



Questionnaire

Part II

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

CHAPTER 1: FREE MOVEMENT OF GOODS

May 2022

The **general principle** of the free movement of goods implies that products must be traded freely from one part of the European Union to another. It is enshrined in the Treaty on the Functioning of the European Union, in particular Articles 34 to 36, 114(4) to 114(9), and 346 to 348, as interpreted in the case law of the Court of Justice of the European Union. Quantitative restrictions and measures having equivalent effect to a quantitative restriction are prohibited, subject to a limited and restrictive set of exceptions. This implies the elimination of technical barriers to trade and compliance with the principle of mutual recognition. Adequate administrative arrangements should be put in place to apply the Regulation (EC) 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC and the "strawberry" Regulation (EC) 2679/98. The notification procedure in the field of technical standards and regulations is laid down in Directive (EU) 2015/1535 and provisions on external border checks are provided in Regulation (EU) 2019/1020. These need sufficient administrative capacity in order to be properly applied.

In a number of sectors, the general principle is complemented by a harmonised regulatory framework. **Horizontal measures** define the quality infrastructure which Member States should put in place in areas such as standardisation, conformity assessment, accreditation, metrology, and market surveillance.

Harmonised European product legislation, which needs to be transposed by each Member State, represents the largest part of the *EU acquis* under this chapter. It is based on the "old approach" (imposing precise product specifications) and the "new and global approach" (imposing general product requirements). The New Legislative Framework (Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, together with Regulation EU 2019/1020 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 is a review of the New Approach and lays down common rules on the marketing of products.

Old Approach product legislation covers the areas of motor vehicles, emissions of gaseous and particulate pollutants from non-road mobile machinery engines, chemicals (REACH), chemical labelling, good laboratory practice, legal metrology, pre-packaging, detergents, and fertilisers.

New and Global Approach product legislation covers the areas of non-automatic weighing instruments and measuring instruments, low voltage equipment (LVD), electromagnetic compatibility (EMC), toys, machinery, lifts, noise emissions by outdoors equipment, personal protective equipment (PPE), equipment and protective systems intended for use in explosive atmospheres (ATEX), pyrotechnic articles, civil explosives, medical devices, gas appliances, pressure equipment, simple pressure vessels, cableway installations, construction products, recreational craft, eco-design requirements for energy-related products, aerosol dispensers, and radio and telecommunications terminal equipment (RED). The majority of this legislation reflects the model provision of Decision No 768/2008/EC.

A series of **procedural measures** also require sufficient administrative capacity in order to be properly applied. These include Directive 91/477/EEC on the control of the *EU acquisition* and possession of weapons and Directive 2014/60/EU on cultural goods, Directive 69/493/EEC on Crystal Glass, Directive 2009/43/EEC on Defence Products & Directive 2009/81/EC on Defence Procurement, Directive & 2009/81/EC on Footwear, Directive 94/11/EC on Textile Labelling & Mixtures and Regulation 1007/2011 on Medicinal Products Pricing.

When answering the questions below, please make references to the state of implementation of such obligations.¹

¹ These questions are of a general nature and do not refer to the industrial sectors specified below or in Chapter 20.

I. GENERAL PRINCIPLES

1. Do measures exist in the laws, regulations or administrative provisions adopted at national or local level on the production, distribution and marketing of industrial products (please provide details):

a) Relating to the price of products²?

The national regulations contain provisions aimed at capping the prices of some products.

Such products include, for example: **medical masks, medical gloves, biocidal products** (medical disinfectants), which are included in the National Register of Biocidal Products and the State Register of Medical Devices³.

National laws also expressly provide for the pricing of:

- medicines and medical devices⁴;
- petroleum products⁵ ;
- electricity and heat⁶.

Moreover, by Government Decision No. 774/2016, the Government approved the Regulation on the formation of the trade prices of socially important products and their list. Thus, the industrial products included in the list are the following: medical masks; medical gloves; biocidal products (medical disinfectants) included in the National Register of Biocidal Products and in the State Register of Medical Devices.

The above-mentioned Regulations sets out the following way of forming of the internal market prices:

- socially important products are sold at purchase prices / delivery prices with the application of the commercial surcharge not exceeding 20%;
- socially important products, both imported and domestic, which have been processed in commercial units, are traded with the application of the

² e.g. fixing the prices above or below which the importation or marketing of a product is prohibited or restricted, laying down profit margins or the other price components, etc.

³ Government Decision No.774/2016 on the marketing prices of the socially important product, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=120517&lang=ro#

⁴ Law No.1456*/1993 on the pharmaceutical activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128121&lang=ro#

⁵ Law No.461/2001 on the petroleum products market, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130210&lang=ro

⁶ Law No.107/2016 on electricity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129837&lang=ro#

commercial surcharge that does not exceed 40% cumulatively from the purchase price / delivery price.

In the sense of the above-mentioned Regulation, processing is the additional activity carried out by the trade unit in order to prepare the products for sale by packing / repackaging them, which does not change the initial characteristics of the products.

b) Which require import licenses or permits for imported goods⁷?

The national legislation contains a unitary normative basis related to obtaining authorizations and licenses⁸.

Licenses required for import or permits for imported products include:

- License for the import and storage of ethyl alcohol; import, storage and wholesale of imported alcohol and / or beer;
- License to import tobacco products; the import and / or industrial processing of tobacco; manufacture of tobacco products and / or wholesale trade in tobacco products and fermented tobacco;
- License for the production, import, export, re-export, trade, storage of explosive materials and / or performance of works with explosives for civil use;
- License for the import and wholesale and / or retail sale of petrol, diesel and / or liquefied gas at refueling stations;

The full list of all licenses and authorizations is contained in a single state nomenclature⁹.

