²⁸

³²⁸ Government Decision No. 427/2014 approving the Agreement between the Ministry of Agriculture and Food Industry of the Republic of Moldova and the Ministry of Agriculture and Food of the Republic of Belarus on economic and scientific-technical cooperation, signed in Minsk on 6 June 2011, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=3724&lang=ro

- Memorandum of Understanding between the National Food Safety Agency of the Republic of Moldova and the General Administration of Customs of the People's Republic of China on cooperation in the field of food imports and exports and food safety. Was signed by correspondence on 27 January 2021;
- On 22 February 2022 was signed the Memorandum of Understanding between the National Food Safety Agency of the Republic of Moldova and the State Food and Veterinary Service of the Republic of Lithuania on cooperation in the field of food safety and veterinary.

V. SPECIFIC RULES FOR FEED

22. Please provide information on the legislative framework on feed;

Government Decision No. 27/2020 approving the Sanitary-Veterinary Requirements for Feed Additives³²⁹ partially transposes Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; and transposes: Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category coccidiostats and histomonostats; Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives; Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and provides for the procedure for the classification and use of feed additives, the procedure for the labelling and packaging of feed additives, the placing on the market and use of feed additives, as well as the contents of the normative-technical file.

Government Decision No. 910/2020 approving the Sanitary-Veterinary Requirements for Animal Feed³³⁰ partially transposes: Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene; and Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC; also transpose: Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials; transposes Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council; Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC; transposes Commission Directive 82/475/EEC of 23 June 1982 laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals; Directive 2002/32/EC of the European Parliament and of the Council of 7 May

³²⁹ Government Decision No. 27/2020 approving the Sanitary-Veterinary Requirements for Feed Additives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=120520&lang=ro

³³⁰ Government Decision No. 910/2020 of 16-12-2020 approving the Sanitary-Veterinary Requirements for Animal Feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125591&lang=ro

2002 on undesirable substances in animal feed - Council statement; point 1.1, paragraphs 3-5 and 8; Point 1.2.1, paragraph 3 of the Annex to Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.

Government Decision No. 311/2012³³¹ transposes the provisions of Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community and lays down the conditions for the preparation, placing on the market and use of medicinal feedingstuffs.

Government Decision No. 686/2012 approving analysis methods for fodder control³³² transposes the provisions of Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed and sets out sampling methods for the official control of feedingstuffs for the determination of constituents, including materials containing, consisting of or produced from genetically modified organisms, feed additives, undesirable substances and pesticide residues, methods for preparing samples for analysis and expressing results, methods for analysis on the control of the composition of feedingstuffs and compound feedingstuffs, methods for analysis for the control of the admissible level of additives in feedingstuffs, methods for the determination of constituents of animal origin for the official control of feed and the methods for determining the energy value of compound feed for farmed birds.

Government Decision No. 657/2014 approving maximum limits for the presence of coccidiostats or histomonostats in food following the inevitable transfer of these substances in feed³³³ transposes the provisions of Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed and establishes that if food contains a contaminant that exceeds the allowable limits, it will not be placed on the market and if a significant amount of residues is found below the established level, the National Food Safety Agency will carry out investigations to confirm that residues are present as a result of the inevitable transfer into food, but not as a result of the illegal administration of coccidiostats or histomonostats. At the same time, foodstuffs complying with the established limits shall not be mixed with foodstuffs exceeding these limits.

³³¹ Government Decision No. 311/2012 approving the Regulation laying down the conditions governing the preparation, placing on the market and use of feed containing medicinal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114649&lang=ro

³³² Government Decision No. 686/2012 approving analysis methods for fodder control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103175&lang=ro

³³³ Government Decision No. 657/2014 approving maximum limits for the presence of coccidiostats or histomonostats in food following the inevitable transfer of these substances in feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=19116&lang=ro

23. Please provide information on the respective areas of responsibilities, organisation and competences of institutions and competent authorities.

In accordance with Art. 4 of Law No. 221/2007 on veterinary activity³³⁴, the Ministry of Agriculture and the Food Industry is responsible for the development of feed policies and strategies and the National Food Safety Agency is the central public authority responsible for implementing feed policies and strategies.

Similarly, in accordance with Art. 24 of Law No. 306/2018 on food safety³³⁵ the supervision and control of feed and feed production, hygiene in feed establishments, as well as surveillance of the harmfulness and quality of feed, is the competence of the National Food Safety Agency.

Art. 18 of Law No. 221/2007 on veterinary activity³³⁶ states that any economic activity relating to animal feed must be authorised/registered by the National Food Safety Agency.

The Agency shall be responsible for implementing official control at all stages and legal requirements concerning: primary production of feed, finished feed production, labelling of feed, control of undesirable substances, control of medicated feed, etc.

All feed operators, at all stages of primary production/final production, distribution and marketing of feed, including import/export operations, are subject to official control by the National Food Safety Agency. Official controls are planned, executed and included in the State Register of Controls (Electronic Automated System managed by the State Chancellery). The frequency of the checks shall be assessed following the risk assessment, a procedure approved by Government Decision No. 1280/2018 approving the methodology for State control of business activity on the basis of the risk analysis relating to the areas of competence of the National Food Safety Agency.³³⁷

Official controls are carried out in all establishments, in accordance with the provisions of Law No. 131/2012 on State control of entrepreneurial activity,³³⁸ Law No. 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules.³³⁹ For the purpose of the uniform and

³³⁴ Law No. 221/2007 on veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

³³⁵ Law No. 306/2018 on food safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

³³⁶ Law No. 221/2007 on veterinary activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125191&lang=ro

³³⁷ Government Decision No. 1280/2018 approving the methodology for State control of business activity on the basis of the risk analysis relating to the areas of competence of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112486&lang=ro

³³⁸ Law No. 131/2012 on State control of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro#

³³⁹ Law No. 50/2013 on official controls to verify compliance with feed and food law and animal health and welfare rules, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122829&lang=ro

qualitative planning and performance of official control, the Agency has drawn up General Procedure PG-19/02 “Preparation and performance of official control in the areas of competence of the National Food Safety Agency”.

It is noted that official controls are carried out using checklists drawn up in accordance with the legislation in force specific to the activity controlled. Checklists were drawn up for all types of activities related to feed and approved by Order No. 79/2019 of the Ministry of Agriculture, Regional Development and the Environment approving checklists for control areas of the National Food Safety Agency.³⁴⁰

24. Please provide information for each item listed below:

a) placing on the market and use of feed

The requirements for the placing on the market of feed are regulated by Government Decision No. 910/2020 for the approval of the sanitary-veterinary requirements for feed.³⁴¹

Government Decision No. 910/2020 states that feed business operators guarantee that the food to be placed on the market is: harmless, original, pure, of good quality and suitable for its intended use. Operators are also required to label and package feed in accordance with the veterinary requirements for feed.

In accordance with Art. 36 of Law No. 221/2007 on veterinary health activity,³⁴² the Agency annually develops and implements a State Feed Monitoring Program which monitors the parameters of harmlessness of animal feed provided by Government Decision No. 910/2020;

b) authorized additives in feedingstuffs

The placing on the market of feed additives is regulated by Government Decision No. 27/2020 for the approval of the sanitary-veterinary requirements for feed additives. According to Government Decision No. 27/2020, the Republic of

³⁴⁰ Order No. 79/2019 of the Ministry of Agriculture, Regional Development and the Environment approving checklists for control areas of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130930&lang=ro

³⁴¹ Government Decision No. 910/2020 for the approval of the sanitary-veterinary requirements for feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130574&lang=ro#

³⁴² Law No. 221/2007 on veterinary health activity, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125191&lang=en

Moldova recognizes and accepts on the domestic market all feed additives provided by the European Union Register of Feed Additives.³⁴³

Operators who place on the market/operate with feed additives are subject to veterinary authorization as well as official controls by the National Food Safety Agency.

c) undesirable substances in animal feed

In accordance with Art. 36 (6) of Law No. 221/2007 on the activity of veterinary health, the content of undesirable substances in animal feed must not exceed the maximum permissible limits set by Annex no. 7 on maximum limits for undesirable substances in feed, component part of Government Decision No. 910/2020³⁴⁴ (Annex 7 is the harmonization with Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement).

Annually, the Agency approves the State Feed Monitoring Program to identify undesirable substances in feed (including pesticides, radiological criteria, mycotoxins, pathogenic microorganisms (*Salmonella* spp.), Heavy metals, nitrites, genetically modified organisms) and to withdraw on the market feed for animals with their excesses.

d) the conditions governing the preparation, placing on the market and use of medicated feedingstuffs

According to the Government Decision No. 311/2012³⁴⁵ for the approval of the Regulation on the conditions for the preparation, placing on the market and use of medicated feed harmonized with Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community , medicated feed may be produced only from medicated premixes.

In accordance with Law No. 119/2018 on veterinary medicinal products medicinal premixes fall into the category of veterinary medicinal products, respectively to be placed on the market premixes must be registered (approved) as a veterinary

³⁴³ Government Decision No. 27/2020, the Republic of Moldova recognizes and accepts on the domestic market all feed additives provided by the European Union Register of Feed Additives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=120520&lang=ro

³⁴⁴ Government Decision No. 910/2020 on the approval of the Sanitary-Veterinary Requirements for Feedingstuffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130574&lang=ro

³⁴⁵ Government Decision No. 311/2012 approving the Regulation laying down the conditions governing the preparation, placing on the market and use of feed containing medicinal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114649&lang=ro

medicinal product and may only be imported by a wholesale importer / distributor of veterinary medicinal products.³⁴⁶

Responsible for the registration (authorization) of medicated premixes together with veterinary drugs, vaccines), according to Law No. 119/2018, is the National Food Safety Agency.

Roles and responsibilities: Within the National Food Safety Agency, the Department for the Control of Veterinary Medicinal Products and Feedingstuffs together with the Commission for Veterinary Medicinal Products have specific roles in the reception and primary evaluation of applications/dossiers and evaluation, scientific records of veterinary medicinal products (evaluation of safety, efficacy and quality documentation, etc.).

In accordance with Art. 36 (9) of Law No. 221/2007 on veterinary health, medicated feed is produced only in accordance with the prescriptions issued by a veterinarian, is delivered only to the persons indicated in the veterinary prescription, in the quantities indicated therein and on the basis of the instructions for use, and the instructions of the veterinarian who prescribed them.

In accordance with the Government Decision No. 311/2012, the manufacture of medicated feed from a medicated premix takes place based on the veterinary prescription issued by the authorized veterinarian of the farm.

The entire procedure regarding the conditions of preparation, placing on the market and use of medicated feed is described in detail in Government Decision No. 311/2012.

³⁴⁶ Law No. 119/2018 on veterinary medicinal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=105483&lang=ro#

VI. PHYTOSANITARY POLICY

25. Please provide information on the legislative framework on phytosanitary policy;

The national normative framework, which regulates the phytosanitary field, is presented as follows:

1. Law No. 119/2004 on plant protection products and fertilizers,³⁴⁷ which establishes legal bases and state policy in the area of activity with phytosanitary products and fertilizers, regulates their conditions of research, testing, experimentation and state approval, manufacturing, import, transportation, storage, marketing and harmless use to humans, animals, environment, relations related to state supervision and control over compliance with the legislation in force, determines the rights and obligations of enterprises, institutions, organizations and citizens, powers of competent authorities in the field, acts that constitute violations, as well as liability for their commission.

Law No. 119/2004 transpose the provisions of Art. 1 and Art. 3 of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for community action with a view to the sustainable use of pesticides and art. 3 and art. 59 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

2. Law No. 228/2010 on plant protection and phytosanitary quarantine,³⁴⁸ the purpose of which is to strengthen the legal and institutional framework, to create economic and legal conditions appropriate to the organization and conduct of plant protection and phytosanitary quarantine, to ensure the prevention of the mass spread of harmful organisms, to avoid the loss of crops and to obtain a high agricultural production, especially ecological.

The scope of the law consists in organizing and conducting plant protection and phytosanitary quarantine on the territory of the Republic of Moldova, measures and activities to protect against the appearance or introduction into the territory of the Republic of Moldova from other countries of harmful organisms, including through related goods subject to the phytosanitary quarantine regime.

This law is harmonized with the Articles 1-6, 10-12, 13a and 13e, 14, 16, 20 and 22 of Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the community of organisms harmful to plants or plant

³⁴⁷ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/search/getResults?doc_id=107644&lang=en

³⁴⁸ Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/search/getResults?doc_id=106744&lang=en

products and against their spread within the community; Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries; Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks; Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register; Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC.

3. Government Decision No. 356/2012 for the approval of some normative acts regarding the implementation of Law No. 228/2010 on plant protection and phytosanitary quarantine³⁴⁹, ruling governing:

List of harmful organisms whose introduction and spread on the territory of the Republic of Moldova is prohibited;

List of harmful organisms whose introduction and spread in the Republic of Moldova is prohibited, if they are present in certain plants or plant products;

List of plants and plant products whose introduction into the Republic of Moldova and certain protected areas is prohibited;

Conditions under which harmful organisms, plants and plant products may be introduced and put into circulation in the Republic of Moldova for testing or scientific purposes and for varietal selection works;

List of plants, plant products and related goods, originating in the Republic of Moldova and other countries, which must undergo phytosanitary control before being put into circulation on the territory of the Republic of Moldova.

This decision transposes Annex I to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community, and Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community (Recast).

³⁴⁹ Government Decision No. 356/2012 for the approval of some normative acts regarding the implementation of Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/search/getResults?doc_id=113833&lang=en

4. Government Decision No. 594/2011 on the approval of the Special Requirements for the introduction and circulation of plants, plant products on the territory of the Republic of Moldova,³⁵⁰ regulating the special requirements for the introduction and movement of plants, plant products on the territory of the Republic of Moldova.

These requirements transpose Annex IV to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community, point 4 of Commission Implementing Directive 2014/78/EU of 17 June 2014 amending Annexes I, II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community ; point 4 of Commission Implementing Directive 2014/83/EU of 25 June 2014 amending Annexes I, II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community; point 4 of Commission Implementing Directive (EU) 2017/1279 of 14 July 2017 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community; Commission Implementing Directive (EU) 2017/1920 of 19 October 2017 amending Annex IV to Council Directive 2000/29/EC as regards the movement of seeds of *Solanum tuberosum* L. originating in the Union and point 4 of the annex to Commission implementing Directive 2019/523 of 21 March 2019 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the community of organisms harmful to plants or plant products and against their spread within the community..

5. Government Decision No. 558/2011 on emergency measures in the field of phytosanitary measures to prevent the introduction and spread in the Republic of Moldova of organisms harmful to plants, plant products and other related goods subject to the phytosanitary quarantine regime³⁵¹

REGULATES according to Annexes:

- Emergency measures to prevent the introduction and spread in the Republic of Moldova of *Anoplophora chinensis* (Forster);
- Provisional emergency phytosanitary measures to prevent the introduction and spread in the Republic of Moldova of *Phytophthora ramorum* Werres, Man in 't Veld sp. nov;

³⁵⁰ Government Decision No. 594/2011 on the approval of the Special Requirements for the introduction and circulation of plants, plant products on the territory of the Republic of Moldova, available in Romanian at: https://www.legis.md/search/getResults?doc_id=123823&lang=en

³⁵¹ Government Decision No. 558/2011 on emergency measures in the field of phytosanitary measures to prevent the introduction and spread in the Republic of Moldova of organisms harmful to plants, plant products and other related goods subject to the phytosanitary quarantine regime, available in Romanian at: https://www.legis.md/search/getResults?doc_id=103256&lang=en

- Protection measures against the spread in the Republic of Moldova of *Pseudomonas solanacearum* (Smith) Smith;
- Measures to prevent the introduction and spread in the Republic of Moldova of the pepino mosaic virus;
- Emergency measures to prevent the spread of *Bursaphelenchus xylophilus* (Steiner and Buhrer) in the Republic of Moldova Nickle et al. (pine wood nematode)
- Provisional emergency measures to prevent the introduction and spread in the Republic of Moldova of *Dryocosmus kuriphilus* Yasumatsu;
- Measures to combat and prevent the spread in the Republic of Moldova of lice from San Jose;
- Provisional emergency phytosanitary measures to prevent the introduction and spread in the Republic of Moldova of *Rhynchophorus ferrugineus* (Olivier);
- Measures to control nematodes with potato cysts in the Republic of Moldova;
- Provisional emergency measures to prevent the introduction and spread in the Republic of Moldova of *Gibberella circinata* Nirenberg & O'Donnell;
- Measures on combating bacterial wilt of potatoes in the Republic of Moldova;
- Measures to control the bacterium *Ralstonia solanacearum* (Smith) Yabuuchi et al. in the Republic of Moldova;
- Measures regarding the control of potato blight in the Republic of Moldova;
- Measures on the control of tortricides on carnation leaves in the Republic of Moldova;
- Emergency measures to prevent the introduction and spread of harmful organisms *Epitrix cucumeris* (Harris), *Epitrix similaris* (Gentner), *Epitrix subcrinita* (Lec.) And *Epitrix tuberis* (Gentner);
- Measures to prevent the introduction and spread in the Republic of Moldova of *Xylella fastidiosa* (Wells et al.).

This Decision is harmonised with: Commission Implementing Decision 2012/138/EU of 1 March 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of *Anoplophora chinensis* (Forster); Commission Decision 2002/757/EC of 19 September 2002 on provisional emergency phytosanitary measures to prevent the introduction into and the spread within the Community of *Phytophthora ramorum* Werres, De Cock & Man in 't Veld sp. nov.; Commission Decision 2004/200/EC of 27 February 2004 on measures to prevent the introduction into and the spread within the Community of Pepino mosaic virus; Commission Implementing Decision 2012/535/EU of 26 September 2012 on emergency measures to prevent the spread within the Union of *Bursaphelenchus xylophilus* (Steiner et Buhrer) Nickle et al. (the pine wood nematode); Commission Decision 2006/464/EC of 27 June 2006 on provisional emergency measures to prevent the introduction into and the spread within the

Community of *Dryocosmus kuriphilus* Yasumatsu; Council Directive 2006/91/EC of 7 November 2006 on control of San José Scale; Commission Decision 2007/365/EC of 25 May 2007 on emergency measures to prevent the introduction into and the spread within the Community of *Rhynchophorus ferrugineus* (Olivier); Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC; Commission Decision 2007/433/EC of 18 June 2007 on provisional emergency measures to prevent the introduction into and the spread within the Community of *Gibberella circinata* Nirenberg & O'Donnell; Council Directive 93/85/EEC of 4 October 1993 on the control of potato ring rot; Commission Directive 2006/56/EC of 12 June 2006 amending the Annexes to Council Directive 93/85/EEC on the control of potato ring rot; Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi et al.; Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease; Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers; Commission Implementing Decision 2012/270/EU of 16 May 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of *Epitrix cucumeris* (Harris), *Epitrix similaris* (Gentner), *Epitrix subcrinita* (Lec.) and *Epitrix tuberis* (Gentner).

6. Government Decision No. 1045/2005 for the approval of the Regulation on the import, storage, marketing and use of plant protection products and fertilizers³⁵², which establishes the conditions and manner of importation, storage, marketing and use of plant protection products and fertilizers, in order to suppress their illicit importation, ensure the protection of the vital interests and security of citizens, in accordance with the requirements of the legislation in force.

7. Government Decision No. 1307/2005 on the approval of the Regulation on the state certification and approval of plant protection products and fertilizers for use in agriculture and forestry³⁵³, provides the state certification, approval of phytosanitary products and new fertilizers, approved by the Interdepartmental Republican Council and included in the State Register of phytosanitary products and fertilizers, to be used in agriculture and forestry.