It shall be noted that “strategic goods” circulation, including import, are regulated separately via the Law No.1163/2000¹⁰. Thus, this provides for the control procedure on the export, re-export, import and transit of strategic goods, that include: products, technologies and services that have a dual use (civil and military); weapons, ammunition, military equipment, technologies and related services; products, technologies and services that may be used in the manufacture and use of nuclear, chemical, biological and missile weapons that may carry such weapons; other products, technologies and services that require special control in

⁷ E.g. license for import of automobiles

⁸ Law No.160/2011 on authorization regulation of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro#

⁹ PERMISSIVE ACTS NOMENCLATURE issued by the issuing authorities to natural persons and legal entities for the practice of entrepreneurial activity, available in Romanian at: [https://www.legis.md/UserFiles/Image/RO/2021/mo302-306md/an_1_160\(1\).doc](https://www.legis.md/UserFiles/Image/RO/2021/mo302-306md/an_1_160(1).doc)

¹⁰ Law No.1163/2000 on control of export, re-export, import and transit of strategic goods, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108380&lang=ro

the interest of national security or foreign policy, in accordance with the international agreements and arrangements to which the Republic of Moldova is a party.

c) Which make access to the domestic market conditional upon having an agent or representative in the territory of the country¹¹?

For the purposes of the national legislation, a foreign investor is to be understood as a person employed in the investment activity in the Republic of Moldova who can be:

- a foreign individual with permanent residence in another state or stateless person with permanent residence abroad;
- a legal entity, incorporated in accordance with the law of another State, having its main office in that State or a legal person having its registered office, central administration or principal place of business registered in another State;
- organization or association created following a treaty between states or other subjects of international law.

Enterprises with foreign investment may be established in the Republic of Moldova and are subject to general legal framework applicable to all legal entities, with some minor exceptions.

The procedure for registration, activity and dissolution of the enterprise with foreign investment is similar to the procedure for registration, activity and dissolution of the domestic enterprise.¹²

A foreign investment can also be incorporated in Moldova in the form of a branch or subsidiary of a foreign entity. As of 2019, the Moldovan legislation was adjusted to the EU legislation, providing that a company's „branch” is not a self-standing legal entity, being part of the parent company, while the „subsidiary”, being controlled by another legal entity (parent), is incorporated and acts as a legal entity.

The activity which, according to the law, is subject to licensing in the Republic of Moldova, can be carried out by the foreign legal entity that registered the branch in the Republic of Moldova only after obtaining the license, unless the law provides otherwise¹³.

¹¹ E.g. legislation which provides for the sale of certain goods in your country subject to authorization that may be obtained only by a person established in your country

¹² Law No.81/2004 on investments in entrepreneurial activity, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122080&lang=ro

¹³ Civil Code No.1107/2002, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=129081&lang=ro#

For example, the activity of selling medical products has to be carried out by the holder of the registration certificate for the medicinal product or through an official representative.¹⁴

d) Which oblige to have storage facilities in the territory of the country¹⁵?

There are mandatory storage provisions for two products: petroleum products and liquefied gas.¹⁶ Importers are required to either hold or rent in warehouses, main petroleum products (standard gasoline and diesel) in a volume of at least 1000 m³, and in case of liquefied gas, a minimum volume of 150 m³.

e) Which impose on the marketing of imported products conditions that are different from those imposed on domestic products or which require/ encourage a certain type of packaging for marketing a product, whether domestic or imported¹⁷?

As a rule, in the Republic of Moldova, investments may not be discriminated on the basis of nationality, domicile, residence, place of registration or activity, state of origin of the investor or investment or for any other reason.

Investors shall be granted fair and equal conditions of activity, which exclude the application of discriminatory measures that could impede the direction, operation, maintenance, use, fruition, acquisition, extension or disposition of investments¹⁸.

f) Which oblige economic operators to label their product with a “Made in ...” marking¹⁹?

As a rule, the manufacturer (packager) must provide information on the product country of manufacture, in accordance with the technical regulations and national standards in force²⁰.

¹⁴ Law No. 1409/1997 regarding drugs, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=115116&lang=ro

¹⁵ e.g. legislation applying only to imported goods which require these imported goods to be stored for some time before being marketed

¹⁶ Law No.461/2001 on the Petroleum Products Market, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130210&lang=ro

¹⁷ Relating in particular to shape, size, weight, composition, presentation, identification and packaging, labelling (shape, size, composition) (e.g. requirement that some goods may only be sold in a package with special form)

¹⁸ Law No.81/2004 on investments in entrepreneurial activity, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=122080&lang=ro

¹⁹ i.e. an obligatory origin marking

²⁰ Law No.105/2003 on consumer protection, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=129082&lang=ro

g) Which encourage or authorize the purchase of domestic products and/or give preference to the purchase of such products in advertising campaigns and/or are there incentives to buy national products²¹?

There are no such requirements under the national law, except for food products. Under Art. 21²² para. (12) of the Law No. 231/2010 on internal trade law, the food traders, but the itinerant trade units, are obliged to purchase and ensure the display on the shelf of food products from the short food chain in a proportion of at least 50% of the linear length of the commercial shelf, if sells products in the same category as those included in the list of foods from the short food chain. The supplier is obliged to ensure the delivery of food products from the short food chain in full quantity according to the concluded contract. The list of food products that fall under this list are approved by the Government and updated annually. Currently this list is stipulated in the Government Decision No. 113/2021²³.

This provision is based on the continuous requests of the food producers' associations and business environment regarding the support of the local producers in marketing on the domestic market, including through the normative regulation offering at least 50% of the trade shelves. Thus, one of the priorities was to support the producer by providing a secure place on the shelves of commercial networks. Providing access to local products on the shelves of trade units stimulates their capitalization with revenue accounting, which also involves increasing payments to local and national public budgets, including more accelerated development of the marketing system in small and medium enterprises, which will inevitably create a healthy competition, based on quality assurance principles, harmlessness and appearance of the products concerned.

However, these provisions do not limit the consumer's choice to food categories, the imported products being also present on the shelves of commercial units, and the trader has the possibility to select the supplier of domestic products, by establishing contractual relations.

Moreover, currently on the Government's agenda is the approval of the draft amendments to the Law No. 231/2010, covering a new chapter on "unfair commercial practices"²⁴. These amendments will partially transpose the provisions of the EU Directive 2019/633 on unfair trading practices in business-to-business relationships in the agricultural and food supply chain.

²¹ e.g. promotion actions with the participation of public authorities applying only to goods produced by producers in your country or from domestic raw materials

²² Law No. 231/2010 on internal trade law, available in Romanian at:

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

²³ Government Decision No. 113/2021 on the approval of the Product List food from the short food chain, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127069&lang=ro

²⁴ Law No. 231/2010 on unfair commercial practices, available in Romanian at:

https://cancelaria.gov.md/sites/default/files/legea_practicilor_neloiale.pdf

Apart of the above, the new advertising law, which will enter into force in 2023, admits that messages of public interest may be aimed at promoting the consumption of local products²⁵.

h) Which exclude imported products in full or in part, from the possibility of using domestic facilities or equipment or which reserve the use of such facilities or equipment, in full or in part, for domestic products?

There are no such requirements under the national law.

i) Which subject imported products to controls, other than those inherent in customs clearance procedures, that are not carried out on domestic products²⁶?

There are no requirements under the national law.

j) Which allow only traders holding a production licence or wholesale licence to import some goods²⁷?

The national legislation contains a unitary normative basis related to obtaining authorizations and licenses, as well as a single state nomenclature of permissive documents (that includes licences, authorisations and certificates)²⁸.

Licenses required for import or permits for imported products include:

- License for the import and storage of ethyl alcohol and import, storage and wholesale of imported alcohol and / or beer;
- License to import tobacco products; the import and / or industrial processing of tobacco; manufacture of tobacco products and / or wholesale trade in tobacco products and fermented tobacco;
- License for the production, import, export, re-export, trade, storage of explosive materials and / or performance of works with explosives for civil use;
- License for the import and wholesale and / or retail sale of petrol, diesel and / or liquefied gas at refueling stations.

²⁵Law No. 62/2022 on advertising, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=130742&lang=ro

²⁶e.g. veterinary, sanitary, phytosanitary and other controls

²⁷e.g. licensing system for the production and wholesale of some goods, which allow only the license holder to import these goods

²⁸Law No.160/2011 on authorization regulation of entrepreneurial activity, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro#

k) Which creates monopolies of sale of some goods (e.g. tobacco products, alcohol products, etc.)?

The national legislation establishes as a general rule that the economy of Moldova is a market economy, and the enterprises are engaged in free competition.

However, national law also operates with so-called "exclusive rights" which are rights granted by a competent public authority through any legislative, normative or administrative act in order to restrict the pursuit of an economic activity within a certain geographical area to one or several undertakings and which substantially affects the ability of other undertakings to carry out such activity in that area.

The rights granted in any form, including by concessions, to a limited number of undertakings on the basis of objective, proportionate and non-discriminatory criteria which allow any interested party fulfilling those criteria to enjoy the rights in question may not be considered exclusive rights²⁹.

Art. 10 (3) of the Law No. 845/1992 on entrepreneurship³⁰ provides that only state enterprises are allowed to practice specific activities. Just very few of them supposes the production and/or sale of specific goods, e.g.: preparation and sale of narcotic substances with strong and toxic effect, including sowing, cultivation and sale of narcotic and toxic substances; making orders and medals; production of emblems confirming the payment of state taxes and fees; making postage stamps; the production and marketing of special military and combat equipment, explosives (except gunpowder), as well as the production of all types of weapons; printing and minting, printing of government securities.

l) Which reserve certain trade names for domestic products alone and, if so, on what conditions³¹?

Protected geographical indications and designations of origin in the territory of the Republic of Moldova may be included in the trademark only if the applicant has the right to use the protected geographical indication or designation of origin³².

²⁹Law No.183/2021 on competition, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=128125&lang=ro#

³⁰Law No.845/1992 on entrepreneurship and enterprise, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=17094&lang=ro

³¹ e.g. rules which reserve the use of the description "mountain" to products prepared in your country from domestic raw materials

³²Law No.38/2008 on trademark protection, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=93464&lang=ro

2. Is the marketing of products with a label and instructions written in a foreign language allowed?

As a rule, it is forbidden to place on the market and / or make available on the market products, and to provide services, in the absence of complete, truthful and correct information in the Romanian language or in the Romanian and Russian languages.

Also, all information, including verbal information, referring to products or services provided to consumers, accompanying documents, and concluded contracts must be presented in Romanian or in Russian and one of the languages of international circulation.³³

3. Is there a procedure set up for parallel imports?

The provisions of the Custom Code³⁴ (Chapter XII) related the protection of intellectual property shall not apply to goods which are the subject to a protected intellectual property right and which have been manufactured with the consent of the right holder, but which are not in one of the following situations:

- are introduced or removed from the customs territory of the Republic of Moldova;
- are declared to the customs authorities for the purpose of placing them under a definitive or suspensive customs regime;
- are under customs supervision in any other situation;
- have not been declared on entry or exit from the country and are revealed by the customs authorities during the customs controls;
- became a state property by confiscation or by abandonment in favor of the state;
- have been released for free circulation.

³³Law No. 105/2003 on protection of consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129082&lang=ro

³⁴Customs Code No. 1149/2000, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130518&lang=ro

II. THE NON-HARMONISED AREA

A. The principle of the Free Movement of Goods

4. Have Steps been taken to ensure that legislation and administrative practices are in accordance with Articles 34-36 TFEU and relevant case-law of the Court of Justice of the European Union, such as a plan or strategy to ensure compliance with Articles 34-36 TFEU and CJEU case-law?