8. Government Decision No. 123/2018 on the approval of the National Integrated Plant Protection Program for the years 2018-2027 and the Action Plan on its implementation³⁵⁴, the main objective of the Program is to optimize phytosanitary treatments by reducing the quantitative pressure of phytosanitary

³⁵² Government Decision No. 1045/2005 for the approval of the Regulation on the import, storage, marketing and use of plant protection products and fertilizers, available in Romanian at: https://www.legis.md/search/getResults?doc_id=113258&lang=en

³⁵³ Government Decision No. 1307/2005 on the approval of the Regulation on the state certification and approval of plant protection products and fertilizers for use in agriculture and forestry, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125303&lang=en

³⁵⁴ Government Decision No. 123/2018 on the approval of the National Integrated Plant Protection Program for the years 2018-2027 and the Action Plan on its implementation, available in Romanian at: https://www.legis.md/search/getResults?doc_id=102113&lang=en

products per unit of agricultural area, in order to provide consumers with quality and safe plant products and a healthy living environment.

9. Government Decision No. 42/2020 for the approval of the Requirements for the sustainable use of plant protection products.³⁵⁵ These Requirements set out requirements for the sustainable use of plant protection products in order to reduce risks and their effects on human health and the environment by promoting integrated pest management and alternative techniques, such as non-chemical methods of plant protection.

This Decision transposes Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

10. Government Decision No. 333/2018 regarding the approval of some model acts³⁵⁶, this decision approves model acts, meant to implement the provisions of Law No. 119/2004 on phytosanitary products and fertilizers and Law No. 228/2010 on plant protection and phytosanitary quarantine.

11. Government Decision No. 938/2018 for the approval of the Regulation on the way of crossing the state border of goods subject to control by the National Food Safety Agency.³⁵⁷ This Decision has been developed in order to ensure the efficient implementation of the one-stop-shop principle, to increase the efficiency of the control of the National Food Safety Agency based on risk analysis, and to regulate and standardize operations on potential risk capitalization that are determined at the border, in particular as regards the procedure for the application of state controls, and the optimization of the way of crossing the state border by transport means for goods and passengers.

12. Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency.³⁵⁸ This decision regulates the mission, fields of activity, functions and rights of the National Food Safety Agency, as well as the organization of its activity.

13. Government Decision No. 960/2020 regarding State Service "State Center for Attestation and Approval of Phytosanitary Products and Fertilizers".³⁵⁹ The State Service "State Center for Attestation and Approval of Phytosanitary

³⁵⁵ Government Decision No. 42/2020 for the approval of the Requirements for the sustainable use of plant protection products, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=120320&lang=en

³⁵⁶ Government Decision No. 333/2018 regarding the approval of some model acts, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=102981&lang=en

³⁵⁷ Government Decision No. 938/2018 for the approval of the Regulation on the crossing of state border of goods subject to control by the National Food Safety Agency, available in Romanian at:

https://www.legis.md/search/getResults?doc_id=125641&lang=en

³⁵⁸ Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/search/getResults?doc_id=127663&lang=en

³⁵⁹ Government Decision No. 960/2020 regarding State Service "State Center for Attestation and Approval of Phytosanitary Products and Fertilizers", available in Romanian at: https://www.legis.md/search/getResults?doc_id=124941&lang=en

Products and Fertilizers”, has the mission to organize, to coordinate the activities of research-testing-experimentation, homologation and registration of phytosanitary products and fertilizers, in order to reduce the risks and their effects on human health and the environment, according to the area of competence of the Ministry of Agriculture and Food Industry.

26. Please provide information on the respective areas of responsibilities, organization and competences of the competent institutions and authorities, in particular with regard to the inspection service both for the internal market and at border crossing points.

According to the regulatory framework and established competences, the following institutions are identified in the area of phytosanitary policy development and implementation:

I. According to the provisions of the Government Decision No. 695/2017 on the organization and functioning of the **Ministry of Agriculture and Food Industry** (*hereinafter Ministry*)³⁶⁰, it is the central specialized body of the public administration that ensures the implementation of government policy in its areas of activity.

The Ministry's mission is to analyse the situation and issues in its areas of activity, develop effective public policies in its areas of competence, monitor the quality of policies and legislation and propose justified state interventions to provide effective solutions, ensuring the best ratio between expected results and costs.

Ministry develops ex-ante analyses, policy documents, draft normative acts, including actions providing for the execution of normative acts and decrees of the President of the Republic of Moldova.

The main areas of activity of the Ministry according to the Regulation are:

- manufacturing products of plant and animal origin;
- processing of products of plant and animal origin;
- wine and spirits;
- plant protection and plant quarantine;
- organic production and products with designation of origin;
- veterinary medicine;
- breeding and reproduction in livestock production;
- food safety;
- development and organization of agricultural and agri-food markets;
- rural development programmes;

³⁶⁰ Government Decision No. 695/2017 on the organization and functioning of the Ministry of Agriculture and Food Industry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro

- agricultural consultancy;
- land improvement and land tenure.

Responsible for "Plant protection and phytosanitary quarantine" is the Division of Plant Protection and Plant-based Foods Safety of the Ministry of Agriculture and Food Industry.

At the same time, the **main functions** of the Ministry are:

- elaboration of ex ante analyses, policy documents, draft normative acts, including those for ensuring the execution of normative acts and decrees of the President of the Republic of Moldova after their publication in the Official Gazette, in collaboration with relevant representatives of civil society and business community;
- cooperation with foreign institutions in areas of interest in accordance with the national legislation;
- monitoring the score and position of the Republic of Moldova in international indicators and rankings related to its specific fields and developing proposals for their improvement;
- monitoring the perception of citizens and economic operators regarding public policies, normative acts and state activity in specific areas of activity of the Ministry and developing proposals for its improvement;
- monitoring the quality of public policies and legislation in the Ministry's specific areas of activity, including in cooperation with civil society and private sector;
- implementing normative acts and international treaties of the Republic of Moldova and preparing reports on their execution;
- examining and endorsing draft normative acts developed by other public administration authorities and submitted for review;
- drafting and submitting budget proposals, drafting the annual action plan, as well as annual monitoring of the degree of implementation by drafting and publishing respective reports;
- organizing budget planning, execution, accounting and reporting systems within the Ministry and where appropriate within subordinate budgetary authorities/institutions;
- coordinating and monitoring the activity of administrative authorities and decentralized public services under its subordination and public institutions in which it is a founder;
- performing other specific functions.

The Ministry is vested with the following rights to:

- ask and receive from other ministries, central administrative authorities and other public authorities, as well as from local government authorities,

the information necessary for the performance of its functions and the exercise of its responsibilities;

- set up consultative councils, specialized commissions, working groups, involving representatives of other ministries, other central administrative authorities and public authorities, local government, academia, civil society, business and specialists in the area for the development of draft legislation, public policy documents, expert opinions and consultations, as well as for the examination of other issues related to specific areas of activity
- prepare development projects in their areas of competence;
- collaborate with local government authorities to implement state policy in the areas assigned to them and solve common issues;
- submit proposals for the establishment, reorganization or dissolution of administrative authorities under its authority to the Government, including devoluted public services, as well as public institutions in which it is a founder, in order to ensure the fulfilment of its mission and functions;
- delegate, in case of necessity on a discretionary basis, some functions to the administrative authorities under its subordination, as well as to public institutions in which it is a founder, provided it is not against the law;
- repeal acts that are against the legislation issued by administrative authorities, decentralized public services subordinated to it and public institutions of which it is the founder;
- file, in accordance with the law, actions for recourse against public officials and staff who have caused damage to public property and state budget;
- request access to and obtain, free of charge, through the interoperability platform, statistical, financial, tax, economic, legal and other information;
- conclude international treaties under the terms of the law;
- exercise control over the efficient use of budgetary and extra-budgetary means for its regulatory functioning;
- draw up and approve instructions and methodological guidelines in matters within its competence, as well as regulatory acts registered in the manner and under the conditions provided for by the law;
- submit requests to the Government, concerning the necessity of suspending the action of normative and administrative acts or decisions of the public administration authorities that contravene the legislation;
- exercise other rights under special normative acts regulating relations in the areas of activity assigned to the Ministry.

The Ministry is run by the Minister, three Secretaries of State who hold an office of public dignity and a Secretary General who is a senior civil servant.

The State Secretaries and the Secretary General of the Ministry are subordinated to the Minister.

II. The competent authority in the phytosanitary area, according to the list of subordinate institutions in which the Ministry of Agriculture and Food Industry is a founder, approved by Annex No. 32 to Government Decision No. 695/2017 is the **State Service "State Centre for Certification and Homologation of Products for Phytosanitary Use and Fertilizers"**, which has the mission to organize, coordinate research-test-experiment, homologate and register products for phytosanitary use and fertilizers with the aim of mitigating risks and their effects on human health and the environment

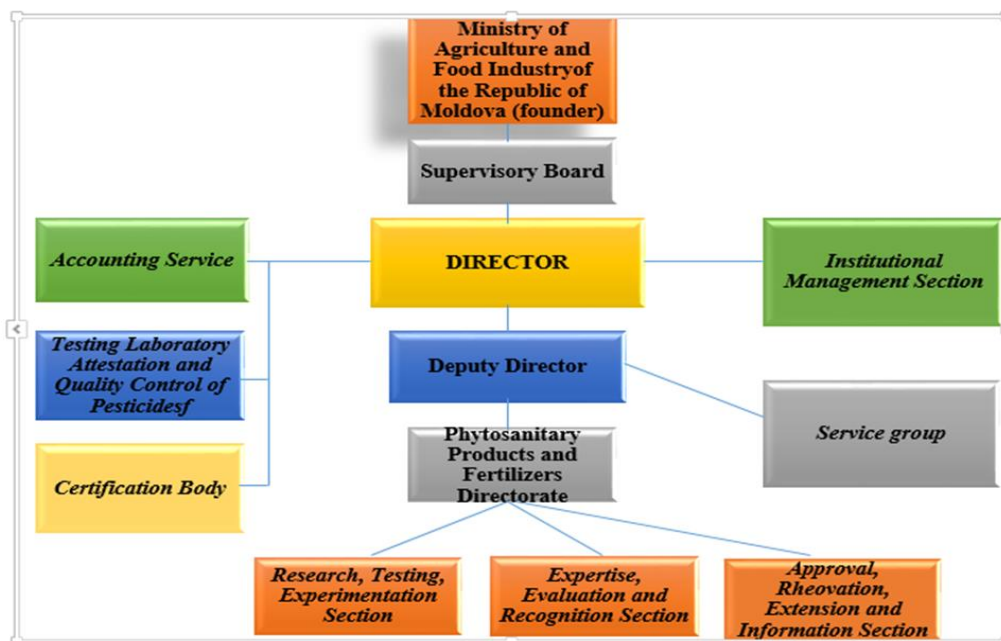
According to provisions of the Government Decision no. 960/2020 on the State Service "State Centre for Certification and Approval of Products for Phytosanitary Use and Fertilizers"³⁶¹, its areas of competence are as follows:

- research-test-experiment and approval of plant protection products and fertilizers;
- analyses of the quality of plant protection products, pesticide residues in plants, soil and foodstuffs of plant origin;
- certification of conformity of plant protection products and fertilizers;
- agricultural services;
- services for forestry and logging;
- other areas, assigned by regulatory acts.

The executive activity of the State Centre is led by the Director, selected through a competition organized by the founder.

Fig. 1. Organization chart of the SC "State Centre for Certification and Approval of Plant Protection Products and Fertilizers"

³⁶¹ Government Decision no. 960/2020 on the State Service "State Centre for Certification and Approval of Products for Phytosanitary Use and Fertilizers", available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=124941&lang=ro



The State Centre has the following functions:

- creation of the range of plant protection products and fertilizers for use in agriculture, forestry and municipal husbandry, and for the protection of stored products, in order to ensure a high level of protection of human and animal health, protect the environment and ensure the competitiveness of agriculture;
- organization, coordination and control of research-testing-experimentation activities of plant protection products and fertilizers in institutions, enterprises, academic and professional organizations with the aim of their approval and/or extension of their area of application;
- examination of applications of domestic and foreign natural and legal entities for carrying out state research-testing-experimentation of new plant protection products and fertilizers;
- conducting the initial assessment of the product dossier submitted for state approval/re-registration;
- requesting samples of products for state testing and submit them to institutions, enterprises and academic and professional organizations for state research-testing-experimentation;
- determining, in agreement with the Republican Interdepartmental Council for the approval of plant protection products and fertilizers, the institutions, enterprises and academic and professional organizations that will carry out research-testing-experimentation work on plant protection products and fertilizers from domestic and imported manufacturers;
- organizing state tests of new products manufactured in the country or abroad, within institutions, enterprises, academic and professional

organizations (agricultural, public health, forestry, fishery, environmental, municipal);

- issuing the approval certificate for the product, according to the template provided by the Government within 5 working days after the date of fulfilling the obligations assumed by the applicant;
- coordinating the packaging labels of plant protection products and fertilizers in order to match them with the information in the dossier;
- carrying out laboratory quality control tests on approved plant protection products;
- determining pesticide residues in plants, soil and foodstuffs of plant origin;
- carrying out certification services for plant protection products and fertilizers;
- updating, placing on the official website of the State Centre and publishing the State Register of plant protection products and fertilizers allowed for use in the Republic of Moldova (hereinafter - State Register) and its supplements;
- other functions assigned by the regulatory framework and by the Founder.

The State Centre determines, in agreement with the Interdepartmental Republican Council for the approval of plant protection products and fertilizers, the scientific organizations authorized to carry out state research-testing-experimenting, that are technically and materially provided and have qualified specialists in the field, if the product is included in the State research-testing-experimenting programme.

The Interdepartmental Republican Council (IRC) is made up of representatives of the Academy of Sciences of Moldova, Ministry of Agriculture, Regional Development and Environment, Ministry of Health, Labour and Social Protection, National Food Safety Agency, research and higher education institutions.

The IRC consists of 11 members, representing the Academy of Sciences of Moldova, Ministry of Agriculture and Food Industry, Ministry of Environment, Ministry of Health, National Food Safety Agency, research and higher education institutions.

The core competences of the IRC are:

- examine, address and submit proposals to improve the regulatory framework governing research-testing-experimentation and approval of plant protection products and fertilizers;
- examine reports of institutions on the results of state research-testing-experimentation of plant protection products and fertilizers and materials related to products submitted for approval;

- examine and coordinate state research-testing-experimentation programme by 30 April of the reporting year. The program coordinated with the IRC shall be approved by the State Centre;
- examine organizational, scientific-methodical and practical issues for the approval of plant protection products and fertilizers;
- adopt decisions:
 - approve/ refuse the approval, re-approval, extension of plant protection products and fertilizers use;
 - prohibit the use of products in the event of identification/recognition of harmful characteristics which may cause unacceptable effects on human health and the environment, on the basis of technical and scientific information.
- Registration of plant protection products and fertilizers in the State Register permitted for use in the Republic of Moldova and issuing the Certificate of Approval.

Thus, according to the provisions of Law No. 160/2011 on the regulation of entrepreneurial activity³⁶², the State Centre issues the Certificate of Approval (registration) of the plant protection product or fertilizer (except for those marked "EC fertilizers"), a permit on the basis of which the State Register of plant protection products and fertilizers is filled in, the information which enables the inspectors of control of plant protection products and fertilizers of the National Food Safety Agency to carry out post-registration control of plant protection products and fertilizers, the purpose of which is to establish traceability from manufacturer/import to verification of the rules of use.

At the same time, at the national level, the Order of the Minister of Agriculture and Food Industry No. 142/2016³⁶³ approved the mandatory indices for the conformity assessment of plant protection products, which aims to prevent the placing on the market of non-compliant products and ensure the compliance of plant protection products by establishing mandatory indices for these products.

Thus, following the laboratory tests carried out in the Testing Laboratory "Pesticide Quality Certification and Control", regarding the quality control of approved plant protection products, it will issue the certificate of conformity of plant protection products only in case of compliance with all the indicators set out in the Annex to Order No 142/2016.

³⁶² Law No. 160/2011 on the regulation of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro#

³⁶³ Order of the Minister of Agriculture and Food Industry No. 142/2016 on the approval of mandatory indices for conformity assessment of plant protection products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=104039&lang=ro

III. According to the Government Decision No 600/2018 on the organization and functioning of the National Food Safety Agency (hereinafter - the Agency)³⁶⁴, **the National Food Safety Agency** is the central administrative authority under the Government that implements the state policy in the following areas of activity:

- veterinary and animal health;
- phytosanitary and plant protection;
- food safety and quality;
- production and circulation of wine and alcoholic products;
- consumer protection in the food sector;
- compliance with licensing requirements in the related area.

The Agency's mission is to ensure the implementation of state policies in areas aimed at guaranteeing food safety and quality of food products, including ethyl alcohol, alcohol production, wine and beer products, maintenance of a system of public measures aimed at ensuring animal health and plant protection, harmlessness of food products and raw materials, and protection of consumers in the food sector.

The phytosanitary field is composed as follows:

- at central level: 3 line Divisions, such as the Plant Protection Division, Plant Protection Products and Fertilizers Control Division and Seeds and Planting Material Division;
- at territorial level: inspectors of territorial subdivisions mirror the structure at the central level.
- The control of plant products and plants, as well as of imported plant protection products and fertilizers, is carried out by the International Trade and Border Inspection Directorate in conjunction with Border Inspection Posts (with the status of Division).

The basic tasks of the Agency in the field of plant protection are: coordinating the elaboration and implementation of monitoring and control programmes for harmful organisms and quarantined organisms, including those detected in imported plant products, elaboration of operational and specific procedures, instructions, regulations on the application of the provisions of the legislation in force, international standards, specific requirements in the area; realization of the strategy on ensuring plant protection, including management of plant protection products and fertilizers, prevention of the introduction and spread of harmful organisms on the territory of the country; implementation of complex, scientifically based state programmes and special measures for the prevention and liquidation of outbreaks of dangerous harmful and quarantined organisms; establishment of single and mandatory phytosanitary rules for all natural and legal

³⁶⁴ Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

persons, holders of agricultural crops and other forms of useful vegetation, as well as for those who store, import, transport and process plants and plant products, as well as phytosanitary products and fertilizers; regulation and supervision of the process of phytosanitary control and certification of plant production for export; application or lifting the protected area regime; participation in carrying out measures on the assessment, documentation and communication of phytosanitary risk for the development and application of phytosanitary measures; registration and state control of the activity of entrepreneurs (operators) in the phytosanitary field; cooperating internationally with organizations involved in plant protection and other related fields in order to keep the Republic of Moldova in the loop of specific European and international policies; initiating, developing and executing externally funded technical assistance projects in the phytosanitary field; participating in national and international phytosanitary activities and meetings.

The phytosanitary inspectors of territorial subdivisions, including border inspection posts, carry out the following tasks: control and monitor quarantined organisms in accordance with the annual monitoring plan developed and approved; participate in carrying out measures on assessment, documentation and communication of phytosanitary risks associated with the phytosanitary quarantine area and certification of plant production; inspect registered sectors and carry out visual observations during the vegetation period of plants whenever necessary in accordance with legal provisions and international standards in the phytosanitary field; prepare reports and information carrying out phytosanitary measures on export and import of plant production under control; controls the process of implementation by operators in the agri-food chain of international standards of phytosanitary measures and phytosanitary requirements of importing countries, as well as phytosanitary procedures in the production, export and import of plant production; registers operators operating in the area of plant products in the Automated Information System "State Phytosanitary Register" (SIA RSF); issues phytosanitary control documents, phytosanitary certificates for the export and import of production, materials and objects subject to phytosanitary quarantine; ensures phytosanitary control over the application of provisions of the legislation on the production, purchase, transport, processing, marketing and use of plant production, including wood packaging used in international trade and import of phytosanitary products and fertilizers.