Import and export prohibitions and restrictions are notified to the WTO and are implemented only on the ground of public safety and moral, human life and protection, environment protection, and compliance with its international obligations³⁵.

The principle of free movement of goods is carried out by economic and administrative means in accordance with the laws³⁶, normative acts of the Government, as well as with the international treaties to which the Republic of Moldova is a Party. The relations of the Republic of Moldova with other states in foreign trade activities are based on the generally accepted principles and norms of international law and of the commitments deriving from the international treaties to which the Republic of Moldova is a party.

B. Notification of Technical Regulations

5. Is the authority in question empowered to contact all authorities/bodies that produce technical regulations, to remind them of the obligation to notify such regulations at a draft stage and to ensure a follow-up of each notification with each authority/body concerned?

Yes. The Technical Barriers to Trade (TBT) National Notification Authority is empowered to contact all relevant authorities and bodies. In the Republic of Moldova within the Ministry of Economy, WTO Notification and Information Center in the field of TBT has been created which operates according to the Regulation approved by Government Decision No.560/2012³⁷. According to the Regulation, all notifications and information are submitted to the WTO Secretariat by the Ministry of Economy, through the Ministry of Foreign Affairs and European Integration.

³⁵WTO documents, available in English at: [G/MA/QR/N/MDA/1/](#); [G/MA/QR/N/MDA/2/](#)

³⁶ Law No. 1031/2000 on state regulation of foreign trade activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=66725&lang=ro

³⁷Government Decision No. 560/2012 on the notification and information centers of the World Trade Organization, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110127&lang=ro

6. Has the competent authority developed a network of contacts among national economic operators who are the beneficiaries of the notification procedure in order to ensure that an alert system or equivalent is in place?

In the process of drafting national laws, but also of notifications of international measures, the interested economic agents from the relevant employers' associations can be contacted or informed (but this practice is not established). Additionally, there is a possibility for the interested national economic operators to register and join the E-ping platform and the alert system, which is established by the WTO Secretariat in cooperation with the International Trade Center (ITC).

III. THE HARMONISED AREA

7. Has the government adopted a strategy and/or action plan that foresees the alignment to all the *EU acquis* in this chapter?

Following the signing of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, ratified by Law No.112/2014³⁸, the Government of the Republic of Moldova adopted the Government Decision 808/2014 on the approval of the National Action Plan for the implementation of the Association Agreement Republic of Moldova - European Union in the period 2014-2016³⁹.

In the context of monitoring the execution of commitments assumed by the Republic of Moldova, the Government adopted Government Decision No.1472/2016 on the approval of the National Action Plan for the implementation of the Association Agreement Republic of Moldova - European Union in the period 2017-2019⁴⁰.

At the same time, the concrete actions for the implementation of the Association Agreement are included in the Government's action plans.

8. If it exists, does the above-mentioned strategy and/or action plan included planning for the alignment to the relevant framework legislation, notably Regulation (EU) 2019/1020, Regulation (EC) 764/2008, Directive 2001/95/EC and/or Regulation (EU) 1025/2012?

The action plans approved by Government Decision No.808/2014 and Government Decision No.1472/2016 include the transposition of Regulation (EU) 765/2008, Directive 2001/95/EC and Regulation (EU) 1025/2012. Following the adoption of Regulation (EU) 2019/1020, the action on its alignment with the national legislations is included in the Government action plan for the years 2021-2022, approved by Government Decision No.235/2021.⁴¹

Regulation (EC) No 764/2008 is not yet transposed into national legislation . At the same time, Law No.235/2011 on accreditation and conformity assessment

³⁸Law No. 112/2014 for the ratification of the Association Agreement between the Republic of Moldova, on the one hand, and the European Union and the European Community Atomic Energy Community and their Member States, of the other part, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=83489&lang=ro

³⁹Government Decision 808/2014 on the approval of the National Action Plan for the implementation of the Association Agreement Republic of Moldova - European Union in the period 2014-2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=88616&lang=ro#

⁴⁰Government Decision No.1472/2016 on the approval of the National Action Plan for the implementation of the Association Agreement Republic of Moldova - European Union in the period 2017-2019, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119199&lang=ro

⁴¹Government Decision No.235/2021 regarding the Government action plan for the years 2021-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128407&lang=ro

activities,⁴² contains provisions on the recognition of certificates of conformity or test reports issued by notified conformity assessment bodies, accredited by national accreditation bodies signatory to the Multilateral Recognition Agreement with European Cooperation for Accreditation, issued for products imported from Member States of the European Union.

Recognition assumes that the presence of the CE marking and markings laid down by technical regulations applicable to the product, shows that it has been subject to conformity assessment procedures and therefore, it is no longer necessary to repeat the conformity assessment procedures already performed when the product is placed or made available on the market.

⁴²Law No.235/2011 on accreditation and conformity assessment activities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

1. NEW LEGISLATIVE FRAMEWORK (NLF)

A. General Aspects

9. Is there a legal basis and administrative structure in place for market surveillance, technical regulations, standards, conformity assessment, accreditation and metrology ?

Market surveillance

The legal basis for market surveillance in the Republic of Moldova is Law No.7/2016 on market surveillance relating to the marketing of non-food products⁴³ and Law No.422/2006 on general products safety.⁴⁴

The authorities responsible for market surveillance are presented in the annex to Law No.7/2016 on market surveillance relating to the marketing of non-food products and Law No.102/2017 on medical devices.⁴⁵

Regulations for the organization and operation of market surveillance authorities are approved by Government Decisions.

No.	Regulated field (group of products)	Market surveillance authority
1	Low voltage equipment	Agency for Consumer Protection and Market Surveillance
2	Electromagnetic compatibility	
3	Toys	
4	Non-automatic weighing machines	Government Decision No.1089/2017 on the organization and functioning of the Agency for Consumer Protection and Market Surveillance ⁴⁶
5	Measuring instruments	
6	Burner machines on gas	
7	Boilers for hot water	
8	Energy labeling	
9	Personal protection equipments	
10	Industrial machines	Agency for Technical Surveillance
11	Lifts	
12	Refrigeration equipment	Government Decision No.1088/2017 on the organization and functioning of the Agency for Technical Surveillance ⁴⁷
13	Potentially explosive atmospheres	
14	Cableway installations for persons transportation	
15	Simple pressure vessels	

⁴³Law No. 7/2016 on market surveillance relating to the marketing of non-food products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

⁴⁴Law No. 422/2006 on general products safety available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro

⁴⁵Law No. 102/2017 on medical devices available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128123&lang=ro#

⁴⁶Government Decision No.1089/2017 on the organization and functioning of the Agency for Consumer Protection and Market Surveillance, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127660&lang=ro

⁴⁷Government Decision No. 1088/2017 on the organization and functioning of the Agency for Technical Surveillance, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125202&lang=ro

16	Pressure equipment	
17	Transportable pressure equipment	
18	Explosives used for civil purposes	
19	Pyrotechnic articles	
20	Environmental noise emissions from equipment used outside the buildings	
21	Construction products	
22	Radio equipment	<p>National Regulatory Agency for Electronic Communications and Information Technology</p> <p>Government Decision No.643/2019 for the approval of the Regulation on the organization and functioning of the National Regulatory Agency for Electronic Communications and Information Technology⁴⁸</p>
23	Recreation crafts	<p>Naval Agency</p> <p>Government Decision No.706/2018 on creation of the Naval Agency of the Republic of Moldova⁴⁹</p>
24	Marine equipment	
25	Interoperability of the trans-European high-speed rail system	Railway Authority
26	Interoperability of the trans-European conventional rail system	Project of Government Decision on the approval of the Regulation on the organization and functioning of the Railway Authority
27	Packaging and packaging waste	<p>Environmental Protection Inspectorate</p> <p>Government Decision No.548/2018 on the organization and functioning of the Environmental Protection Inspectorate⁵⁰</p>
28	Medical devices	<p>National Public Health Agency</p> <p>Government Decision No.1090/2017 on the organization and functioning of the National Public Health Agency⁵¹</p> <p>Medicines and Medical Devices Agency</p> <p>Government Decision No.71/2013 on the approval of the Regulation, structure and</p>

⁴⁸Government Decision No.643/2019 for the approval of the Regulation on the organization and functioning of the National Regulatory Agency for Electronic Communications and Information Technology, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125209&lang=ro

⁴⁹Government Decision No.706/2018 on creation of the Naval Agency of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125207&lang=ro

⁵⁰Government Decision No.548/2018 on the organization and functioning of the Environmental Protection Inspectorate, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127671&lang=ro

⁵¹Government Decision No.1090/2017 on the organization and functioning of the National Public Health Agency available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129690&lang=ro

	staff of the Medicines and Medical Devices Agency ⁵²
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Technical Regulations

The legal framework on technical regulations in the Republic of Moldova is the Law No.420/2006 on the activity of technical regulation⁵³ and normative acts approving technical regulations. The way of organizing and functioning of the process of legislation harmonization of the Republic of Moldova with the legislation of the European Union is established by the Government Decision No.1171/2018⁵⁴. The program of drafting the technical regulations is set out by the Government's and the regulatory authorities' action plans.

The empowerment of the authorities with technical regulatory functions and the areas of competence are established by the organization and functioning regulations approved by the Government. The following legal acts regulate the organization and functioning of the relevant Ministries:

- Government Decision No.143/2021 on the organization and functioning of the Ministry of Economy⁵⁵;
- Government Decision No.690/2017 on the organization and functioning of the Ministry of Infrastructure and Regional Development⁵⁶;
- Government Decision No.693/2017 on the organization and functioning of the Ministry of Internal Affairs⁵⁷;
- Government Decision No.148/2021 on the organization and functioning of the Ministry of Health⁵⁸;
- Government Decision No.145/2021 on the organization and functioning of the Ministry of Environment⁵⁹.

⁵²Government Decision No.71/2013 on the approval of the Regulation, structure and staff of the Medicines and Medical Devices Agency, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128144&lang=ro

⁵³Law No.420/2006 on the activity of technical regulation, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=121207&lang=ro

⁵⁴Government Decision No.1171/2018 for 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

⁵⁵Government Decision No. 143/2021 on the organization and functioning of the Ministry of Economy, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129163&lang=ro

⁵⁶Government Decision No. 690/2017 on the organization and functioning of the Ministry of Infrastructure and Regional Development, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=127649&lang=ro

⁵⁷Government Decision No. 693/2017 on the organization and functioning of the Ministry of Internal Affairs available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129543&lang=ro

⁵⁸Government Decision No. 148/2021 on the organization and functioning of the Ministry of Health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119192&lang=ro

⁵⁹Government Decision No.145/2021 on the organization and functioning of the Ministry of Environment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127621&lang=ro

Standardization

The legal framework on standardization in the Republic of Moldova is established by Law No. 20/2016 on national standardization⁶⁰.

The administrative structure for standardization is presented in the Law No. 20/2016 and Government Decision No. 969/2016 on the Regulation for the organization and functioning of the Moldovan Institute of Standardization⁶¹.

Accreditation

The legal framework for accreditation and conformity assessment in the Republic of Moldova is established by Law No. 235/2011 on accreditation and conformity assessment activities⁶².