At the same time, phytosanitary inspectors specializing in phytosanitary monitoring and phytosanitary crisis management monitor the timely detection, localization and permanent observations of the development of pests, diseases and weeds, carry out systematic surveys of agricultural areas and timely warn land beneficiaries about their occurrence; draw up and send warning bulletins on the control of harmful plant varieties to agricultural households and local public administration; carry out diagnosis and monitoring of pest agents, their occurrence and evolution; keep records on the development stages of agricultural crops, pests and diseases; control and supervise the implementation of and compliance with the procedures for the establishment and/or cancellation of protected areas or pest-free areas; monitor the implementation of plant protection measures and the elimination

of harmful organisms by land owners, regardless of their subordination and type of ownership, plant protection measures and control of harmful organisms.

The phytosanitary inspectors, both at central and territorial level, carry out their work in accordance with the legal framework in the respective field, orders, provisions and memoranda issued by the management of the Agency, as well as procedures developed:

- PS/FS-AL-01/01: Control of compliance with phytosanitary requirements for wood packaging used in international trade;
- PS/FS-MSD-01/01: Registration and supervision of phytosanitary operators;
- PS/FS-MSD-06/01: Certification of products of plant origin for export and re-export;
- PS/FS-MSD-05/01: Establishment and/or maintenance of the status of 'Place and/or production area free from plant pests';
- PS/FS-PP 01/01: Monitoring and prevention of the spread of the harmful organism *Phytoplasma - Grapevine flavescence D'ore*;
- PS/FS-MSD-07/01: Monitoring and prevention of the spread of the plant pest *Diabrotica virgifera* Le Conte;
- PO(D-06/1A-01/01: Plant health import control (products);
- PO(D-06/1A-03/01: Plant health import control (seeds);
- PO(D-06/1A-02/01: Plant health import control - wood packaging material;

Methodical instruction for sampling in the framework of phytosanitary control and phytosanitary assessment at import of products of plant origin, approved by ANSA Order No 119/2013

In order to ensure transparency and inform the general public, information relevant to the field of activity is being placed on the Agency's official website under "Plant health and protection"³⁶⁵.

Since 2000, the Republic of Moldova has been party to the International Plant Protection Convention (IPPC) (Law No. 926/2000 on the accession of the Republic of Moldova to the International Plant Protection Convention³⁶⁶ and the Agency represents the interests of the Republic of Moldova at the International Plant Protection Convention of the World Food and Agriculture Organization (FAO). The Director General of ANSA is the national contact point of IPPC.

³⁶⁵ ANSA Order No 119/2013 approved by Methodological instruction for sampling in the framework of phytosanitary control and phytosanitary expertise at import of products of plant origin, available in Romanian at: <https://ansa.gov.md/ro/content/sanatatea-si-protectia-plantelor>

³⁶⁶ Law No. 926/2000 on the accession of the Republic of Moldova to the International Plant Protection Convention, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108573&lang=ro

At the same time, in accordance with the provisions of Law No. 16/2006 on the accession of the Republic of Moldova to the Convention establishing the European and Mediterranean Plant Protection Organization (EPPO), as amended, the Republic of Moldova through the Agency is present in the EPPO.³⁶⁷

It should be mentioned that the Agency is the founder of the State Enterprise "Central Phytosanitary Laboratory", which provides its assistance in diagnosing plant pests.

For carrying out the phytosanitary control and phytosanitary certification function, 72 employees are involved at the territorial level located in 37 offices and 7 employees at the central level. Both central and territorial inspectors have higher education in the area of plant protection, during the year they participate in various training courses with the participation of national and international experts, including from EU Member States (e.g. Romania, UK, Lithuania, Netherlands, USA), organized within the framework of international projects or according to bilateral agreements, as well as domestic/national.

At the same time, inspectors are provided with office equipment and equipment for visual inspection and sampling for laboratory tests.

In accordance with the provisions of Law No. 119/2004 on plant protection products and fertilizers³⁶⁸, **the National Food Safety Agency is responsible** for determining the requirements of plant protection products and fertilizers and for coordinating the volume of their manufacturing or import. The National Food Safety Agency specifies the annual quotas of these products by sections and allows the import of each imported or manufactured lot, in the manner established by the Government.

State supervision and control over the manufacturing, import, transport, storage, marketing and use of plant protection products and fertilizers, as well as control over residues of these products in agri-food and feed production and in the environment, is the responsibility of the National Food Safety Agency. The Ministry of Health, Labor and Social Protection, Ministry of Agriculture, Regional Development and Environment, Licensing Chamber and other competent bodies carry out such activities within the limits of the competence laid down by law. State control of persons engaged in entrepreneurial activity is planned, carried out and registered in accordance with the provisions of the Law No. 131/2012 on State Control of Entrepreneurial Activity.³⁶⁹

³⁶⁷ Law No. 16/2006 on the accession of the Republic of Moldova to the Convention establishing the European and Mediterranean Plant Protection Organization (EPPO), available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107190&lang=ro

³⁶⁸ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁶⁹ Law No. 131/2012 on State Control of Entrepreneurial Activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro

Conducting activities with plant protection products and fertilizers and taking measures to stimulate the interest of agricultural producers in applying recommended technologies and avoiding misuse of plant protection products and fertilizers by promoting integrated plant protection and sustainable use of plant protection products.

In the area of control and management of plant protection products and fertilizers, the Agency is vested with the following powers:

- require enterprises, institutions and organizations of all types of ownership, natural and legal persons who manufacture, import, transport, store, market and use plant protection products and fertilizers to comply with the law on plant protection products and fertilizers and other relevant laws and regulations;
- have free access to enterprises, institutions, organizations of any type of ownership which are engaged in the manufacturing, import, transport, storage, marketing and use of plant protection products and fertilizers in order to inspect them, including taking samples for investigations to determine their quality;
- prohibit the import, marketing and use of plant protection products and fertilizers that do not comply with national standards, phytosanitary and sanitary regulations and other technical and regulatory acts, processing and marketing of agri-food products and use of water if residues of plant protection products and fertilizers are found in excess of the maximum permissible limits;
- prohibit the work of persons engaged in activities with plant protection products and fertilizers who have not passed the medical examination or have not been trained in occupational safety for such activities, until the non-conformities have been removed;
- receive from ministries, departments, enterprises, institutions, organizations, natural and legal persons engaged in activities with plant protection products and fertilizers statistical and other information necessary for state supervision and control in this field;
- establish contraventions and conclude minutes on the violation of this law and other legislative acts on phytosanitary products and fertilizers.

At the same time, the representative of the Agency is a member of the Interdepartmental Republican Council for the approval of plant protection products and fertilizers and included in the State Register of plant protection products and fertilizers.

The Interdepartmental Republican Council for the Approval of Products for Phytosanitary Use and Fertilizers may definitively or temporarily prohibit the use of the approved product if it is found to be no longer phytosanitary, toxicologically or ecologically suitable and in other cases determined by the health and environmental protection authorities, informing the manufacturing company and stating the reasons for its decision.

Pursuant to Art. 151 of Law No. 119/2004 on plant protection products and fertilizers³⁷⁰ and in accordance with provisions of Law No. 131/2012 on State control of entrepreneurial activity³⁷¹ and PS(D03/2C)-05/01 **Specific procedure for the issuance of operating authorisation for the storage of products for phytosanitary use and fertilizers.** The Agency officially registers in the Register of specialized storage facilities for fertilizers and products for phytosanitary use and issues Extracts following Notifications submitted by economic operators.

Import. Economic operators who are holders of Extracts according to art.12 of Law 119/2004³⁷² and Government Decision No. 1045/2005 on the approval of the Regulation on the import, storage, marketing and use of PUFF,³⁷³ are authorized to carry out the activity of importing or as appropriate, manufacturing PUFF.

The import and/or marketing of plant protection products and fertilizers is carried out on the basis of:

- sale-purchase contract;
- the manufacturer's quality certificate;
- the import invoice;
- notification of import or, as appropriate, manufacturing of plant protection products and fertilizers, which must contain details of the officially registered specialized warehouse, which is sent to the electronic address of the PUFF Control Directorate which in accordance with specific procedure PS (D03/2B)-02/01 - issues authorisation for import of plant protection products and fertilizers, admits (or refuses) the import. The following conditions must be complied with when carrying out activities in the field of import and/or marketing of plant protection products and fertilizers:
- import and/or trade only in plant protection products and/or fertilizers approved in the Republic of Moldova and included in the State Register of Plant Protection Products and Fertilizers, as well as fertilizers marked "EC Fertilizer;
- quarterly submission to the National Food Safety Agency, by the 5th of the month immediately following the quarter of the reporting period of information on the quantities of imported and/or traded (with specification of the buyer) plant protection products and/or fertilizers from the Register of import, trade and stock of plant protection products;

³⁷⁰ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁷¹ Law No. 131/2012 on State control of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro

³⁷² Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁷³ Government Decision No. 1045/2005 on the approval of the Regulation on the import, storage, marketing and use of PUFF, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113258&lang=ro

- keeping records of the import, marketing and stock of plant protection products and/or fertilizers in the Register of Records, registered and sealed by the National Food Safety Agency;
- prohibit the import of plant protection products and/or fertilizers, the shelf life of which expires earlier than one year after their introduction into the customs territory of the Republic of Moldova

The storage and marketing of PUFF is carried out under Law No. 119/2004³⁷⁴ and Government Decision No. 1045/2005 approving the Regulation on the import, storage, marketing and use of PUFF³⁷⁵, as well as the Regulation on the management of plant protection products and fertilizers in the national economy, approved by Order of the Ministry of Agriculture and Food Industry No 231/2003.³⁷⁶ by economic operators, including owners of specialized shops, who market PUFF and who must have:

- an extract issued in accordance with the legislation;
- a specialist with studies in plant protection or other agronomy area;
- a sale-purchase contract
- quality certificate from the producer;
- Register of import, marketing and stock of PUFF.

Pursuant to Art. 22 of the Law No. 119/2004 on plant protection products and fertilizers³⁷⁷, Article 23 of Law 131/2012 on state control of entrepreneurial activity³⁷⁸, point 73 of Government Decision No. 1045/2005³⁷⁹, point 13 of the Regulation on the organization and functioning of ANSA approved by Government Decision No. 600/2018³⁸⁰ approve the Programme for monitoring the quality of products for phytosanitary use carried out by phytosanitary inspectors according to the Specific Procedure sampling of samples of products for phytosanitary use Code: PS(D 03/2C)-04/01.

According to provisions of Art. 16 of the Law No. 119/2004 on plant protection products and fertilizers counterfeit plant protection products and fertilizers placed

³⁷⁴ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁷⁵ Government Decision No. 1045/2005 approving the Regulation on the import, storage, marketing and use of PUFF, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113258&lang=ro

³⁷⁶ Regulation No. 231/2003 on the management of plant protection products and fertilizers in the national economy, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=37349&lang=ro

³⁷⁷ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁷⁸ Law No. 131/2012 on state control of entrepreneurial activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro

³⁷⁹ Government Decision No. 1045/2005 for the approval of the Regulation on the import, storage, marketing and use of plant protection products and fertilizers, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=113258&lang=ro

³⁸⁰ Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

on the domestic market are returned to the producer or are subject to confiscation and subsequent liquidation.

In the event of non-compliance with Law No. 119/2004 on plant protection products and fertilizers and other legislation on activities with plant protection products and fertilizers, the specialized warehouse (shop) shall be deleted from the Register of specialized warehouses for fertilizers and plant protection products.

Agricultural raw materials, food and feed of plant origin made available on the market, in the production, transport or storage of which plant protection products and/or fertilizers have been used, shall comply with health regulations. Certification of the compliance of agricultural raw material of plant origin, including fresh vegetables and fruit, and animal feed of plant origin with the health standards shall be based on tests carried out by an accredited laboratory. At the request of the economic operator, compliance may be further attested by the safety certificate provided for in Art. 23 (1) of Law No. 119/2004 on plant protection products and fertilizers.

The safety certificate is issued, upon request, based on the results of laboratory tests or on the basis of a self-declaration of compliance with the rules for the use of plant protection products and fertilizers, which is received by the phytosanitary inspector and verified in accordance with the specific procedure for the verification of documents concerning compliance with the rules for the use of plant protection products and fertilizers Code: PS (D 03/2A)-01/01. The safety certificate is an optional document, which can be obtained by economic operators for products intended for export/re-export or in other cases where the economic operator wishes to provide additional proof that products comply with health rules. When laboratory tests are carried out for the purpose of issuing the safety certificate, sampling shall be carried out by the authority issuing the safety certificate.

Following the specific procedure PSCGPUFF-01 inspection of management of products of phytosanitary use and fertilizers, the phytosanitary inspectors of the Agency carry out planned and unannounced controls in the area of management of PUFF at the site of economic operators who manufacture, import, store, market and use PUFF, according to the Annual Control Plan.

Pursuant to Art. 27(1) of Law No. 119 /2004 on phytosanitary products and fertilizers³⁸¹, the following actions stipulated in the Contravention Code of the Republic of Moldova³⁸² constitute a violation of the rules on manufacturing, import, transport, storage, marketing and use of phytosanitary products and fertilizers and are subject to sanctions: the introduction onto the territory of the country, production, marketing, promotion, repackaging and use of phytosanitary products, fertilizers and pharmaceutical products for veterinary use without

³⁸¹ Law No. 119/2004 on plant protection products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁸² Contravention Code of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125094&lang=ro

certificates of conformity, unapproved, prohibited or counterfeit. Violation of the rules on registering, transport, storage or use of plant protection products or fertilizers. Failure to comply or inadequate compliance with the legal provisions of persons in charge of the state supervision and control of plant protection. Withholding or misrepresenting information about plant protection products or fertilizers that pose danger to humans, animals or the environment. Pollution of agri-food production, fodder, agricultural raw materials with residues of plant protection products or fertilizers beyond the maximum permissible limit. Violation of mandatory standards, phytosanitary or environmental protection standards or rules, other regulatory acts in the manufacturing, import, transport, storage, marketing or use of plant protection products, fertilizers and technical means of application of these products. The discharge of unused plant protection product solutions, as well as water used for washing transport, machinery, special equipment and packaging of plant protection products or fertilizers onto the ground, ponds or other water sources. Violation of the methodology of research, testing, experimentation and state registration of plant protection products or fertilizers. Preventing inspectors of the National Food Safety Agency from exercising phytosanitary supervision and control.

27. Please provide information on Plant health, harmful organisms:

- a) General control measures;**
- b) Specific control measures;**
- c) Protected zones;**
- d) Registration of operators (plant passports);**
- e) Imports;**
- f) Inspections and notification of interceptions;**
- g) Expenditure in the phytosanitary field;**
- h) Status of harmful organisms listed in the EU *acquis*.**

a) General control measures

Phytosanitary control is carried out in strict compliance with Law No. 228/2010 on plant protection and phytosanitary quarantine and applies to plants, plant products and related goods subject to the phytosanitary quarantine regime by actively applying processes (surveillance, monitoring, inspection), regulations (measure, norms) and mandatory phytosanitary procedures (method, process) with the objective of eradicating or isolating quarantine organisms, or managing regulated non-quarantine pests.³⁸³

General control measures shall be carried out by phytosanitary inspectors, on a mandatory basis, at the place of production and at the state border crossing points, and shall apply to all plants and plant products grown, imported, produced, used or otherwise present within the perimeter of the production premises and border control line, as well as to the growing environment used in that area.

³⁸³ Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

Phytosanitary inspectors shall supervise the implementation of agro-technical, biological and chemical plant protection measures, compliance with the rules on the preservation, transport and use of plant protection means by natural and legal persons, irrespective of the type of ownership and legal form of organisation; monitor the causes and conditions of occurrence of pests and quarantine pests, determine the set of measures to combat them; take samples of imported, exported and re-exported plant products, including the plant contents of parcels, hand luggage, other luggage and related goods subject to phytosanitary quarantine;

At the same time, general control measures involve the collection of information on pests present and quarantined relevant for the Republic of Moldova from various sources.

b) Specific control measures include:

The process of collecting information on relevant pests for a given period of time, the vegetation period, and the species they damage. Phytosanitary inspectors actively collect and keep records of data on specific pest species according to surveys/instructions developed and approved to characterise the population of plant pests.

National surveillance programmes for organisms harmful to plants and plant products, including imported ones, are drawn up and approved annually. Thus, the presence of 19 pests on agricultural areas in the country and 19 insects using feromonal traps is monitored annually, as well as 19 pests in products imported from other countries. The programmes include bodies that are also relevant for the territory of the European Union.

The results received as part of the execution of the monitoring programmes and the surveillance during the vegetation period of plants shall be systematised and mapped out limiting the area of distribution of the organism, where appropriate.

At the same time, quantitative population records shall be kept on each individual harmful organism, based on the results of laboratory assessments.

In addition, according to the Agency's orders, specific/improved controls are carried out, in particular for imported production, for certain organisms (e.g. *Clavibacter michiganensis*, *Erwinia amylovora*, *Xylella fastidiosa*, *Monilinia fructicola*, etc.)

At the same time, the data collected and systematised include the results of the visual check and laboratory surveys of samples taken prior to export of plant products, are used for risk assessment and control planning.

c) Protected areas;

The process of collecting information on the presence of certain pests in limited areas is only 2 years, which is not sufficient for the establishment of protected zones. One should be notified of the complexity of measures necessary for the application of the ‘protected zone’ principles. This is as follows:

- procedure PS/FS-MSD-05/01: Establishing and/or maintaining the status of “place and/or zone of products free of plant pests ” is drafted³⁸⁴;
- statistical data are in the process of being collected;
- producers in the agricultural sector are kept informed.

d) Registration of operators (plant passports)

In accordance with provisions of Art. 24 of Law No. 228/2010, all the economic operators with relevance in the field of plant health are registered using the Automated Information System ‘State Phytosanitary Register’ (hereinafter SIA RSF). Government Decision No. 82/2021 approves the Concept and Regulation of SIA RSF **on certain information systems and state registers of the National Food Safety Agency**³⁸⁵.

SIA RSF also includes the “Phytosanitary Certificate” module, which provides for the preparation and issuance of Phytosanitary Certificates and the “Plant Passport” module for drafting and issuing the plant passport, as well as replacing plant passport for plants and plant products referred to in Section 2 of Annex 5 to the Government Decision No. 356/2012.³⁸⁶

Exporters of plant products who supply to the market of Member States of the European Union, shall be registered in addition by the Agency and in the TRACES-NT system.

e) Imports;

Verification of plant production at import are carried out by 56 phytosanitary inspectors from 7 Border Inspections Posts under Art. 19 of Law No. 228/2010.

Government Decision No. 600/2018³⁸⁷.

The nomenclature of goods subject to phytosanitary control and the Regulation on crossing the state border of goods subject to control by the National Food Safety

³⁸⁴ Procedure PS/FS-MSD-05/01, available in Romanian at: <https://ansa.gov.md/ro/content/sanatatea-si-protectia-plantelor#tab-0-2>

³⁸⁵ Government Decision No. 82/2021 approves the Concept and Regulation of SIA RSF, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=126883&lang=ro

³⁸⁶ Government Decision No. 356/2012 for the approval of some normative acts regarding implementation of Law No. 228/2010 regarding plant protection and phytosanitary quarantine available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113833&lang=ro

³⁸⁷ Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

Agency are approved by Government Decision No. 938/2018 approving the Regulation on crossing the state border of goods subject to control by the National Food Safety Agency³⁸⁸.

Upon importing of plant products inspectors shall carry out documentary, identity and physical checks with sampling, where appropriate, including checks on imported plant protection products and fertilisers. The phytosanitary control is completed with the filling of the inspection act, while in the case of control of plant protection products the import permit stamp is affixed to the notification approved in Annex 1 to Government Decision No. 333/2018. The information on consignments inspected at import shall be recorded online and on paper.³⁸⁹

Imports into, or transit through the territory of the Republic of Moldova of plants, plant products and related goods subject to the phytosanitary quarantine regime shall be admitted upon presentation of the original Phytosanitary Certificate issued by the competent phytosanitary authorities of the exporting State certifying the phytosanitary status of each consignment of plants, plant products (load) and related goods subject to phytosanitary quarantine.

In order to ensure phytosanitary control, at the import (transit) of plants, plant products and related goods subject to the phytosanitary quarantine regime, the importer shall submit to the National Food Safety Agency, at least 24 hours before the import operation, a Self-Declaration in electronic format of the intention to import, indicating the points of entry. The template of Declaration can be downloaded from the Agency's webpage³⁹⁰.

f) Inspections and reporting interceptions;

If control finds that a part of the lot of plants and/or plant products is contaminated by harmful organisms, the introduction of other lots/parts thereof shall be allowed provided that there is no danger of contamination or release. In the event of non-compliance with the phytosanitary requirements laid down in Government Decision No. 594/2011 approving special requirements for the introduction into and movement of plants, plant products on the territory of the Republic of Moldova³⁹¹, and/or the detection of organisms listed in Government Decision No. 356/2012 approving certain legislative acts implementing Law No. 228 of 23 September 2010 on plant protection and phytosanitary quarantine, one or more of the following measures shall apply:

³⁸⁸ Government Decision No. 938/2018 approving the Regulation on how to cross the state border of goods subject to control by the National Food Safety Agency, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=125641&lang=ro

³⁸⁹ Government Decision No. 333/2018 regarding the approval of some model acts, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=102981&lang=ro

³⁹⁰ The template Declaration, available in Romanian at: <https://ansa.gov.md/content/iban-rechezite-bancare-declaratie/>

³⁹¹ Government Decision No. 594/2011 approving special requirements for the introduction into and movement of plants, plant products on the territory of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123823&lang=ro

- appropriate treatment if inspection considers that the requirements have been met;
- removal of infested/infected products from the consignment;
- imposing a quarantine period pending the results of official investigations or tests;
- refusal of import (transit);
- destruction of plants, plant products and, where appropriate, related goods subject to phytosanitary quarantine;
- carrying out other actions provided for in the legislation.

At the same time, the country of export shall be notified of the detection of non-compliances and of the measures taken. The notification procedure is approved by Government Decision No. 572/2012 approving the Rules establishing a procedure for the notification of interception of a consignment or pest from other countries and presenting an imminent phytosanitary danger.³⁹²

If in the framework of the phytosanitary control prior to export, non-compliances are detected for the country of import, the Phytosanitary Certificate shall not be issued and the phytosanitary control act shall prescribe measures to eliminate non-compliances with a time limit for execution and repeated submission of samples for laboratory tests.

g) Expenditure in the area of plant health;

In accordance with point 4 of the Regulation on the organisation and functioning of the National Food Safety Agency approved by Government Decision No. 600/2018, the financing, technical and material endowment of the Agency shall be made from the State budget and other means not prohibited by law, such as technical assistance to support the Agency.³⁹³

At the same time, the Agency's phytosanitary inspectors provide paid services. Fees for services are approved by Government Decision No. 90/2019 approving the Methodology for the calculation of charges for services provided by the National Food Safety Agency and the classification of services provided by the National Food Safety Agency.³⁹⁴ The proceeds obtained by applying the tariffs shall be paid back to the accounts of the State Treasury.

³⁹² Government Decision No. 572/2012 approving the Rules establishing a procedure for the notification of interception of a consignment or pest from other countries and presenting an imminent phytosanitary danger, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=20987&lang=ro

³⁹³ Government Decision No. 600/2018 on the organization and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

³⁹⁴ Government Decision No. 90/2019 on the approval of the Methodology for the calculation of tariffs for services provided by the National Agency for Food Safety, as well as the Nomenclature of services provided by the National Agency for Food Safety and their tariffs, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125644&lang=ro

h) Status of harmful organisms listed in the EU acquis.

Abbreviations used:

A = absent, no reports

No.	Harmful organisms not known to occur in the territory	EU Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019, Annex II	Republic of Moldova
	A. Bacteria		
1.	<i>Candidatus Liberibacter africanus</i> [LIBEAF]	X	A
2.	<i>Candidatus Liberibacter americanus</i> [LIBEAM]	X	A
3.	<i>Candidatus Liberibacter asiaticus</i> [LIBEAS]	X	A
4.	<i>Curtobacterium flaccumfaciens</i> pv. <i>flaccumfaciens</i> (Hedges) Collins and Jones [CORBFL]	X	A
5.	<i>Pantoea stewartii</i> subsp. <i>stewartii</i> (Smith) Mergaert, Verdonck & Kersters [ERWIST]	X	A
6.	<i>Ralstonia pseudosolanacearum</i> Safni <i>et al.</i> [RALSPS]	X	A
7.	<i>Ralstonia syzygii</i> subsp. <i>celebesensis</i> Safni <i>et al.</i> [RALSSC]	X	A
8.	<i>Ralstonia syzygii</i> subsp. <i>indonesiensis</i> Safni <i>et al.</i> [RALSSI]	X	A
9.	<i>Xanthomonas oryzae</i> pv. <i>oryzae</i> (Ishiyama) Swings <i>et al.</i> [XANTOR]	X	A
10.	<i>Xanthomonas oryzae</i> pv. <i>oryzicola</i> (Fang <i>et al.</i>) Swings <i>et al.</i> [XANTTO]	X	A
11.	<i>Xanthomonas citri</i> pv. <i>aurantifolii</i> (Schaad <i>et al.</i>) Constantin <i>et al.</i> [XANTAU]	X	A
12.	<i>Xanthomonas citri</i> pv. <i>citri</i> (Hasse) Constantin <i>et al.</i> [XANTCI]	X	A
	B. Fungi and oomycetes		
1.	<i>Anisogramma anomala</i> (Peck) E. Müller [CRSPAN]	X	A
2.	<i>Apiosporina morbosa</i> (Schwein.) Arx [DIBOMO]	X	A
3.	<i>Atropellis</i> spp. [1ATRPG]	X	A
4.	<i>Botryosphaeria kuwatsukai</i> (Hara) G.Y. Sun and E. Tanaka [PHYOPI]	X	A
5.	<i>Bretziella fagacearum</i> (Bretz) Z.W de Beer, T.A. Duong & M.J. Wingfield, comb. nov. [CERAFA]	X	A
6.	<i>Chrysomyxa arctostaphyli</i> Dietel [CHMYAR]	X	A
7.	<i>Cronartium</i> spp. [1CRONG], except <i>Cronartium gentianeum</i> , <i>Cronartium pini</i> (Willdenow) Jørstad [ENDCPI] and <i>Cronartium ribicola</i> Fischer [CRONRI].	X	A
8.	<i>Davidsoniella virescens</i> (R.W. Davidson) Z.W. de Beer, T.A. Duong & M.J. Wingfield [CERAVI]	X	A
9.	<i>Elsinoë australis</i> Bitanc. Jenkins [ELSIAU]	X	A
10.	<i>Elsinoë citricola</i> X.L. Fan, R.W. Barreto & Crous [ELSICI]	X	A
11.	<i>Elsinoë fawcettii</i> Bitanc. Jenkins [ELSIFA]	X	A

12.	<i>Fusarium oxysporum</i> f. sp. <i>albedinis</i> (Kill. Maire) W.L. Gordon [FUSAAL]	X	A
13.	<i>Guignardia loricata</i> (Sawada) W. Yamam & Kaz. Itde [GUIGLA]	X	A
14.	<i>Gymnosporangium</i> spp. [1GYMNG], except for: <i>Gymnosporangium amelanchieris</i> E. Fisch. ex F. Kern, <i>Gymnosporangium atlanticum</i> Guyot & Malenc Bon, <i>Gymnosporangium clavariiformes</i> (Wulfen) DC [GYMNCF], <i>Gymnosporangium confusum</i> Plowr. [GYMNCO], <i>Gymnosporangium cornutum</i> Arthur ex F. Kern [GYMNCR], <i>Gymnosporangium fusisporum</i> E. Fisch., <i>Gymnosporangium gaeumanani</i> H. Zogg, <i>Gymnosporangium gracile</i> Pat., <i>Gymnosporangium minus</i> Crowell, <i>Gymnosporangium orientale</i> P. SYD. SYD., <i>Gymnosporangium sabinae</i> (Dicks.) G. Winter [GYMNFU], <i>Gymnosporangium torminali-juniperini</i> E. Fisch., <i>Gymnosporangium tremelloides</i> R. Hartig [GYMNTR]	X	A
15.	<i>Coniferonia sulphurascens</i> (Pilát) L.W. Zhou & Y.C. Dai [PHELSU]	X	A
16.	<i>Coniferaria weirii</i> (Murrill) L.W. Zhou & Y.C. Dai [INONWE]	X	A
17.	<i>Melampsora farlowii</i> (Arthur) Davis [MELMFA]	X	A
18.	<i>Melampsora medusae</i> f. sp. <i>tremuloidis</i> Shain [MELMMT]	X	A
19.	<i>Mycodiella laricis-leptolepidis</i> (Kaz. It- [MYCOLL] Crous [MYCOLL]	X	A
20.	<i>Phoma Andina</i> Turkensteen [PHOMAN]	X	A
21.	<i>Phyllosticta citricarpa</i> (McAlpine) Van der Aa [GUIGCI]	X	A
22.	<i>Phyllosticta solitaria</i> Ellis Everhart [PHYSSL]	X	A
23.	<i>Phymatotrichopsis omnivora</i> (Duggar) Hennebert [PHMPOM]	X	A
24.	<i>Phytophthora ramorum</i> (non-EU isonalt) Werres, De Cock & Man in 't Veld [PHYTRA]	X	A
25.	<i>Pseudocercospora angolensis</i> (T. Carvalho & O. Mendes) Crous & U. Braun [CERCAN]	X	A
26.	<i>Pseudocercospora pini-densiflorae</i> (Hori & Nambu) Deighton [CERSPD]	X	A
27.	<i>Puccinia pittieriana</i> Hennings [PUCCPT]	X	A
28.	<i>Septoria malagutii</i> E.T. Cline [SEPTLM]	X	A
29.	<i>Sphaerulina musiva</i> (Peck) Quaedv., Verkley & Crous. [MYCOPP]	X	A
30.	<i>Stegophora ulmea</i> (Fr.) SYD. P. SYD [GNOMUL]	X	A
31.	<i>Thecaphora solani</i> Thirumalachar & O'Brien Mordue [THPHSO]	X	A
32.	<i>Tilletia indica</i> Mitra [NEOVIN]	X	A
33.	<i>Venturia nashicola</i> S. Tanaka & S. Yamamoto [VENTNA]	X	A
C. Insects and mites			
1.	<i>Acleris</i> spp. (non-European) [1ACLRG]	X	A
2.	<i>Acrobasis pyrivorella</i> (Matsumura) [NUMOPI]	X	A
3.	<i>Agrilus anxius</i> Gory [AGRLAX]	X	A

4.	<i>Agrilus planipennis</i> Fairmaire [AGRLPL]	X	A
5.	<i>Aleurocanthus citripedus</i> Quaintance & Baker [ALECCT]	X	A
6.	<i>Aleurocanthus woglumi</i> Ashby [ALECWO]	X	A
7.	<i>Amauromyza maculosa</i> (Malloch) [AMAZMA]	X	A
8.	<i>Orientalis</i> Waterhouse anomaly [ANMLOR]	X	A
9.	<i>Anoplophora glabripennis</i> (Motschulsky) [ANOLGL]	X	A
10.	<i>Anthonomus bisignifer</i> Schenkling [ANTHBI]	X	A
11.	<i>Anthonomus eugenii</i> Cano [ANTHEU]	X	A
12.	<i>Anthonomus grandis</i> (Boh.) [ANTHGR]	X	A
13.	<i>Anthonomus quadrigibbus</i> Say [TACYQU]	X	A
14.	<i>Anthonomus signatus</i> Say [ANTHSI]	X	A
15.	<i>Arrhenodes minutus</i> Drury [ARRHMI]	X	A
16.	<i>Aschistonyx eppoi</i> Inouye [ASCXEP]	X	A
17.	<i>Bactericera cockerelli</i> (Sulc.) [PARZCO]	X	A
18.	<i>Bemisia tabaci</i> Genn. (non-European populations) known to be vector of viruses [BEMITA]	X	A
19.	<i>Carposina sasakii</i> Matsumara [CARSSA]	X	A
20.	<i>Choristoneura</i> spp. (non-European) [1CHONG]	X	A
21.	<i>Cicadellidae</i> (non-European) [1CICDF] known to be vector of <i>Xylella fastidiosa</i> , such as: (a) <i>Carneocephala fulgida</i> Nottingham [CARNFU] (b) <i>Draeculacephala Minerva</i> Ball [DRAEMI]; (c) <i>Graphocephala atropunctata</i> (Signoret) [GRCPAT]. (d) <i>Homalodisca vitripennis</i> (Germar) [HOMLTR]	X	A
22.	<i>Conotrachelus nenuphar</i> (Herbst) [CONHNE]	X	A
23.	<i>Dendrolimus sibiricus</i> Chetverikov [DENDSI]	X	A
24.	<i>Diabrotica barberi</i> Smith and Lawrence [DIABLO]	X	A
25.	<i>Diabrotica undecimpunctata howardi</i> Barber [DIABUH]	X	A
26.	<i>Diabrotica undecimpunctata</i> Mannerheim [DIABUN]	X	A
27.	<i>Diabrotica virgifera zea</i> Krysan & Smith [DIABVZ]	X	A
28.	<i>Diaphorina citri</i> Kuwayana [DIAACI]	X	A
29.	<i>Eotetranychus lewisi</i> (McGregor) [EOTELE]	X	A
30.	<i>Grapholita inopinata</i> (Heinrich) [CYDIIN]	X	A
31.	<i>Grapholita packardii</i> Zeller [LASPPA]	X	A
32.	<i>Grapholita prunivora</i> (Walsh) [LASPPR]	X	A
33.	<i>Heliothis zea</i> (Boddie) [HELISE]	X	A
34.	<i>Hishimonus phycitis</i> (Distant) [HISHPH]	X	A
35.	<i>Keiferia lycopersicella</i> (Walsingham) [GNORLY]	X	A
36.	<i>Lopholeucaspis japonica</i> Cockerell [LOPLJA]	X	A
37.	<i>Liriomyza sativae</i> Blanchard [LIRISA]	X	A
38.	<i>Listronotus bonariensis</i> (Kuschel) [HYROBO]	X	A
39.	<i>Margarodes</i> , non-European species [1MARGG], such as: (a) <i>Margarodes prieskaensis</i> (Jakubski) [MARGPR]; (b) <i>Margarodes vitis</i> (Philippi) [MARGVI];	X	A

	(c) <i>Margarodes vredendalensis</i> de Klerk [MARGVR].		
40.	<i>Monochamus</i> spp. (non-European populations) [1MONCG]	X	A
41.	<i>Myndus crudus</i> van Duzee [MYNDCR]	X	A
42.	<i>Naupactus leucoloma</i> Boheman [GRAGLE]	X	A
43.	<i>Neoleucinodes elegantalis</i> (Guenée) [NEOLEL]	X	A
44.	<i>Oemona hirta</i> (Fabricius) [OEMOHI]	X	A
45.	<i>Oligonychus perditus</i> Pritchard and Baker [OLIGPD]	X	A
46.	<i>Pissodes cibriani</i> O'Brien	X	A
47.	<i>Pissodes fasciatus</i> Leconte [PISOFA]	X	A
48.	<i>Pissodes nemrensis</i> Germar [PISONE]	X	A
49.	<i>Pissodes nitidus</i> Roelofs [Pisoni]	X	A
50.	<i>Pissodes punctatus</i> Langor & Zhang [PISOPU]	X	A
51.	<i>Pissodes strobi</i> (Peck) [PISOST]	X	A
52.	<i>Pissodes terminalis</i> Hopping [PISOTE]	X	A
53.	<i>Pissodes yunnanensis</i> Langor & Zhang [PISOYU]	X	A
54.	<i>Pissodes zitacuarensis</i> Sleeper	X	A
55.	<i>Polygraphus proximus</i> Blandford [POLGPR]	X	A
56.	<i>Premnotrypes</i> spp. (non-European) [1PREMG]	X	A
57.	<i>Pseudopityophthorus minutissimus</i> (Zimmermann) [PSDPMI]	X	A
58.	<i>Pseudopityophthorus pruinosus</i> (Eichhoff) [PSDPPR]	X	A
59.	<i>Rhizococcus hibisci</i> Kawai and Takagi [RHIOHI]	X	A
60.	<i>Rhynchophorus palmarum</i> (L.) [RHYCPA]	X	A
61.	<i>Saperda candida</i> Fabricius [SAPECN]	X	A
62.	<i>Scirtothrips aurantii</i> Faure [SCITAU]	X	A
63.	<i>Scirtothrips citri</i> (Moulton) [SCITCI]	X	A
64.	<i>Scirtothrips dorsalis</i> Hood [SCITDO]	X	A
65.	<i>Scolytidae</i> spp. (non-European) [1SCOLF]	X	A
66.	<i>Spodoptera eridania</i> (Cramer) [PRODER]	X	A
67.	<i>Spodoptera frugiperda</i> (Smith) [LAPHFR]	X	A
68.	<i>Spodoptera litura</i> (Fabricius) [PRODLI]	X	A
69.	<i>Tecia solanivora</i> (Povolný) [TECASO]	X	A
70.	<p><i>Tephritidae</i> (non-European) [1TEPHF], such as:</p> <p>(a) <i>Anastrepha fraterculus</i> (Wiedemann) [ANSTFR];</p> <p>(b) <i>Anastrepha ludens</i> (Loew) [ANSTLU];</p> <p>(c) <i>Anastrepha obliqua</i> (Macquart) [ANSTOB];</p> <p>(d) <i>Anastrepha suspensa</i> (Loew) [ANSTSU];</p> <p>(e) <i>Bactrocera dorsalis</i> (Hendel) [DACUDO];</p> <p>(f) <i>Bactrocera tryoni</i> (Froggatt) [DACUTR];</p> <p>(g) <i>Bactrocera tsuneonis</i> (Miyake) [DACUTS];</p> <p>(h) <i>Bactrocera zonata</i> (Saunders) [DACUZO];</p> <p>(i) <i>Dacus ciliatus</i> Loew [DACUCI];</p> <p>(j) <i>Epochra canadensis</i> (Loew) [EPOCCA];</p> <p>(k) <i>Pardalaspis cyaneus</i> Bezzi [CERTCY];</p>	X	A