The administrative structure for accreditation is presented in Law No. 235/2011 and Government Decision No.77/2013 on the reorganization of the State Enterprise Accreditation Center in the field of Product Conformity Assessment⁶³.

Metrology

The legal framework for the metrology field in the Republic of Moldova is established by Law on metrology No. 19/2016⁶⁴, the Government Decision No. 909/2014 on the approval of legal measurement units⁶⁵ and normative documents in the field of legal metrology. The list of normative documents is available on the website of the National Institute of Metrology⁶⁶.

⁶⁰Law No.20/2016 on national standardization available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106043&lang=ro

⁶¹Government Decision No. 969/2016 on the Regulation for the organization and functioning of the Moldovan Institute of Standardization, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=127659&lang=ro

⁶²Law No.235/2011 on accreditation and conformity assessment activities, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

⁶³Government Decision No. 77/2013 on the reorganization of the State Enterprise Accreditation Center in the field of Product Conformity Assessment, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=127658&lang=ro#

⁶⁴Law on metrology No. 19/2016, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106060&lang=ro

⁶⁵Government Decision No. 909/2014 on the approval of legal measurement units, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=122677&lang=ro#

⁶⁶Available in Romanian at: <https://inm.md/eng/national-database-of-normative-documents>

The administrative structure for metrology is presented by the Law No.19/2016 and Government Decision No. 976/2016 regarding the approval of the Regulation on the organization and functioning of the National Institute of Metrology⁶⁷.

B. Checks for conformity on product safety rules of products imported from third countries

10. Is there legislation in place providing for conformity with the rules on product safety in the case of imported products?

Conformity with the rules on product safety in the case of imported products is ensured by:

- Law No. 7/2016 on market surveillance relating to the marketing of non-food products⁶⁸, which in Chapter VI establishes the control regarding the safety and conformity of imported products, requirements regarding the release for free movement of goods, competences of the customs authority;
- Law No. 422/2006 on general product safety⁶⁹ establishing the general legal framework ensuring the safety of products making available on the market of the Republic of Moldova, including requirements for the exchange of information on dangerous products;
- Law No. 420/2006 on the activity of technical regulation⁷⁰, which establishes that national technical regulations, national conformity assessment procedures applied to products imported from the territory of the member states of the World Trade Organization shall be accorded a treatment no less favorable than similar products of national origin and similar products originating from other countries.

In addition, the Government Decisions on the approval of the technical regulations transposing the acquis of the New Approach, Global Approach and the Old Approach, establish that the making available on the market of the products complying with the provisions of the technical regulations cannot be prevented.

⁶⁷Government Decision No. 976/2016 regarding the approval of the Regulation on the organization and functioning of the National Institute of Metrology, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=94505&lang=ro

⁶⁸Law No.7/2016 on market surveillance relating to the marketing of non-food products available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

⁶⁹Law No. 422/2006 on general product safety available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro

⁷⁰Law No. 420/2006 on the activity of technical regulation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=121207&lang=ro

C. International Agreements

11. Has the country signed mutual recognition or co-operation agreements in the field of standards, testing, certification and conformity assessment (based on international standards)?

The Republic of Moldova is a signatory member to several intergovernmental agreements in the field of standardization, metrology and certification, which contain provisions on the mutual recognition of the results of conformity assessment of products:

- The agreement on carrying out coordinated policy in the field of standardization, metrology and certification (Moscow, 13 March 1992), Vol 16 71;
- The agreement between the Government of the Republic of Moldova and the Government of the Russian Federation on cooperation in the field of standardization, metrology and certification (Chisinau, 27 May 1993), Vol 2172;
- The agreement between the Government of the Republic of Moldova and the Government of the Republic of Uzbekistan on cooperation in the field of standardization, metrology and certification (Tashkent, 24 May 1997), Vol 22 (Tashkent, 24 May 1997), Volume 2273;
- The agreement between the Government of the Republic of Moldova and the Government of the Republic of Azerbaijan on cooperation in the field of standardization, metrology and certification (Baku, 27 November 1997), Vol 2374;
- The agreement between the Government of the Republic of Moldova and the Cabinet of Ministers of Ukraine on cooperation in the field of mutual recognition of the results of certification activities (Kyiv, 4 August 1998), Vol 23 75;
- The agreement between the Government of the Republic of Moldova and the Government of the Republic of Bulgaria on cooperation in the field of

⁷¹The agreement on carrying out coordinated policy in the field of standardization, metrology and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=118085&lang=ro

⁷²The agreement between the Government of the Republic of Moldova and the Government of the Russian Federation on cooperation in the field of standardization, metrology and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=116077&lang=ro

⁷³The agreement between the Government of the Republic of Moldova and the Government of the Republic of Uzbekistan on cooperation in the field of standardization, metrology and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=46770&lang=ro

⁷⁴The agreement between the Government of the Republic of Moldova and the Government of the Republic of Azerbaijan on cooperation in the field of standardization, metrology and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=49738&lang=ro

⁷⁵The agreement between the Government of the Republic of Moldova and the Cabinet of Ministers of Ukraine on cooperation in the field of mutual recognition of the results of certification activities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=52143&lang=ro

standardization, metrology and certification (Sofia, 22 June 2000), (OJ no.81-83/657 of 20.07.2001)76;

- The agreement between the Government of the Republic of Moldova and the Government of the Republic of Belarus on cooperation in the field of standardization, accreditation and certification (Chisinau, 22 February 2001), Vol 2977.
- The above-mentioned agreements were concluded for an indefinite period during 1992-2001. However, the implementation of the Agreements has become difficult due to government reforms and quality infrastructure reforms (standardization, metrology, accreditation) that have taken place in the signatory countries for more than 21 years. The signatories to the Agreements have not notified the termination.