	(l) <i>Pardalaspis quinaria</i> Bezzi [CERTQU]; (m) <i>Pterandrus rosa</i> (Karsch) [CERTRO]; (n) <i>Rhacochlaena japonica</i> Ito [RHACJA]; (o) <i>Rhagoletis fausta</i> (Osten-Sacken) [RHAGFA]; (p) <i>Rhagoletis indifferens</i> Curran [RHAGIN]; (q) <i>Rhagoletis mendax</i> Curran [RHAGME]; (r) <i>Rhagoletis pomonella</i> (Walsh) [RHAGPO]; (s) <i>Rhagoletis ribicola</i> Dane [RHAGRI]; (t) <i>Rhagoletis suavis</i> (Loew) [RHAGSU]; (u) <i>Zeugodacus cucurbitae</i> (Coquillett) [DACUCU].		
71.	<i>Thaumatotibia leucotreta</i> (Meyrick) [ARGPLE]	X	A
72.	<i>Thrips palmi</i> Karny [THRIPL]	X	A
73.	<i>Unaspis citri</i> (Comstock) [UNASCI]	X	A
	D. Nematodes		
1.	<i>Hirschmanniella</i> spp. Luc & Goodey [1HIRSG], with the exception of: <i>Hirschmanniella behningi</i> (Micoletzky) Luc & Goodey [HIRSBE], <i>Hirschmanniella gracilis</i> (de Man) Luc -Goodey [HIRSGR], <i>Hirschmanniella halophila</i> Sturhan & Hall, <i>Hirschmanniella loofi</i> Sher [HIRSLO] and <i>Hirschmanniella zostericola</i> (Allgén) Luc -Goodey [HIRSZO]	X	A
2.	<i>Longidorus diadecturus</i> Eveleigh and Allen [LONGDI]	X	A
3.	<i>Nacobbus aberrans</i> (Thorne) Thorne and Allen [NACOBAB]	X	A
4.	<i>Xiphinema americanum</i> Cobb <i>sensu stricto</i> [XIPHAA]	X	A
5.	<i>Xiphinema bricolense</i> Ebsary, Vrain & Graham [XIPHBC]	X	A
6.	<i>Xiphinema californicum</i> Lamberti & Bleve-Zacheo [XIPHCA]	X	A
7.	<i>Xiphinema inaequale</i> Khan et Ahmad [XIPHNA]	X	A
8.	<i>Xiphinema intermedium</i> Lamberti & Bleve-Zacheo	X	A
9.	<i>Xiphinema rivesi</i> (non-European populations) Dalmaso [XIPHRI]	X	A
10.	<i>Xiphinema tarjanense</i> Lamberti & Bleve-Zacheo [XIPHTA]	X	A
	E. Parasitic plants		
1.	<i>Arceuthobium</i> spp. [1AREG], except for: <i>Arceuthobium azoricum</i> Wiens & Hawksworth [AREAZ], <i>Arceuthobium gambyi</i> Fridl and <i>Arceuthobium oxycedri</i> DC. M. Bieb. [AREOX]	X	A
	F. Viruses, viroids and phytoplasmas		
1.	<i>Beet curly top virus</i> [BCTV00]	X	A
2.	<i>Black raspberry latent virus</i> [TSVBL0]	X	A
3.	<i>Coconut cadang-cadang viroid</i> [CCCVD0]	X	A

4.	<i>Chrysanthemum stem necrosis virus</i> [CSNV00]	X	A
5.	<i>Citrus tristeza virus</i> (non-EU isolates) [CTV000]	X	A
6.	<i>Citrus leprosis viruses</i> [CILV00]: (a) CiLV-C [CILVC0]; (b) CiLV-C2 [CILVC2]; (c) HGSV-2 [HGSV20] (d) Citrus strain of OFV [OFV00] (citrus strain); (e) CiLV-N <i>sensu novo</i> .	X	A
7.	<i>Palm lethal yellowing phytoplasmas</i> [PHYP56]	X	A
8.	Potato viruses, viroids and phytoplasmas, such as: (a) <i>Andean potato latent virus</i> [APLV00]; (b) <i>Andean potato mottle virus</i> [APMOV0]; (c) <i>Arracacha virus B</i> , oca strain [AVBO00]; (d) <i>Potato black ringspot virus</i> [PBRSV0]; (e) <i>Potato virus T</i> [PVT000]; (f) Non-European isolates of potato viruses A, M, S, V, X and Y (including Y ^o , Y ⁿ and Y ^c) and <i>Potato leafroll virus</i> (PVA000, PVM000, PVS000, PVV000, PVX000, PVY000 (including Y ^o , PVYN00, PVYC00)) and [PLRV00].	X	A
9.	<i>Satsuma dwarf virus</i> [SDV000]	X	A
10.	<i>Tobacco ringspot virus</i> [TRSV00]	X	A
11.	<i>Tomato ringspot virus</i> [TORSV0]	X	A
12.	Viruses, viroids and phytoplasmas of Cydonia Mill., Fragaria L., Malus Mill., Prunus L., Pyrus L., Ribes L., Rubus L. and Vitis L., such as: (a) Blueberry leaf mottle virus [BLMOV0]; (b) Cherry rasp leaf virus [CRLV00]; (c) Peach mosaic virus [PCMV00]; (d) Peach rosette mosaic virus [PRMV00]; (e) American plum line pattern virus [APLPV0]; (f) Raspberry leaf curl virus [RLCV00]; (g) Strawberry witches' broom phytoplasma [SYWB00]; (h) Non-European viruses, viroids and phytoplasmas of Cydonia Mill., Fragaria L., Malus Mill., Prunus L., Pyrus L., Ribes L., Rubus L. and Vitis L.	X	A
13.	Begomoviruses, except for: <i>Abutilon mosaic virus</i> [ABMV00], <i>Sweet potato leaf curl virus</i> [SPLCV0], <i>Tomato leaf curl New Delhi Virus</i> [TOLCND], <i>Tomato yellow leaf curl virus</i> [TYLCV0], <i>Tomato yellow leaf curl Sardinia virus</i> [TYLCSV], <i>Tomato yellow leaf curl Malaga virus</i> [TYLCMA], <i>Tomato yellow leaf curl Axarquia virus</i> [TYLCAX]	X	A
14.	<i>Cowpea mild mottle virus</i> [CPMMV0]	X	A
15.	<i>Lettuce infectious yellows virus</i> [LIYV00]	X	A

16.	<i>Melon yellowing-associated virus</i> [MYAV00]	X	A
17.	<i>Squash vein yellowing virus</i> [SQVYVX]	X	A
18.	<i>Sweet potato chlorotic stunt virus</i> [SPCSV0]	X	A
19.	<i>Sweet potato mild mottle virus</i> [SPMMV0]	X	A
20.	<i>Tomato chocolate virus</i> [TOCHV0]	X	A
21.	<i>Tomato marchitez virus</i> [TOANV0]	X	A
22.	<i>Tomato mild mottle virus</i> [TOMMOV]	X	A
23.	<i>Witches' broom disease of lime phytoplasma</i> [PHYPAF]	X	A

28. Please provide information on Plant health, plant protection products:

a) Placement of plant protection products on the market:

Legislative framework: Law No. 119/2004 on phytosanitary products and fertilizers³⁹⁵

This law establishes the legal basis and state policy in the area of plant protection products and fertilizers, regulates their conditions of research, testing, experimentation and state approval, manufacturing, import, transportation, storage, marketing and harmless use for humans, animals and the environment, reports on state control over compliance with the legislation in force, it also determines the rights and obligations of companies, institutions, organizations and citizens, the powers of the competent authorities in the field, facts constituting infringements, and the responsibility for committing them.

The law partially transposed the provisions of Art. 1 and 3 of Directive 2009/128/EC of the European Parliament and of the European Council of 21 October 2009 establishing a community action framework for the sustainable use of pesticides and Art.3 and 59 of Regulation (EC) No 1107/2009 of the European Parliament and of the European Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Competent authority

Through the Government Decision No. 960/2020 State Service "State Center for Attestation and Approval of Phytosanitary Products and Fertilizers"³⁹⁶ (hereinafter - State Center), in which the Ministry of Agriculture and Food Industry acts as founder, is delegated as the competent authority for the organization, coordination of research-testing-experimentation, approval and registration of plant protection products and fertilizers.

³⁹⁵ Law No. 119/2004 on phytosanitary products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

³⁹⁶ Government Decision No. 960/2020 State Service "State Center for Attestation and Approval of Phytosanitary Products and Fertilizers", available in Romanian at: https://www.legis.md/search/getResults?doc_id=124941&lang=en

The State Center has the following functions:

- creation of the range of phytosanitary products and fertilizers for use in agriculture, forestry and municipal husbandry, as well as for the protection of stored products, in order to ensure a high level of protection of human and animal health, protect the environment and ensure the competitiveness of agriculture;
- organization, coordination and control of research-testing-experimentation of plant protection products and fertilizers in institutions, enterprises, academic and professional organizations, in order to approve and/or extend the scope of application;
- examination of requests of individuals and legal entities from the country and abroad regarding the state research-testing-experimentation of new phytosanitary products and fertilizers;
- performing the initial assessment of the product file presented for state approval / re- approval;
- requesting samples of products for conducting state tests and transmitting them to institutions, enterprises and academic and profile organizations for conducting state research-testing-experimentation;
- the establishment, in agreement with the Interdepartmental Republican Council for approval of plant protection products and fertilizers, of academic institutions, enterprises and organizations which will carry out research-testing-experimentation of plant protection products and fertilizers, manufactured locally or imported;
- organization of state tests of new products manufactured in the country or abroad, within institutions, enterprises, academic and line organizations (agricultural, public health, forestry, fisheries, environment, municipal husbandry);
- issuance of the approval certificate for the product, according to the model established by the Government within 5 working days from the date of fulfilment of the obligations assumed by the applicant;
- coordinating the packaging labels of plant protection products and fertilizers in order to match them with the information in the dossier;
- carrying out laboratory tests on the quality control of approved plant protection products;
- determination of pesticide residues in plants, soil and food of plant origin;
- carrying out certification services for plant protection products and fertilizers;
- updating, posting on the official website of the State Center and publication of the State Register of phytosanitary products and fertilizers allowed for use in the Republic of Moldova (hereinafter - State Register) and its supplements;
- other functions assigned by the regulatory framework and by the founder.

The procedure for approval of PPP is provided in the Government Decision no. 1307/2005 on the approval of the Regulation on state certification and approval of plant protection products and fertilizers for use in agriculture and forestry.³⁹⁷

The regulation lays down the procedure for the state attestation and approval of plant protection products and fertilizers.

The steps for state certification and approval of plant protection products (PPP) are as follows:

1. State research-testing-experimentation of PPP in field conditions in the pedoclimatic zones of the Republic of Moldova.

State research-testing-experimenting is carried out by specialized scientific research institutions within the Academy of Sciences of Moldova, Ministry of Agriculture and Food Industry, and Ministry of Environment and the Ministry of Health.

State research-testing-experimentation is carried out on the basis of methodological guidelines approved by the Interdepartmental Republican Council for the Approval of Plant Protection Products and Fertilizers at its meeting on February 20, 2002. EPPO standards are not applied for testing plant protection products according to GEP.

Phytosanitary products containing a new active substance are subject to state research-testing-experimentation, depending on climatic conditions for 2-3 cycles of vegetation, those whose active substance is known in other preparatory forms - for 1 -2 vegetation cycles.

2. Submission of the complete toxicological dossier of the plant protection product containing:

- general information;
- product information;
- product usage information;
- toxicological evaluation;
- hygiene evaluation;
- action on environmental objects;
- physical and chemical properties;
- information on the active substance;
- destination of product;
- protection measures.
- product use recommendations;

³⁹⁷ Government Decision no. 1307/2005 on the approval of the Regulation on state certification and approval of plant protection products and fertilizers for use in agriculture and forestry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125303&lang=ro

- methods for the determination of residues of the plant protection product proposed for approval in agricultural crops (food products) and environmental bodies (water, soil, air);
- preliminary instructions for use, transportation and storage of the product, personal protection measures, methods of diagnosis in case of intoxication (SDS Safety Data Sheet).
- the label, in Romanian or Romanian and Russian, according to the model approved by the State Center.

3. Assessment of the toxicological file by the Ministry of Health and the Ministry of Environment for sanitary and environmental approval.

4. Assessment of the results of research-testing-state experiments of the product in order to determine the biological efficiency by the State Center.

5. Presentation of the results of the above-mentioned assessment for examination to the Interdepartmental Republican Council for the approval of phytosanitary products and fertilizers (IRC) according to the competencies.

The evaluation of active substances is not performed in the Republic of Moldova. The list of active substances, approved by the European Union is unconditionally recognized by the IRC in the process of approval of plant protection products.

IRC consists of 11 members, representatives of the Academy of Sciences of Moldova, Ministry of Agriculture and Food Industry, Ministry of Environment, Ministry of Health, National Food Safety Agency, research and higher education institutions.

The core competencies of IRC are:

- examination, assessment approval and submission of proposals to improve the regulatory framework governing the area of research-testing-experimentation and approval of plant protection products and fertilizers;
- examination of reports of institutions on the results of state research-testing-experimentation of plant protection products and fertilizers, as well as of materials related to products submitted for approval;
- examination and coordination of the state research-testing-experimentation program until April 30 of the reporting year. The program coordinated with IRC is approved by the State Center;
- examination of organizational, scientific-methodological and practical issues for the approval of plant protection products and fertilizers;
- decision making:
 - approving or refusing approval, re-approval, extension of use of plant protection products and fertilizers;

- prohibiting the use of products in case of identification/finding of harmful particles which may cause effects on human health and the environment, on the basis of technical and scientific information.

6. Registration in the State Register of phytosanitary products and fertilizers allowed for use in the Republic of Moldova and issuance of the approval certificate.

Based on recommendations of experts from the EU Member States within the Twinning Support Project for Moldova in the area of food safety norms and standards for plant products D10/ENP-PCA/AG/06 and in line with Government Decision No. 710/2015 () the procedure for the approval of plant protection products, fertilizers and fertilizers marked "EC Fertilizer" by the procedure for the recognition of authorizations granted by a Member State of the European Union was developed and approved.

The procedure consists in the recognition and use of assessments carried out by one of the Member States of the European Union in relation to the product containing indices identical to the indices of the product submitted for approval in the Republic of Moldova, provided that:

- the product contains an active substance approved in accordance with European standards;
- authorization to be issued in accordance with the uniform principles of evaluation and authorization of plant protection products of the European Union.

The applicant for the approval of plant protection products in accordance with the recognition procedure may be the holder of the authorization, who shall submit:

- the application, according to the form;
- legalized copy of the authorization granted by one of the Member States of the European Union and its legalized translation into Romanian;
- the draft label for the product proposed for approval in Romanian and the copy of the original label with translation in Romanian;
- an affidavit in Romanian, confirming that the product requested for approval by the recognition procedure is the same as the one authorized in one of the Member States of the European Union;
- assessment report of the Member State of the European Union, which will contain information on the assessment and reference decisions on the plant protection product, including information on risk assessment for operators, workers and consumers.

The placing on the market of plant protection products and fertilizers involves several stages: import / manufacturing, transport, storage, marketing and application of the nominated products.



Under Art. 151 of Law No. 119/2004 on phytosanitary products and fertilizers and in accordance with the provisions of Law No. 131/2012 on state control on entrepreneurial activity³⁹⁸ and SP (D03 / 2C) -05/01 Specific procedure regarding the issuance of the authorization operating the storage of phytosanitary products and fertilizers, the agency officially registers in the Register of specialized storage units for fertilizers and plant protection products and issues Extracts following the Notifications submitted by economic operators.

PPP Storage and Marketing is carried out under Law No. 119/2004 and Government Decision No. 1045/2005 on the approval of the Regulation on the import, storage, marketing and use of PPP³⁹⁹, as well as the Regulation on the management of plant protection products and of fertilizers in the national economy, approved by the Order of the Ministry of Agriculture and Food Industry No. 231/2003,⁴⁰⁰ by economic operators, including owners of specialized shops who sell PPP and who must have an:

- extract issued in accordance with the law;
- specialist with studies in the field of plant protection or other agronomic profile;
- sale-purchase contract
- quality certificate from the manufacturer;
- PPP import, trade and stock registry.

Under Art. 22 of Law No. 119/2004 on phytosanitary products and fertilizers, Art.23 of Law No. 131/2012 on state control of entrepreneurial activity p. 73 of Government Decision No. 1045/2005, p. 13 of the Regulation on the organization and functioning of ANSA approved by Government Decision No. 600/2018⁴⁰¹ is approved the Program for monitoring the quality of phytosanitary products carried

³⁹⁸ Law No. 131/2012 on state control over entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130023&lang=ro

³⁹⁹ Government Decision No. 1045/2005 on the approval of the Regulation on the import, storage, marketing and use of PPP, available in Romanian at: https://www.legis.md/search/getResults?doc_id=113258&lang=en

⁴⁰⁰ Regulation no. 231/2003 on the management of plant protection products and fertilizers in the national economy, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=37349&lang=ro

⁴⁰¹ Government Decision No. 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

out by phytosanitary inspectors according to the specific procedure for sampling of phytosanitary use products Code: PS(D 03/2C)-04/01.

According to provisions of art. 16 of Law No. 119/2004 on phytosanitary products and fertilizers, phytosanitary products and counterfeit fertilizers put on the domestic market are returned to the manufacturer or are subject to subsequent confiscation and liquidation.

In case of non-compliance with Law No. 119/2004 on phytosanitary products and fertilizers and other legislative acts on activities with phytosanitary products and fertilizers, the specialized warehouse (storage) is deleted from the Register of specialized warehouses for fertilizers and phytosanitary products.

Agricultural raw materials, food products and plant-based animal feed, made available on the market, in the process of production, transport or storage of which phytosanitary products and / or fertilizers have been used, must comply with sanitary regulations. Certification of compliance of plant-based agricultural raw materials, including fresh vegetables and fruits, and plant-based feed with health regulations shall be carried out on the basis of tests carried out by an accredited laboratory. At the request of the economic operator, the correspondence can be additionally attested by the inoffensiveness certificate provided in art. 23 (1) of Law No. 119/2004 regarding phytosanitary products and fertilizers.

b) Setting up and controls of maximum residue levels:

According to provisions of art. 25 let. 1) of Law No. 306/2018 on food safety⁴⁰², the competence of the Ministry of Health shall be with regard to establishing the content of pesticide residues and contaminants in food products with an impact on public health.

The establishment and control of maximum residue levels in food products are within the competence of the Ministry of Health and are regulated by the provisions of Government Decision No. 1191/2010 on the approval of the Sanitary Regulation on maximum permitted residue limits for plant protection products in or on food and feed of plant and animal origin for animals⁴⁰³.

The Government Decision partially transposes Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

The mentioned regulation establishes the list of products and groups of products to which maximum permissible residue limits (LMAs) apply. That list shall cover

⁴⁰² Law No. 306/2018 on food safety, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122838&lang=ro

⁴⁰³ Government Decision No. 1191/2010, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=114320&lang=ro

all products for which it is appropriate to apply LMAs, taking into account its place in the diet of consumers or in trade. The regulation is mandatory for all economic operators. The responsibility for the fulfilment and observance of residues of phytosanitary products in the food of vegetal and animal origin, as well as in the animal feed lies with the economic operators who carry out works with the phytosanitary products at all stages of their circuit (storage, transport, marketing, use).

In order to ensure compliance with that Regulation, official controls on residues of plant protection products shall be carried out, consisting of the taking samples, their subsequent submission for analyses and the identification of pesticides existing therein and the levels of residues. The National Food Safety Agency establishes, in agreement with the Ministry of Health, a national program for the control of residues of plant protection products in or on food products, which is updated annually.

At national level, maximum levels of residues in plants, food products are established and controlled by:

- Government Decision No. 1191/2010 on the Health Regulation on maximum permitted residue limits for plant protection products in or on food and feed of plant and animal origin partially transposing Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels for pesticide residues in or on food and feed of plant and animal origin for animals;
- Government Decision No. 1004/2010 on the sampling methods for the official control of pesticide residues on and in plants and products of plant and animal origin⁴⁰⁴ has been approved. The normative document transposes Commission Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues on and in products of plant and animal origin;
- Annex no. 1 to Government Decision No. 686/2012 on the approval of certain methods of analysis for the control of feed.⁴⁰⁵
- Annual national monitoring and surveillance programs in the field of safety and quality of food, feed and veterinary medicinal products, plant health and the quality of plant protection products. The program also monitors/supervises compliance with maximum pesticide residue levels in food of plant origin, both in-house and imported;
- Provisions of the general procedure ANSA PG-12_01 *Actions taken in the case of non-compliant foodstuffs*, according to which food and feed exceeding the maximum residue levels of plant protection products may

⁴⁰⁴ Government Decision No. 1004/2010 the sampling methods for the official control of pesticide residues on and in plants and products of plant and animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125571&lang=ro

⁴⁰⁵ Government Decision No. 686/2012 on the approval of certain methods of analysis for the control of feed, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103175&lang=ro

not be transformed and/or mixed with other similar products or not, with a view to being placed on the market as food or feed or used as feed. Thus:

I) in case of food and feed, originating from the Republic of Moldova, the following shall take place:

- suspending the placement of that food or feed on the market;
- suspending the use of the food or feed in question;
- monitoring and, as appropriate, recovery, withdrawal and/or destruction of feeding stuffs or foodstuffs;
- authorizing the use of the feed or food for purposes other than those for which it was originally intended;

II) in case of imported food and feed, there shall be:

- suspension of the import of food or feed concerned from the state of origin of the product or from a region thereof and, where appropriate, from the state of transit;
- establishment of special import measures (where food products in which excess pesticide residue levels have been detected, agency inspectors carry out improved border controls, which target the establishment of origin/supplier in the country concerned and the type of product concerned. The following shipments of this type of food coming from the company of origin/supplier concerned are subject to full controls including sampling with laboratory analysis carried out for the risk that triggered the program of consolidated checks. Consolidated checks shall be concluded after obtaining three consecutive results).

29. Please provide information on Quality of seeds and plant propagating material regarding the marketing of seed and propagating material of agricultural crops and vegetables, vine, forestry, ornamentals and fruit plants:

- a) Registration of varieties, catalogues;**
- b) Seed certification;**
- c) Approval of propagating material.**

The overall system of seed production in the Republic of Moldova consists of a number of state and private republican organizations, which generally address the problems regarding their production, quality control and marketing (Annexes 1 and 2).

The functions of the system organisations are different, the Ministry of Agriculture and Food Industry (MAFI) and line research institutions develop and approve the seed production system and schemes; the breeders of seed varieties and hybrids produce in primary links through state applied research programmes; the State Committee for Testing Plant Varieties tests the plant varieties and hybrids and evaluates the seed productive qualities, the economic operators registered for seed production and marketing; the National Food Safety Agency (Ro: ANSA) performs field inspections and approves seed sowing, and carries out the seed

quality control together with the Public Institution "Central Phytosanitary Laboratory" .

According to this system, the seed production involves the creation of varieties, their storage, marketing and use.

a) Registration of varieties, catalogues

Based on Art. 5 of Law No. 39/2008 on the protection of plant varieties⁴⁰⁶, the state policy on the protection of the breeder's right to plant varieties is promoted by 2 administrative bodies: the State Committee for Testing Plant Varieties (hereinafter referred to as the State Committee) and the State Agency on Intellectual Property.

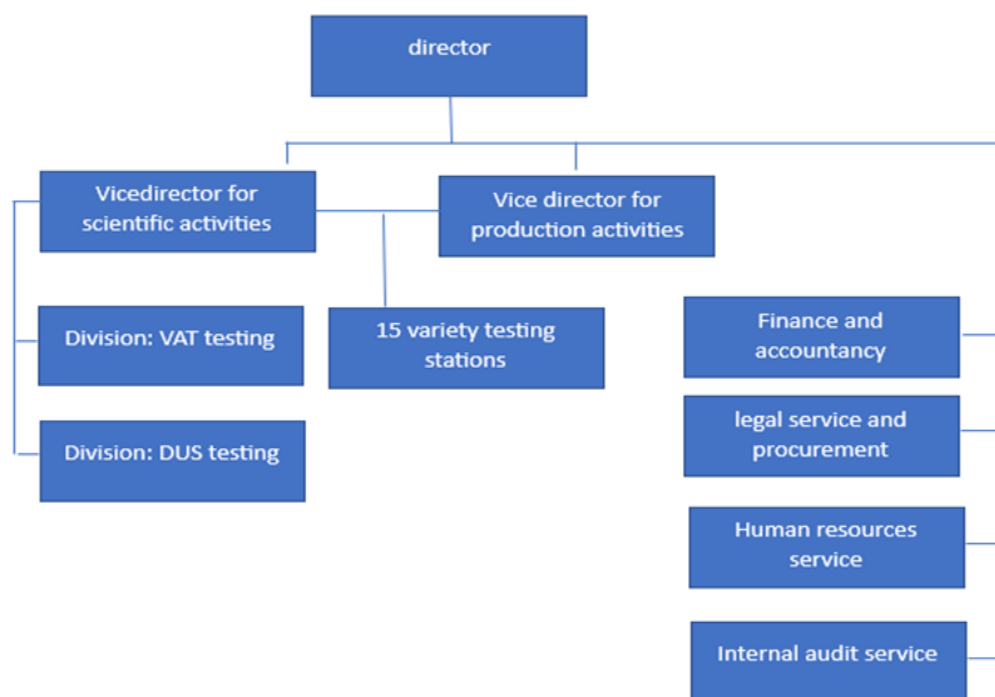
The State Committee is a public authority empowered to carry out official testing of plant varieties and is subordinated to the MAFI.

1. Administrative organisation and structure

The State Committee organisation chart includes: director; 2 deputy directors (one for scientific activity and the other for production activity), 3 directorates (VCU Testing and variety registration, DUS Testing and Financial accounting); 15 variety testing stations located in different pedo-climatic areas; and 3 services (legal and procurement; human resources; and internal audit). Out of the testing stations, 4 are specialised in testing plant varieties for field crops; 2 – in testing the varieties of fruit crops and 3 – in testing the varieties of vegetables.

⁴⁰⁶ Law No. 39/2008 on the protection of plant varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93465&lang=ro

Organisation chart of the State Committee for Testing Plant Varieties.



The State Committee operates in 2 directions:

- testing, selection and admission of new plant varieties in the agricultural production process with their registration in the plant variety Catalogue (VCU test); and
- technical examination of new plant varieties (testing the distinctness, uniformity and stability of the variety - DUS) to ensure the protection of the breeder's right in the process of agricultural exploitation of the variety on the territory of the Republic of Moldova.

Core Activities of VCU (Value for Cultivation and Use) Testing Directorate.

- formal examination of applications for variety testing;
- planning the tests, collecting the samples of seeds/seedlings;
- coordination with the heads of variety testing stations;
- monitoring the testing process on site;
- examination and analysis of experimental data;
- drafting the order on registration of new varieties in the Catalogue and development of the new edition of the Catalogue of Plant Varieties;
- improving theoretical and practical knowledge.

Core Activities of DUS Testing Directorate:

- registration and formal examination of applications;
- planning the technical examination work;
- selection of reference varieties for inclusion in the examination process;
- monitoring the examination of plant varieties and review of DUS data;
- development of the report on technical examination of the variety;
- communication with the applicants on the protection of the breeder's right;
- development of the national guide on the examination of varieties for some plant species;
- monitoring of legislative acts and recommendations of UPOV, CPVO in the field of protection of the breeder's right for the plant variety;
- schooling and development of recommendations on the variety examining practice.

Basic activities of variety testing stations:

- coordination of testing works with lead experts in the area of testing plant varieties;
- fulfilment of the plant variety test plan (VCU test) and technical examination of varieties with the DUS test;
- ensuring compliance with the technology of crops cultivation;
- maintenance of agricultural machinery and equipment working condition;
- maintenance of plants in experimental nurseries during their growing season;
- loss-free harvesting and storage of agricultural production.

1. Resources (human)

The list of tenured employees constitutes 80 units (Government Decision no.1031 of December 29, 2011 on the approval of the staff limit of public services created under the MAFI). To date, 75 out of 80 positions are active, and only 5 are vacant (3 units of lead experts, auditor and lead engineer).

The staff members are paid in accordance with Law No. 270/2018 on the unitary salary system in the budget sector⁴⁰⁷ and Government Decision No. 1231/2018 for the implementation of Law 270/2018⁴⁰⁸.

⁴⁰⁷ Law No. 270/2018 on the unitary salary system in the budget sector, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129289&lang=ro

⁴⁰⁸ Government Decision No. 1231/2018 for the implementation of Law 270/2018, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=126510&lang=ro

2. Current and planned structure

On October 28, 1998 the Republic of Moldova joined the UPOV Convention on the protection of intellectual property for plant varieties (Parliament Decision No. 1355 dated October 22, 1997⁴⁰⁹). As a member of the UPOV, the State Committee is the authority that:

- at the national level promotes the UPOV Policy in the field of intellectual property for plant varieties in the Republic of Moldova;

The State Committee lead experts obtained certification in the field of intellectual property protection for plant varieties during the remote training DL205 and DL305 courses, organised by UPOV; participated in a technical assistance and information exchange training (TAIEX) organized by UPOV; one expert received training on preparing and submitting information for the PLUTO database, and some lead experts and examiners from the variety testing stations received training on examining the distinctness, uniformity and stability of plant varieties (DUS) in Korea, Poland, and the United Kingdom.

3. Legal framework of the State Committee work

The State Committee works pursuant to:

- the Regulation on testing and acceptance of varieties in the Catalogue of plant varieties approved by Government Decision No. 43 dated January 15, 2013⁴¹⁰;
- Law No. 39/2008 on the protection of plant varieties;
- Law No. 68 /2013 on seeds⁴¹¹;
- Law No. 728/1996 on fruit growing⁴¹²;
- Law No. 57/2006 of vine and wine⁴¹³;
- Law No. 658/1999 on walnut crops⁴¹⁴.

4. Registration of plant varieties in the Catalogue

⁴⁰⁹ Parliament Decision No. 1355/1997 for the ratification of the International Convention for the Protection of New Varieties of Plants: https://www.legis.md/cautare/getResults?doc_id=61183&lang=ro

⁴¹⁰ Government Decision No. 43/2013 approving the Regulation on testing and acceptance of varieties in the Catalogue of plant varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114401&lang=ro

⁴¹¹ Law No. 68/2013 on seeds, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106315&lang=ro

⁴¹² Law No. 728/1996 on fruit growing, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118834&lang=ro

⁴¹³ Law No. 57/2006 on vine and wine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=25282&lang=ro

⁴¹⁴ Law No. 658/1999 on walnut crops, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108460&lang=ro

The procedure for registering new plant varieties in the Catalogue is compliant with the international requirements for testing and admission of plant varieties.

In this connection, the procedure begins with the receipt and registration of the Application (using the template approved by the UPOV), in which the Applicant requests the registration of the variety in the Catalogue. The State Committee issues a certificate for the plant variety. Upon request, the Applicant submits the technical questionnaire of the variety, the detailed characteristics of the cultural value and use of the variety (VCU), its distinctness. The State Committee concludes a Contract on testing the variety in competition testing (VCU) with the Applicant, signed by both parties.

Receiving, registering and examining of the Application. When registering the Application, the lead expert reviews it, requests seeds/seedlings from the Applicant, selects the varieties registered as a witness and includes the variety in the test. After the receipt and registration of applications, the lead expert for each group of varieties/crop determines the test location, taking into account the maturity group and the destination of the variety in agricultural production; receives the seeds, develops the randomised scheme of placement of varieties in the test set, coordinates the location of test sites with the test station professionals, the list of characteristics to be evaluated (Art. 27, Art. 30 of the Regulation on testing and acceptance of varieties in the Catalogue of plant varieties, adopted by Government Decision No. 43/2013), the peculiarities regarding the foundation and maintenance of experiences and training of professionals.

Determination of variety test location (Art. 28 of Regulation No. 43/2013). The field crop varieties are tested in 5 testing stations (one in the North, 2 in the Centre and 2 in the South), the vegetable varieties are tested in 3 stations (two in the North and one in the South), the fruit tree varieties are tested at least in 2 test stations (one in the North and one in the South), and the vine varieties are tested in at least one testing station.

For perennial crops (fruit trees, vines, etc.) and some vegetable species, the State Committee accepts the variety testing outside its testing stations, such as testing under production conditions (Art. 34 and Art. 35 of Regulation No. 43/2013), located on the territory of the Republic of Moldova.

Duration of testing of new varieties. According to Art. 29 of Regulation No. 43/2013, the variety shall be tested alongside the best performing registered varieties, selected by the Committee, for three years, starting with the year when the plants bear fruit.

Maintenance and monitoring of testing. During the vegetation of plants, the lead expert and the methodical Commission of the State Committee (at least 2 field visits) monitor the compliance with the methodology of test location, assessment of the expected characteristics and development of plants in all test stations. Should any deficiencies be detected related to plant development, the necessary

measures are taken to improve the situation or to discard the test in case of sustainable drought, severe hail and other unfavourable natural phenomena.

Receiving and analysing the testing data. The lead expert receives and compares the testing data with the standard registered varieties. Based on the testing data, he/she makes decisions on the promotion of the variety in the next year of testing or registration of the variety in the Catalogue. The test results shall be submitted to the Applicant for information.

Decisions on the promotion of the variety in the next year of testing (art.25 of Regulation No. 43/2013)

The Applicant shall maintain the right of withdrawal of the variety from the testing as early as the first or second year of testing if the variety is presented with values lower than the standard varieties. The cultural and utilisation value of the variety is recognised satisfactory if, in comparison with the standard registered variety, its qualities, taken as a whole, offered at least in terms of production, in any area considered, has a clear improvement either in cultivation or in the use of the crop or the products thereof. Wherever, if higher features are present, lower individual features may not be taken into account. Based on the testing data, the lead expert selects and presents the list of varieties for issuing the order of the State Committee to register the varieties in the Catalogue of plant varieties.

Decisions on the registration of the variety in the Catalogue of plant varieties (art.29 of No. 43/2013).

Depending on the results the variety presents relative to the standard registered varieties in the Catalogue of plant varieties⁴¹⁵, there are registered varieties that show significant performance compared to the standard registered varieties in all test locations for two years of testing, and local varieties – with a satisfactory presentation throughout the 3-year test cycle. Varieties registered in the EU Catalogue shall be registered in the National Catalogue if the variety shows significant performance in a single test year. The State Committee maintains the right to reject the variety from registration only based on the results of all years, in all test locations.

In this regard, the State Committee issues 2 orders for registration of varieties in the Catalogue of plant varieties, the first in September – for crops with autumn sowing and the second in December – for all other plant species under testing. On the basis of these State Committee orders, the lead experts draw up the new edition of the Catalogue, which is published in the first months of the following year.

⁴¹⁵ More information about the State Commission for Plant Variety Testing can be found on the website: www.cstsp.md

When registering the variety in the Catalogue, the author(s) issues the Certificate for the plant variety with a validity of 10 years for field and vegetable crops and 15 years – for vines, fruit trees and other species of fruit plants.

Catalogue of plant varieties (Ch. III of Regulation No. 43/2013). Acceptance and registration of new plant varieties in the Catalogue is based on the testing results in all years and all test locations throughout the Republic of Moldova.

Revocation of registration of the variety in the Catalogue. This is done at the request of the person/persons responsible for the variety or if, upon examination, it is proved that the variety does not meet the conditions of distinctiveness, uniformity and stability, does not possess the cultural and/or use value.

Removal of varieties from the Catalogue. (Ch. VIII of Regulation No. 43/2013). It takes place when a request has been submitted to this effect; finding that the variety no longer meets the DUS conditions; the Application contained false data; there is no longer a person in charge of maintaining the variety; it is proved that the variety is known under a different name; if the re-listing of the variety in the Catalogue is no longer requested; if certified seeds are no longer produced. When making the decision on the removal of the variety, the validity of the marketing of seeds/seedlings is 2 years from the date of removal.

Maintenance of varieties in the Catalogue. The varieties of field crops, vegetables, annual ornamental plants are maintained in the Catalogue for 10 years, and the varieties of vines, fruit tree species and fruit shrubs – for 15 years. However, the varieties with the expired term of protection are kept in the Catalogue as long as they are competitive in the domestic market and there is a person responsible for maintaining them.

Re-registration of varieties in the Catalogue (Ch. IX of Regulation No. 43/2013). It takes place at the request of producer associations; it is distinct, uniform and stable; has a person responsible for maintaining the variety. The re-registration of the variety is carried out on the basis of a DUS test, carried out at the request of the Applicant 2 years before the expiration of the term of protection of the variety and in which it is found that the characteristics are identical to those at the time of registration of the variety in the Catalogue. The duration of re-registration of the variety is 5 years.

Publication of the Catalogue. The Catalogue is displayed on the official website of the State Committee in its latest edition⁴¹⁶. The archive of the State Committee maintains all editions of the Catalogue of plant varieties, since 1991.

It should be mentioned that the import of seeds of varieties are recorded in the Catalogue of varieties of plants of the Republic of Moldova, as well as those recorded in the EU Common Catalogue of Varieties of Agricultural Plant Species,

⁴¹⁶ More information about the State Commission for Plant Variety Testing can be found on the website: www.cstsp.md

the EU Catalogue of Varieties of Vegetable Species, the EU Common Catalogue of Varieties of Vine and/or in the Fruit Reproductive Material Information System (FRUMATIS). Therefore, the EU common catalogues mentioned above are recognized in the Republic of Moldova.

At the same time, in the area of DUS testing, the State Committee performs only the technical part of the activities related to the granting of the protected patent/variety title from the reception of the application for the variety examination until the issuance of the Technical Report of Examination and the Description of the variety to AGEPI.

In this respect, the State Committee:

- receives from AGEPI the Applicant's request regarding the protection of the breeder's right for the plant variety, registers and examines it;
- selects the reference varieties from its reference collection, which will allow more accurate description of the degree of expression of the characteristics;
- selects the test guide on the evaluation of the characteristics (one approved by UPOV or CPVO), coordinates the location of the test and the person responsible for conducting the test;
- requests seeds/seedlings from the Applicant;
- develops the log of registration of observations during the variety examination of the;
- coordinates the peculiarities of the installation and maintenance of the nursery where the varieties will be examined;
- monitors the development of plants in nurseries and compliance with the methodology for examining the characteristics;
- provides examination assistance;
- receives observations data, analyses them and makes decisions on the uniformity and stability of the variety;
- submits the results of the examination for confirmation to the Applicant;
- based on the description confirmed by the breeder, the State Committee takes the decision on the distinctiveness of the variety; if the variety exhibits at least one distinct characteristic from a similar variety, already protected, the Committee shall draw up the Technical Report and the official Description of the variety and submit it to AGEPI.

As for the DUS test guide, the State Committee shall develop a national guide in case one like this is missing in the UPOV or CPVO library.

B) Seed Certification

The Republic of Moldova has been a member of the International Union for the Protection of New Varieties of Plants (UPOV) since 1998, and is a member of the OECD Seed Schemes and the International Association for Seed Testing (IAST) since 2008.

Currently, the field of production, processing, quality control and marketing of seed and planting material is regulated by the following legislative and normative acts:

Laws:

- Law No. 68/2013 on seeds;
- Law No. 39/2008 on the protection of plant varieties;
- Law No. 57/2006 on vine and wine;
- Law No. 658/1999 on walnut crops;
- Law No. 728 /1996 on fruit growing;
- Law No. 228/2010 on plant protection and phytosanitary quarantine.⁴¹⁷
- The Administrative Offence Code (in the field of seed and planting material).⁴¹⁸

Government Decisions:

- Government Decision No. 600/2018 on the organisation and functioning of the National Food Safety Agency;⁴¹⁹
- Government Decision No. 600/2014 on the quality and marketing of seeds of cereal crops;⁴²⁰
- Government Decision No. 43/2013 on the testing and acceptance of varieties in the Catalogue of plant varieties of the Republic of Moldova;⁴²¹
- Government Decision No. 415/2013 on the production, control, certification and marketing of propagating and planting material;
- Government Decision No. 713/2013 on the production and marketing of seeds and vegetable planting material;⁴²²

⁴¹⁷ Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

⁴¹⁸ The Administrative Offence Code (in the field of seed and planting material), available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130832&lang=ro

⁴¹⁹ Government Decision No. 600/2018 on the organisation and functioning of the National Food Safety Agency, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127663&lang=ro

⁴²⁰ Government Decision No. 600/2014 on the quality and marketing of seeds of cereal crops, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114716&lang=ro

⁴²¹ Government Decision No. 43/2013 on the testing and acceptance of varieties in the Catalogue of plant varieties of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114401&lang=ro

⁴²² Government Decision No. 713/2013 on the production and marketing of seeds and vegetable planting material, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114415&lang=ro

- Government Decision No. 598/2012 on the quality and placement on the market of propagating material for ornamental plants;⁴²³
- Government Decision No. 915/2011 on the quality and marketing of seeds of oil and fibre plants;⁴²⁴
- Government Decision No. 836/2011 on the quality and marketing of fodder plant seeds⁴²⁵;
- Government Decision No. 189/2010 on minimum marketing requirements for seed potatoes;⁴²⁶
- Government Decision No. 418 dated July 9, 2009 on the production, control, certification and marketing of propagating and planting material;⁴²⁷
- Government Decision No. 1211 dated October 29, 2008 on technical regulations for maize and sorghum seed material.⁴²⁸

ANSA has developed operational and specific procedures to implement the provisions of normative acts on practical completion and extension of the main provisions of Law No. 68/2013 on seeds. In order to facilitate the activities carried out by inspectors trained in the field of seed control ANSA has established single requirements for carrying out inspections and completing the related documents.