Cooperation in the field of standardization:

The Institute for Standardization of Moldova has signed collaboration agreements with other standardization bodies to establish mutually beneficial relationships and to take over good practices:

- In 2013, the Partnership Agreement in the field of standardization was signed between the Institute for Standardization of Moldova and the Romanian Standardization Association.
- In 2013, the Memorandum of Understanding was signed between the Institute for Standardization of Moldova and the American Society for Testing and Materials.
- In 2017, the Collaboration Agreement was signed between the Institute for Standardization of Moldova and the Georgian National Agency for Standards and Metrology.
- In 2017, the Collaboration Agreement was signed between the Institute for Standardization of Moldova and the Ukrainian Standardization Agency.
- In 2017, the Partnership Agreement in the field of standardization was signed between the Institute for Standardization of Moldova and the Lithuanian Standards Board.
- In 2017, the Memorandum of Understanding and Cooperation was signed between the Institute for Standardization of Moldova and the Office for Standardization, Metrology and Testing of the Czech Republic.

⁷⁶The agreement between the Government of the Republic of Moldova and the Government of the Republic of Bulgaria on cooperation in the field of standardization, metrology and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=117175&lang=ro

⁷⁷The agreement between the Government of the Republic of Moldova and the Government of the Republic of Belarus on cooperation in the field of standardization, accreditation and certification, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=42576&lang=ro

Cooperation in the field of accreditation:

National Accreditation Center of the Republic of Moldova MOLDAC, is signatory to the:

- European Co-operation for Accreditation Multilateral Agreement (EA-BLA), being recognized for 6 types of accreditation activities (testing, calibration, medical examinations, product certification, management systems certification, and inspection), starting with October, 2017;
- Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation (ILAC MRA), being recognized for 4 types of accreditation activities (testing, calibration, medical examinations, and inspection), starting with October, 2017;
- Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA), being recognized for 2 types of accreditation activities (product certification, and management systems certification), starting with February, 2019.
- The results of accreditation activities, recognized at European and international levels, are shown through the number of accredited conformity assessment bodies, which are as follows:
 - Testing laboratories (according to ISO/IEC 17025) – 65;
 - Calibration laboratories (according to ISO/IEC 17025) – 3;
 - Testing laboratories (medical examinations according to ISO 15189) – 3;
 - Inspection bodies (according to ISO/IEC 17020) – 16;
 - Product certification bodies (according to ISO/IEC 17065) – 13;
 - Management systems certification bodies (according ISO/CEI 17021-1 and ISO/TS 22003) – 2.

Based on the provisions of these agreements, as well as the provisions of Regulation (EC) No.765/2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93, MOLDAC was subjected to EA Peer-evaluation in 2017 and 2019. Next Peer-evaluation is planned for February 2023.

In addition, MOLDAC has signed 19 Cooperation Agreements in the field of accreditation, with National Accreditation Bodies from Europe and other neighboring countries:

- TURKAK – national accreditation body from Turkey – 24.06.2005;
- RENAR – national accreditation body from Romania – 22.11.2006;
- KCA – national accreditation body from Kyrgyzstan – 27.09.2007;
- SNAS – national accreditation body from Slovakia – 17.04.2008;

- NCA – national accreditation body from Kazakhstan – 20.10.2008;
- IARM – national accreditation body from Macedonia – 24.08.2011;
- NAAU – national accreditation body from Ukraine – 08.02.2012;
- BSCA – national accreditation body from Belarus – 04.04.2012;
- CYS-CYSAB – national accreditation body from Cyprus – 21.11.2012;
- CAI – national accreditation body from Czech Republic – 02.07.2013;
- PCA – national accreditation body from Poland – 05.08.2013;
- RussAccreditation – national accreditation body from Russian Federation – 23.12.2013;
- EAK – national accreditation body from Estonia – 10.04.2014;
- BATA – national accreditation body from Bosnia & Herzegovina – 10.04.2014;
- HAA – national accreditation body from Croatia – 30.05.2014;
- ATCG – national accreditation body from Montenegro – 23.12.2014;
- AZAK – national accreditation body from Azerbaijan – 01.06.2017;
- LATAK – national accreditation body from Latvia – 23.11.2017;
- NAH – national accreditation body from Hungary – 18.09.2020.

The main objectives of the above mentioned Cooperation Agreements lay in organization of common activities as:

- Training sessions for personnel involved in accreditation processes (lead assessors, technical experts and assessors);
- Study visits oriented towards accumulating the experience of other national accreditation bodies in the fields in which MOLDAC has lack of experience;
- Other activities which are of interest for both accreditation bodies.
- Based on these agreements, MOLDAC throughout the years has obtained valuable knowledge from colleagues coming from Turkey, Poland, Slovakia, Romania, Hungary and other countries.

Cooperation in the field of metrology:

In the field of metrology, the Republic of Moldova concludes and implements mutual recognition agreements. The cooperation with international organizations has been achieved through membership, public communication, exchange of documentation, technical assistance, education and other forms, depending on the nature and manner of its achievement.

The Agreements in the field of metrology

Since 15.12.2005, the Republic of Moldova has been an associate member of the International General Conference on Weights and Measures (CGPM), which operates under the Meter Convention (1875 Treaty), which established the International Bureau of Weights and Measures (BIPM). The foundation of metrology comparability and equivalence is under the coordination of BIPM, and it has been expanded by signing (at 18.05.2007) the CIPM MRA (MRA – Mutual Recognition Arrangement) – the arrangement on mutual recognition of certificates and standards issued and maintained by the state institutes that are the signatories to this arrangement.