Procedures⁴²⁹:

- PO-01/03 of August 4, 2014 "Certification of fruit planting material";
- PS-(D03/03A) – 01/01 of September 26, 2014 "Reception, verification and registration of seed multiplication declarations";
- PS - (D03/03A) -01/02 of September 29, 2014 "Field inspection in seed production sectors and issuance of field inspection Document";
- PS - (D03/03A) -01/01 of October 27, 2014 "Certification of vegetable seedlings";
- PS - (PS/FS-MS01/01) of November 12, 2017 "Certification of ornamental plant planting material";

⁴²³ Government Decision No. 598/2012 on the quality and placement on the market of propagating material for ornamental plants, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=114383&lang=ro

⁴²⁴ Government Decision No. 915/2011 on the quality and marketing of seeds of oil and fibre plants, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114353&lang=ro

⁴²⁵ Government Decision No. 836/2011 on the quality and marketing of fodder plant seeds, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114351&lang=ro

⁴²⁶ Government Decision No. 189/2010 on minimum marketing requirements for seed potatoes, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=90699&lang=ro

⁴²⁷ Government Decision No. 418/2009 on the production, control, certification and marketing of propagating and planting material, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=114870&lang=ro

⁴²⁸ Government Decision No. 1211/2008 on technical regulations for maize and sorghum seed material, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114246&lang=ro

⁴²⁹ The related procedures are available on the ANSA website, available in Romanian at:

[https://ansa.gov.md/ro/content/direc%C8%9Bia-semin%C8%9Be-%C8%99i-material-s%C4%83ditor#tab-0-](https://ansa.gov.md/ro/content/direc%C8%9Bia-semin%C8%9Be-%C8%99i-material-s%C4%83ditor#tab-0-1)

- PS - (03/03A) -01/04 of March 30, 2015 "Specific procedure for post-control seed sampling";
- (PS/FS-MSD-04/01) of June 13, 2018 "Registration of economic operators regarding the production and/or processing and/or marketing of seeds";
- PS-(PS/FS-MSR-01/01) "Issue of seed quality certificate";
- (PS/FS-MSD-02/01 of February 27, 2020 "Admission of import of seeds and/or planting material of varieties not listed in the Catalogue of plant varieties of the Republic of Moldova";
- PO-(PS/FS-MS-01/01) of February 2021 "Issuance of export quality certificate for propagating, planting, fruit growing, viticulture, berry-bearing and decorative material";
- PS - (PS/FS-MSR-02/01) of February 2021 "Issuance of quality certificate on export of seeds";
- PO - (D03/03B)-02/02 of October 28, 2015 "Certification of wine planting material".

Seed control, issuance of certificates and supervision of registered economic operators is carried out by the National Food Safety Agency (ANSA) in accordance with the provisions of Law No. 68/2013 on seeds and includes the following steps:

- verification of the authenticity of the variety and determination of the biological category;
- checking the location of seed batches;
- control of the application of technologies specific to different crops and varieties;
- verification of biological purity;
- control of hybridisation batches;
- the assessment of the weeds of seed lots;
- the control and preparation of documents and post-control of seed from seed crops.

ANSA may issue, at the request of economic operators, the following certificates:

- seed quality certificate/seed analysis report for internal use;
- certificate of biological value.

The term for issuing the documents referred to at Para a) is 7-21 working days, depending on the species tested, and the period for issuing the certificate referred to at Para b) is one working day from the date of application submission.

(3) ANSA shall determine the seed quality at the request of the economic operator, upon the submission of the:

- laboratory sample taken by the state inspector in accordance with the national or international requirements;
- minutes of sampling, drawn up by the state inspector and signed by both parties;
- field inspection document or the quality certificate previously issued;
- documents certifying the origin of imported seeds;

(4) The following categories of seeds are subject to seed control and certification under the actual law:

- pre-basic seeds;
- basic seeds;
- certified seeds;
- commercial seeds of oil and fodder plants.

(5) The certificate for the imported propagating and planting material may be issued by the territorial subdivision of the National Food Safety Agency, at the request of the economic operator.

(6) The term of validity, as well as the way of issuing, withdrawing and/or suspending the certificates provided in Para. (2) and (5) shall be established in the procedures developed by ANSA and approved by the Government.

In accordance with the provisions of Government Decision No. 600 of June 27, 2018, ANSA shall exercise the status of founder at the Public Institution "Central Phytosanitary Laboratory", which also performs the control of seed and planting material with the issuance of test reports, and issues quality certificates for exported seeds according to ISTA international norms.

c) Approval of seed and planting material

A fundamental and obligatory link in the system of seed production is the recognition and approval of the variety.

Under the Law on seeds, No. 68/2013, Art. 5, ANSA shall approve:

- the seed and crop hybridisation sectors;
- the parent plantations of vineyards, fruit trees, fruit bushes and strawberries;
- the list of inspectors responsible for inspecting the seed and hybridisation sectors of agricultural crops, as well as for the recognition of varietal purity in wine and fruit growing nurseries.

Official checks in the field of seed control consist of field inspections carried out in the seed production, propagation and planting sectors, as well as checks carried

out when placing them on the market (checks carried out in agricultural shops and markets, as well as at economic operators authorised for marketing).

ANSA performs seed certification, field inspections in order to establish the conformity of variety identity, biological purity, cultural value and phytosanitary status.

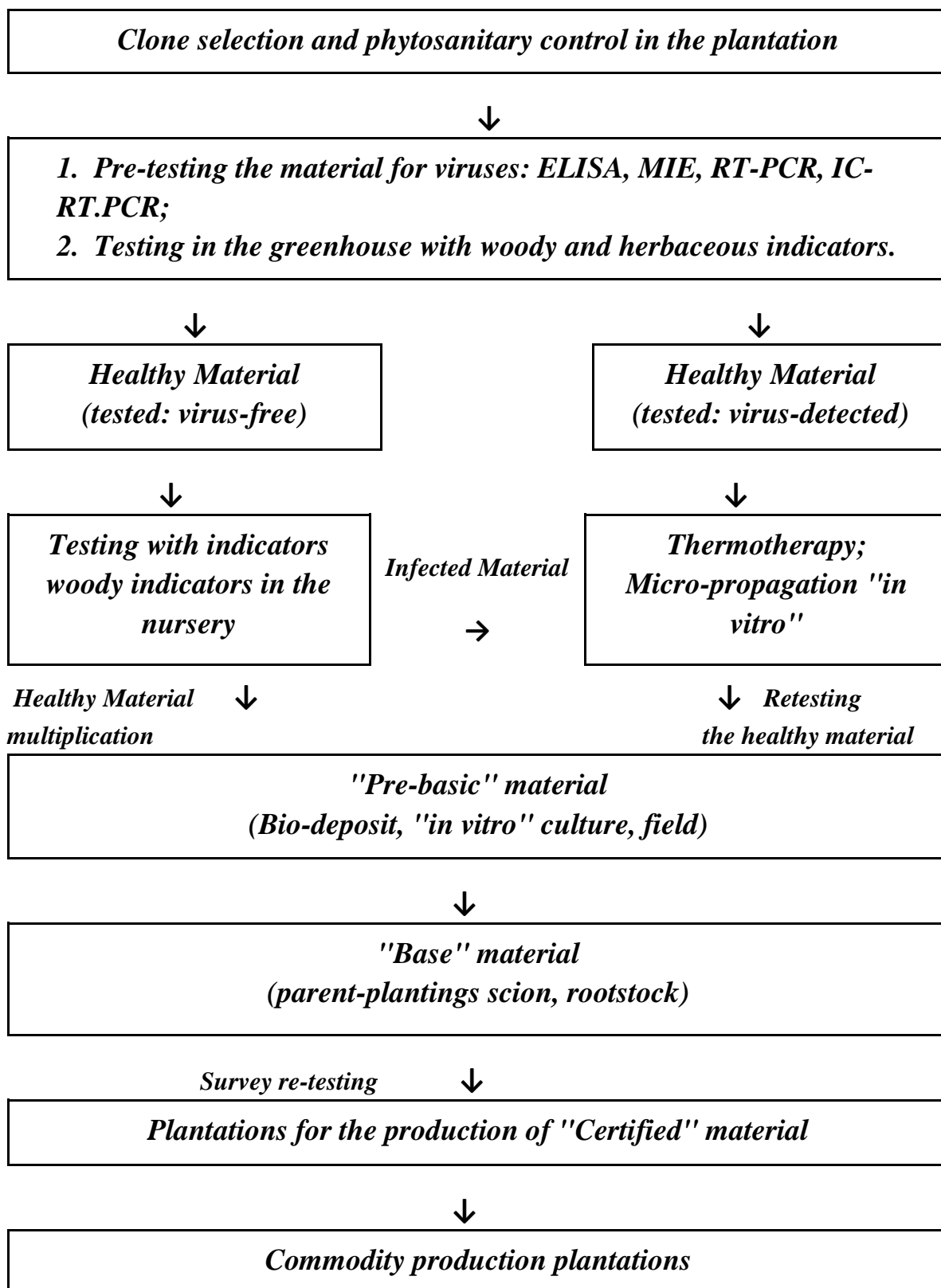
Annually, ANSA develops and executes the field inspection sequence in order to establish and maintain the traceability of the product (seeds, propagation material and/or seedlings).

The OECD Variety Certificate is issued on the basis of the field inspection guidelines for the seed and hybridisation sectors in sunflower, maize, vegetable and cereal crops in accordance with the OECD seed schemes, approved by ANSA Order No. 113/2018. The Order was issued to fulfil the recommendations of the Government Decision SANTE expert audit, conducted in 2016 regarding the equivalence of field inspections carried out in the Republic of Moldova to the European requirements.

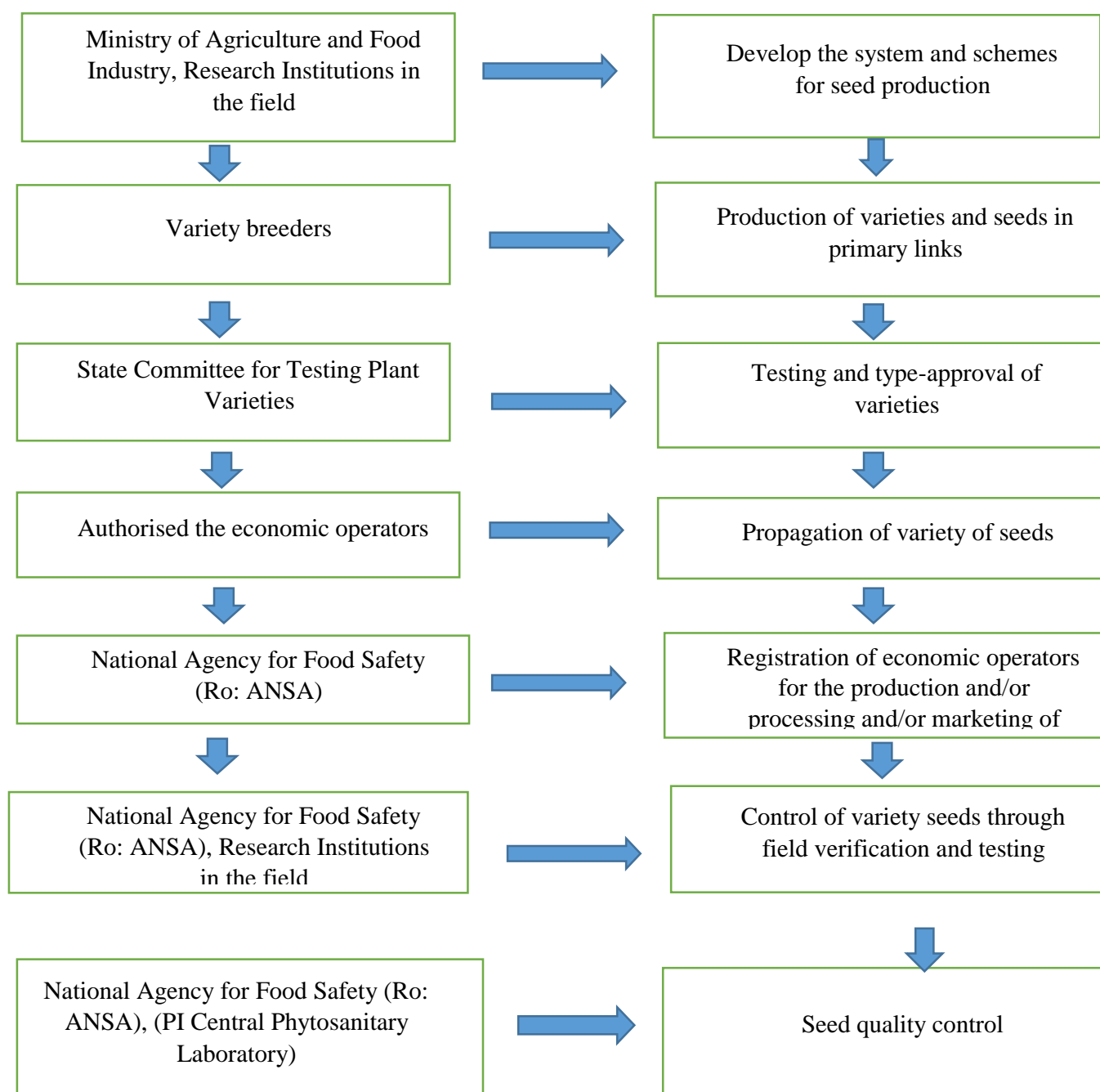
Decision 2018/1674 of the European Parliament and of the Council of October 23, 2018 amending Council Decision 2003/17/EC shall apply as regards the equivalence of field inspections carried out in the Republic of Moldova for cereal seed-producing crops, vegetable seed-producing crops and oil and fibre seed-producing crops and the equivalence of cereal seed, vegetable seed and oil and fibre plant seed produced in the Republic of Moldova).

Recently, by letter No. 01-6/248 of January 21, 2022, a request was sent to the European Commission – to the General Director for Health and Food Safety (DG SANTE) to recognise the equivalence of field inspections carried out in the Republic of Moldova to crops producing fodder plant seeds, for which the filling file was received.

Annex 1 General scheme of planting material production in the Republic of Moldova



Annex 2 General Seed Production System in the Republic of Moldova



30. Please provide information on Plant variety rights.

In accordance with Law No. 39/2008 on the Protection of Plant Varieties⁴³⁰, the variety rights shall be obtained and protected on the territory of the Republic of Moldova by means of a plant variety patent (hereinafter referred to as patent),

⁴³⁰ Law No. 39/2008 on the Protection of Plant Varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93465&lang=ro

granted by the State Agency on Intellectual Property (hereinafter referred to as AGEPI).

The authorities implementing the state policy in the field of legal protection of varieties are: the State Agency on Intellectual Property and the State Committee for Testing Plant Varieties (hereinafter referred to as the State Committee). The State Committee carries out the state policy on the use of new varieties in breeding.

State Agency on Intellectual Property

Organisation and structure:

AGEPI is the national office in the intellectual property protection field and is the sole authority in the Republic of Moldova that provides for the legal protection of new varieties of plants, exercising the following competencies:

- drafts legislative and other normative acts in the field of protection of plant varieties, approves the procedural acts necessary to perform functions established by law;
- registers and examines patent applications, grants and issues patents on behalf of the State, publishes official data in the Official Newsletter of Intellectual Property (hereinafter referred to as BOPI);
- maintains and administers the National Collection of Plant Variety Patents and exchanges information with international organisations and administrations for the protection of plant varieties of other countries;
- keeps the National Register of Plant Variety Patent Applications and the National Register of Plant Variety Patents, establishes and approves the procedure by which they are to be maintained.

AGEPI and the State Committee shall represent the Republic of Moldova in the International Union for the Protection of New Varieties of Plants (hereinafter referred to as UPOV), as well as in other international and intergovernmental organisations for the protection of plant varieties, maintain relations of bilateral and multilateral cooperation with them in this area.

Resources (human resources, financial)

Human resources

AGEPI has got 4 people involved in the procedures for granting plant variety protection (2 persons from the department administration and 2 examiners). An examiner carries out the procedures related to the examination of variety patent applications and granting protection, being supervised by another examiner and by the department administration.

Financial resources

The state budget covers all funding sources for granting plant variety protection by AGEPI.

Legislation

Protection of plant varieties is governed in the Republic of Moldova by Law No. 39/2008 on the Protection of Plant Varieties⁴³¹ and Government Decision No. 295/2009 approving the Regulation on the Procedure of Filing and Examination an Application, Grant and Maintenance of a Plant Variety Patent⁴³²;

Law No. 39/2008 on the Protection of Plant Varieties is in line with the International Convention for the Protection of New Varieties of Plants (UPOV), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), and partially has transposed the *EU acquis*: Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights; Council Regulation (EC) No 2470/96 of 17 December 1996 providing for an extension of the terms of a Community plant variety right in respect of potatoes; Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions; Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

Implementation

The procedure for granting plant variety protection shall be carried out on the basis of the plant variety patent application, filed with AGEPI by the Applicant or his authorised attorney. AGEPI carries out the formal, preliminary examination of the application, publishes the application in the Official Newsletter of Intellectual Property and examines the substance of the application, after which it sends the application materials to the State Committee for Testing Plant Varieties. The latter carries out the technical examination of the variety, draws up a technical examination report, which it sends to AGEPI. Based on the technical examination report, AGEPI decides to grant a plant variety patent or to reject the patent application.

The plant variety patent shall be granted if the variety is new, distinct, uniform and stable and is designated by a denomination in accordance with the provisions of Law No. 39/2008 on the Protection of Plant Varieties.⁴³³

Any person or his successor-in-title who has filed, in accordance with the law, a plant variety patent application in any Member State of the UPOV or any Member State of the World Trade Organization shall, for the purpose of filing a patent application for the same

⁴³¹ Law No. 39/2008 on the Protection of Plant Varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93465&lang=ro

⁴³² Government Decision No. 295/2009 on the approval of the Regulation on the Procedure of Filing and Examination the an Application, Grant and Maintenance of a Plant Variety Patent, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100021&lang=ro

⁴³³ Law No. 39/2008 on the Protection of Plant Varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93465&lang=ro

variety, enjoy a right of priority for a period of 12 months from the filing date of the earlier application.

The term of patent protection for a plant variety shall extend up to 25 years or, in case of varieties of vine, potato and trees – up to 30 years, as from the date of publication of the mention of granting the patent in BOPI. At the request of the patent owner, the term of patent protection may be extended for further 5 years.

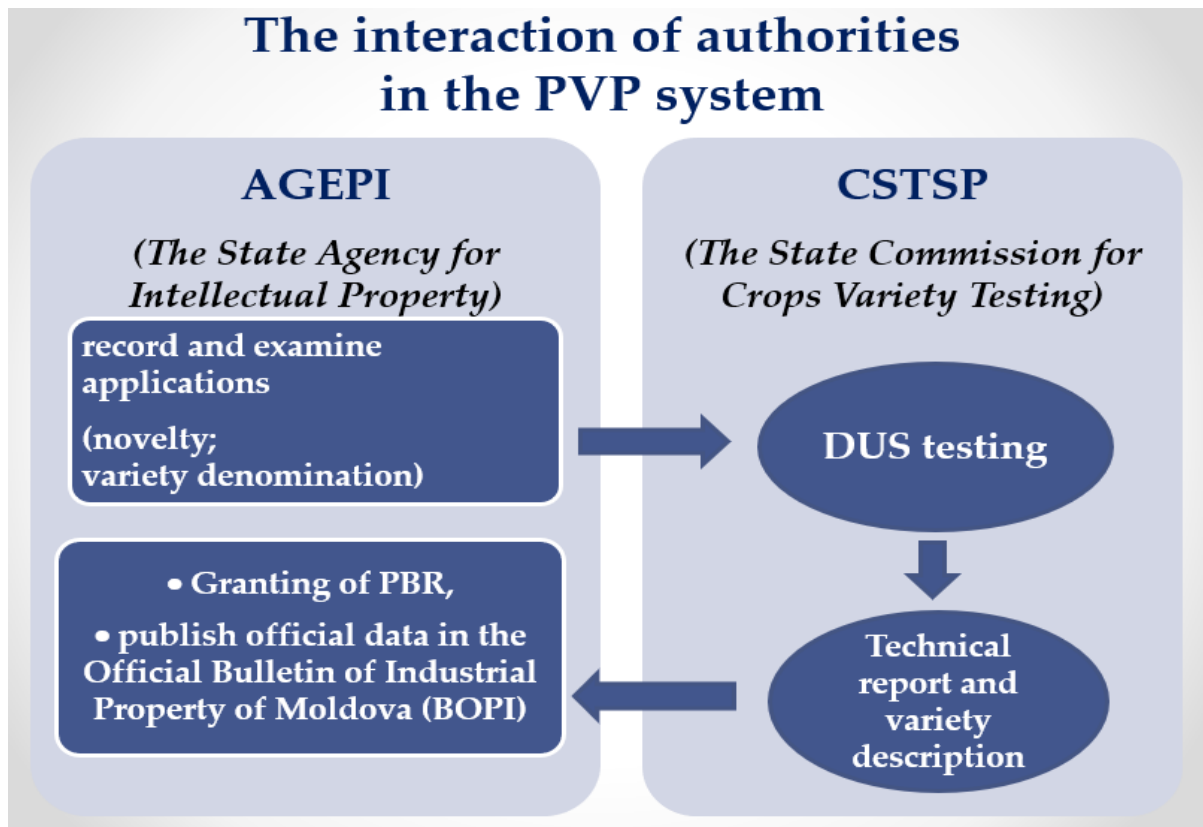
For plant varieties, belonging to plant species included in the list of agricultural plant species, to which the rights of patent owners for plant varieties are not extended, in accordance with the Regulation on the Procedure of Filing and Examination of an Application, Grant and Maintenance of a Plant Variety Patent, the right of the patent owner of the plant variety shall be deemed not to have been infringed by the use by agricultural producers for the purpose of propagation on his own lands, of the product of the harvest obtained by cultivating on his own lands the propagating material of a protected variety, save the hybrids, synthetic varieties, varieties of trees, shrubs and vines.

The patent owner shall be entitled to remuneration for the use of the product of the harvest of a protected variety included in the said list, which may be established by the means of a contract, but which must be less than the price charged for the licensed production of the propagating material of the same variety.

State Committee for Testing Plant Varieties

The State Committee is a public authority empowered in the official testing of plant varieties and is subordinated to MAFI (Government Decision No. 695/2017⁴³⁴). The State Committee maintains the Catalogue of Plant Varieties, including the varieties approved for production and sale in the Republic of Moldova.

⁴³⁴ Government Decision No. 695/2017 on the organization and functioning of the Ministry of Agriculture and Food Industry, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro



The State Commission operates in 2 directions:

- Testing, selection and admission of new varieties of plants in the process of agricultural production with their registration in the Catalogue of plant varieties (VCU test) and
- Technical examination of new varieties of plants (testing of distinction, uniformity and stability of the variety) in order to ensure the protection of the breeder's right in the process of agricultural exploitation of the variety in the territory of the Republic of Moldova.

The basic activities of the VCU Testing directorate:

- the formal examination of the applications for the testing of varieties;
- planning tests, collecting seed/seedling samples;
- coordination with resort bosses on variety testing;
- field testing process monitoring;
- examination and analysis of experimental data;
- drawing up the order on the registration of new varieties in the Plant Varieties Catalogue and elaborating the new edition of the Catalogue;
- improving theoretical and practical knowledge.

Basic activities of the direction DUS testing:

- registration and formal examination of applications;
- planning technical examination work;
- selection of reference varieties for inclusion in the examination process;
- monitoring the examination of plant varieties and analysis of distinction, uniformity and stability examination data;
- preparation of the technical report on the examination

The basic activities of the test stations:

- coordination of testing works with the main specialists in the direction of plant variety testing;
- fulfilment of the plant variety test plan (VCU test) and technical examination of the varieties at DUS;
- compliance with crop cultivation technology;
- keeping the agricultural mechanisms and utilities in working order;
- maintenance of plants in experimental nurseries during their growing season;
- loss-less harvesting and storage of agricultural production.

The legal framework of the state commission's activity the State Commission operates on the basis of:

- Government Decision No. 43/2013 Regulation on the testing and admission of varieties in the Catalogue of plant varieties ⁴³⁵;
- Law No. 39/2008 on the protection of plant varieties⁴³⁶;
- Law No. 68/2013 on seeds⁴³⁷;
- Law No. 728/1996 on fruit growing ⁴³⁸;
- Law No. 57/2006 vine and wine ⁴³⁹;
- Law No. 658/1999 of walnut crops⁴⁴⁰

⁴³⁵ Government Decision No. 43/2013 Regulation on the testing and admission of varieties in the Catalogue of plant varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114401&lang=ro

⁴³⁶ Law No. 39/2008 on the protection of plant varieties, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93465&lang=ro

⁴³⁷ Law No. 68/2013 on seeds, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106315&lang=ro

⁴³⁸ Law No. 728/1996 on fruit growing, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118834&lang=ro

⁴³⁹ Law No. 57/2006 vine and wine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=25282&lang=ro

⁴⁴⁰ Law No. 658/1999 of walnut crops, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108460&lang=ro

Based on the experimental data, the State Commission decided on the promotion of the variety or the registration of the variety in the Catalogue. At the same time, varieties registered in the EU Catalogue are registered in the National Catalogue if the variety has a significant performance in a single year of testing. The State Commission maintains the right to reject the variety from the registration only on the basis of the results of all years, in all test sites. In this regard, the State Commission issues 2 orders for the registration of varieties in the Catalogue of plant varieties, the first in September – for the crops with the autumn sowing and the second – in December, for all the other plant species tested. Based on these orders of the State Commission, the main specialists elaborate the new edition of the Catalogue, which is published in the first months of the following year.

VII. GENETICALLY MODIFIED ORGANISMS

31. Please provide information on the legislative framework on genetically modified organisms (GMOs);

The Republic of Moldova is Party to the Cartagena Protocol on Biosafety (Law No. 1381/2002)⁴⁴¹ and to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (Law No. 96/2018)⁴⁴².

The political framework for Biosafety in Moldova has been established by the National Biodiversity Strategy and its Action Plan (NBSAP) approved by Government Decision No. 112/2001⁴⁴³ and later through an Aichi targets' updated NBSAP for the years 2015-2020 approved by Government Decision No. 274/2015⁴⁴⁴. The Ministry of Environment (MoE) intends to develop another NBSAP document adapted to new challenges, and discussions with CBD and UNEP are ongoing. The specific Objective B of the latest NBSAP is aimed at reducing pressure on biological diversity by ensuring biosafety measures through developing procedures on risk assessment of GMOs, which are intended for deliberative release into the environment, all in accordance with the National Biosafety Framework and provisions of the Cartagena Protocol on Biosafety.

According to the Environmental Strategy for the years 2014-2023, approved by Government Decision No. 301/2014⁴⁴⁵, and its Specific Objective 1, it aims to ensure conditions of good governance and efficiency of institutional and managerial potential in the field of environmental protection to draft a new law on biological security in line with the provisions of Directive 2001/18/EC of the European Parliament on the deliberative release into the environment of genetically modified organisms.

*Law No. 755/2001 on Biosafety*⁴⁴⁶ covers all types of GMO uses, including their cross-border movement, contained use. It is applicable for the following activities: a) obtaining, multiplying, handling and contained use of genetically modified microorganisms, plants and animals resulted from modern biotechnology

⁴⁴¹ The Republic of Moldova is Party to the Cartagena Protocol on Biosafety, available in Romanian at: <https://www.legis.md/cautare/downloadpdf/2617>

⁴⁴² Nagoya-Kuala Lumpur Additional Protocol on Liability and Reparation for Damage to the Cartagena Protocol on Biosafety, available in Romanian at: <https://www.legis.md/cautare/downloadpdf/105466>

⁴⁴³ Government Decision No. 112/2001 approved by Biosafety in Moldova has been established by the National Biodiversity Strategy and its Action Plan (NBSAP), available in Romanian at https://www.legis.md/cautare/getResults?doc_id=77328&lang=ro

⁴⁴⁴ Government Decision No. 274/2015 on the approval of the Biodiversity Strategy of the Republic of Moldova for the years 2015-2020 and the Action Plan for its implementation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=66444&lang=ro

⁴⁴⁵ Government Decision No. 301/2014 on the approval of the Environmental Strategy for 2014-2023 and the Action Plan for its implementation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114539&lang=ro

⁴⁴⁶ Law No. 755/2001 on Biosafety, available in Romanian at: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=312871>

techniques; b) deliberative release into the environment; c) unintentional release into the environment; d) placing the products resulting from such organisms to the market; e) research projects with GMOs, including laboratory, clinical, field trials; f) deliberative cross-border movement via import/export operations with GMOs and products resulting from such organisms; g) illegal cross-border movements.

According to *Government Decision No. 197/2003 on designation of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity*⁴⁴⁷, the Ministry of Environment (MoE) is appointed to serve as the National Competent Authority (NCA) on Biosafety issues.

According to *Government Decision No. 603/2003 on the National Biosafety Commission*⁴⁴⁸, the National Biosafety Commission has been established within the Ministry of Environment as an advisory body to provide scientific and technical advice to the National Competent Authority and to contribute to the decision-making process under the Advanced Informed Agreement procedure.

*Government Decision No. 1153/2003 approving the Regulation regarding the authorisation of activities related to the obtaining, testing, use and marketing of genetically modified organisms*⁴⁴⁹ provides an enforcement mechanism for the main law and stipulates procedures for risk assessment, monitoring, emergency measures, etc.

A new *Law on regulation and control of genetically modified organisms* drafted by the MoE has been pre-approved by Government Decision No. 256/2022 and is now pending approval of the Parliament⁴⁵⁰. The new Law has been developed in line with the requirement of the Moldova-EU Association Agreement (2014) to transpose Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The previous Law No. 755/2001 on biosafety will be repealed⁴⁵¹ afterwards. The new law stipulates establishing the legislative and institutional framework to carry out activities on obtaining, testing, using, marketing⁴⁵² and import/export operations with GMOs, respecting the precautionary principle to ensure the protection of human health and the environment, and taking into account the socio-economic aspects. The new law

⁴⁴⁷ Government Decision No. 197/2003 on designation of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=9912&lang=ro

⁴⁴⁸ Government Decision No. 603/2003 on the National Biosafety Commission, available in Romanian at: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353>

⁴⁴⁹ Government Decision No. 1153/2003 on approval of the Regulation regarding the authorization of activities related to the obtaining, testing, use and marketing of genetically modified organisms, available in Romanian at: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=297868>

⁴⁵⁰ Government Decision No. 256/2022 For the approval of the draft law on regulation and control of genetically modified organisms, available in Romanian at: <https://gov.md/sites/default/files/document/attachments/subiect-02-nu-391-mm-2021.pdf>

⁴⁵¹ Law No. 755/2001 on biosafety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=65063&lang=ro

⁴⁵² The web page of the institution, available in Romanian at: <http://www.mediugov.md/>

covers activities on (a) deliberate release into the environment of genetically modified organisms for purposes other than placing on the market; (b) placing on the market of genetically modified organisms, as products or its derivatives; (c) cross-border movement of genetically modified organisms, as products or its derivatives.

32. Please provide information on the respective fields of responsibilities, organisation and powers of the competent institutions and authorities.

The *Ministry of Environment* is appointed to serve as the National Competent Authority on Biosafety, by Government Decision No. 197/2003 on designation of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity⁴⁵³. Its *Division on Biodiversity Policy* is in duty to provide policy and legislative development, coordinate activities on biosafety in relation of any kinds of genetically modified organisms.

The *National Focal Point to Cartagena Protocol National Focal Point, Emergency Measures (Article 17) Contact Point, BCH National Focal Point, Global Strategy for Plant Conservation National Focal Point* was recently appointed by the MoE Order No. 12/2022⁴⁵⁴.

The recently established *Environment Agency*⁴⁵⁵, subordinated to the MoE, is the executive body responsible for the implementation of the Law on Biosafety, it coordinates and monitors all GMO-related activities, it also examines notifications and issues the necessary authorizations for all types of activities with GMOs. For this purpose, it has a specialised *Division on Biodiversity, Biosafety and Protected Areas* as part of its organisation chart.

The *National Biosafety Commission* has been established within the MoE, by Government Decision No. 603/2003 on the National Biosafety Commission. It provides scientific and technical advice to the Ministry of Environment and contributes to the decision-making process. A total number of 13 members of the Committee are representing sector governmental bodies (environment, agriculture, health protection), academic research institutions, Academia and non-governmental organisations. According to the current Law on Biosafety (2001), the National Biosafety Commission is in charge to issue the authorization to the

⁴⁵³ Government Decision No. 197/2003 on the designation of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=9912&lang=ro

⁴⁵⁴ MoE Order No. 12/2022, available in Romanian at: <https://bch.cbd.int/en/countries/MD/NFP>

⁴⁵⁵ The web page of the institution, available in Romanian at: <https://am.gov.md/>

notifier, in consultation with the scientific opinion of the National Biosafety Commission and the public opinion.⁴⁵⁶

According to Article 24 of Law No. 306/2018, ANSA is responsible for the surveillance and control of the use of genetically modified organisms (GMOs) related to food safety. Within the Central Phytosanitary Laboratory (where ANSA is the founder) there is a Laboratory for Genetically Modified Organisms (GMOs) which uses the PCR (Polymerase Chain Reaction) method to test the GMOs. Laboratory for Genetically Modified Organisms (GMOs) has been accredited as per ISO17025 Acreditare - Laboratorul Central Fitosanitar (carantina.md) and actually has capacities for testing genetically modified organisms (GMOs) from soybeans, maize, rapeseed, etc.

The *State Committee for Testing Plant Varieties*⁴⁵⁷ keeps the *Catalogue of Plant Varieties of the Republic of Moldova*⁴⁵⁸.

33. Please provide information on the rules concerning the release of GMOs into the environment; Please provide information on the rules concerning genetically modified food and feed.

The national rules on deliberative release of GMOs into the environment are established by the Law on Biosafety⁴⁵⁹. According to Art.19, any *person or legal entity*, before introducing a genetically modified organism into the environment intended to be used for research purposes, testing, and/or for any other purpose, save food/feed or processing to be introduced on market, is obligatory required to submit a *notification* to the *National Biosafety Commission*. The *notification* shall include: a) a technical information *on assessment of adverse risks*, either of immediate or prolonged effects to the human health and/or the environment; b) *post-release impact assessment generated* by the genetically modified organisms to human health and environment; or c) information on the results of the introduction of the same genetically modified organisms in the territory of the Republic of Moldova and/or abroad. A *simplified procedure for authorization* is allowed if the referred GMO has already been approved by the EU Member States and the Organisation for Economic Cooperation and Development.

According to Art.20, the *decision-making process* involves the following procedures: after receiving the notification, the National Biosafety Commission, based on the information contained in the notification: a) will *inform and consult the public* regarding the notification received; b) will *request the opinions* of the *central public authorities for agriculture and food industry, health and consumer*

⁴⁵⁶ Government Decision No. 603/2003 on the National Commission for Biosafety, available in Romanian at: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=303353>

⁴⁵⁷ The web page of the institution, available in Romanian at: <http://cstsp.md/ro/?page=1is>

⁴⁵⁸ Catalogue of plant varieties for the year 2022, available in Romanian at: <http://cstsp.md/uploads/files/Catalogul%20Soiurilor%20de%20Plante%202022.pdf>

⁴⁵⁹ Law No. 755/2001 on biological security, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=65063&lang=ro

rights protection. The National Biosafety Commission, within 90 days from receiving the notification, will inform the notifier that: a) the notification is in accordance with the legal provisions and the authorisation is issued; or b) the notifier must submit additional information; or c) the proposed activity does not meet the legal requirements and the notification has been rejected; or d) the proposed activity presents a damage to human health and/or the environment, and the notification has been rejected; or e) the proposed activity is not subject to the present law.

The notifier may start the proposed activity with GMOs only after obtaining an official authorisation issued by the National Biosafety Commission and in compliance with the *conditions established* by it, including the condition regarding the determination of the *genetic safety zone*. In case of deliberative release of GMOs in the proximity of the natural protected areas such area has to be outlined at least for 3 km.

All varieties originating from genetically modified plants that meet the conditions for testing the agronomic and technological value shall *be introduced in the Catalogue of Plant Varieties of the Republic of Moldova* which is kept by the State Committee for Testing Plant Varieties⁴⁶⁰.

After deliberative release of a genetically modified organism into the environment, the notifier shall submit regular reports to the National Biosafety Commission on the result of the introduction, the observance of the genetic safety zone, mentioning any identified risk to human health and environment (Art.21 and 22).

Review of decision. The National Biosafety Commission may review its decision taken in accordance with Art. 32 and may amend it on the basis of new scientific information regarding the potential adverse effects on human health and/or environment.

The existing Law on Biosafety, 2001 (Chapter V - Placing LMOs to the market of) stipulates the authorization for using of all types of GMOs products including *for food, feed and processing* (LMOs-FFP). Along with the general requirements for information to be submitted during the notification process for LMOs-FFP, there are specific requirements regarding the *packaging and labelling*. According to Art.23, placing of genetically modified organisms and/or the products resulting from such organisms on the market shall be made only based on *the authorisation* issued by the National Biosafety Commission. The authorisation shall be issued only if the products and organisms meet the requirements regarding the risk assessment for human health and environment; the products and bodies are labelled in accordance with the provisions of Art. 24 and recommendations for packaging and transportation. The presence of genetically modified organisms will be specified on the label and/or in the accompanying documentation. The words "*The product contains genetically modified organisms* "are required both on the

⁴⁶⁰ Catalogue of plant varieties for the year 2022, available in Romanian at: <http://cstsp.md/uploads/files/Catalogul%20Soiurilor%20de%20Plante%202022.pdf>

label and in the accompanying documents. Information on the content of genetically modified organisms must occupy at least 10% of the surface of the label and/or the accompanying documentation. A *product* is labelled as OMG if its content of such organisms is of at least 1% of the total mass of product, and for seeds – 0.3%.