A great number of memorandum of mutual cooperation with National Metrology Institutes (NMI) and Designated Institutes (DI) in Europe and internationally have been signed. The signature dates with individual institutes are:

- BelGIM– the Belarus NMI - 12.02.2014;
- BRML - the Romania Bureau of Legal Metrology - 09.04.2014;
- INM - the Romanian NMI - 10.12.2015;
- CMI - the Czech NMI - 19.10.2016;
- TUBITAK UME - the Turkish NMI - 15.12.2016;
- GUM - the Poland NMI - 24.08.2017;
- IMBiH - the Bosnia and Herzegovina NMI - 2017;
- NSC "IM" - the Ukrainian NMI - 19.04.2018;
- UzNIM - the Uzbek NMI - 11.04.2018;
- GEOSTM - the Georgia NMI - 04.10.2018;
- Ukrmetrteststandard - the Ukrainian DI - 26.10.2018;
- FTMC - the Lithuania NMI - 11.04.2019.

12. Is there legislation in place providing for conformity with the rules on product safety in the case of imported products?

Conformity with the rules on product safety in the case of imported products is ensured by:

- Law No.7/2016 on market surveillance relating to the marketing of non-food products⁷⁸, which in Chapter VI establishes the control regarding the

⁷⁸Law No.7/2016 on market surveillance relating to the marketing of non-food products, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

safety and conformity of imported products, requirements regarding the release for free movement of goods, competences of the customs authority;

- Law No.422/2006 on general product safety⁷⁹ establishing the general legal framework ensuring the safety of products making available on the market of the Republic of Moldova, including requirements for the exchange of information on dangerous products;
- Law No.420/2006 on the activity of technical regulation⁸⁰, which establishes that national technical regulations, national conformity assessment procedures applied to products imported from the territory of the member states of the World Trade Organization shall be accorded a treatment no less favorable than similar products of national origin and similar products originating from other countries.

In addition, the Government Decisions on the approval of the technical regulations transposing the acquis of the New Approach, Global Approach and the Old Approach, establish that the making available on the market of the products complying with the provisions of the technical regulations cannot be prevented.

D. Technical Regulations & Conformity Assessment

13. Is there a basis for product conformity regulation and has legislation moved towards the principles applied in European harmonized legislation, i.e. minimum requirements, absence of mandatory standards, self-certification and the presumption of conformity?

The legal framework regulating product conformity includes Law No. 420/2006 on the activity of technical regulation⁸¹, Law No. 235/2011 on the activity of accreditation and conformity assessment⁸², as well as the specific technical / sectoral regulations applicable to the product, which include requirements for products, conformity assessment procedures, as well as administrative procedures.

Law No. 420/2006 provides that the technical regulations must include essential requirements that allow the application of harmonized standards, adopted as Moldovan standards, to remain voluntary. The application of the harmonized standards offers the presumption of conformity of the products with the essential

⁷⁹Law No.422/2006 on general product safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro

⁸⁰Law No.420/2006 on the activity of technical regulation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=121207&lang=ro

⁸¹Law No. 420/2006 on the activity of technical regulation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=121207&lang=ro

⁸²Law No. 235/2011 on the activity of accreditation and conformity assessment available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

requirements. The technical regulations must establish one or more relevance conformity assessment procedures for the products.

According to the provisions of Law No. 235/2011 Art. 25 the introduction and/or making available on the market of the products for which the community harmonized legislation exists, is carried out only if they meet the essential requirements, established in technical regulations, respecting the principles of free movement of products and only if they are accompanied by documents attesting their conformity.

Furthermore, for the products listed in Annex No. 3 of Law No. 235/2011, covered by the New Approach and Global Approach Directives, technical regulations are elaborated and approved by Government decisions or laws. Each technical regulation establishes that products are manufactured in accordance with Moldovan standards that adopt harmonized standards whose references have been published in the Official Journal of the European Union or parts thereof and have a presumption of conformity with the relevant essential requirements contained in the applicable technical regulation.

Economic operators (producers, authorized representatives, importers, distributors) are responsible for the compliance of the products they have introduced and made available on the market with all applicable technical regulations.

The conformity assessment of the products with the essential requirements shall be carried out by the manufacturer by carrying out, at his choice, one of the conformity assessment procedures provided for in the applicable technical regulations.

Not all products are subject to conformity assessment procedures. According to Articles 17 and 18 of Law No. 235/2011, the conformity assessment can be done voluntarily when it is not imposed by the technical regulations. This assessment may be carried out by certification, inspection, testing or a combination of these. Voluntary certification is based on contracts between stakeholders, such as producer-supplier, or the provisions set out in tenders.

2. QUALITY INFRASTRUCTURE

A. Accreditation

14. Has a single national accreditation body been set up, that acts under public authority, which is independent from conformity assessment & other public authorities?

According to Law No. 235/2011 Art.7 para (3), which is harmonized with the provisions of Regulation (EC) 765/2008, the accreditation activity is performed by the National Accreditation Center of the Republic of Moldova MOLDAC, designated as the single national accreditation body. MOLDAC is the public institution, monitored by the Ministry of Economy, designated as the specialized body of the central public administration, responsible for quality infrastructure. MOLDAC is not subordinated to any public or private authorities, it is independent from conformity assessment and other public authorities. Operation of the accreditation body is in line with ISO/IEC 17011:2017 standard and the Regulation (EC) 765/2008. The compliance of MOLDAC with these documents was proven already through the processes of Peer-evaluation performed by the European Cooperation for Accreditation (EA) performed in 2017 and 2019. Last evaluation of MOLDAC ended with zero nonconformities; this being the result of proper implementation of the provisions and requirements of ISO/IEC 17011:2017 standard and the Regulation (EC) no.765/2008.

MOLDAC is recognized at the European and International level, as being a sole accreditation body, by signing recognition agreements with European Cooperation for Accreditation (EA BLA), with International Laboratory Accreditation Cooperation (ILAC MRA), and with International Accreditation Forum (IAF MLA). By means of these agreements, the signatories recognize and accept the equivalence of the accreditation systems operated by the signing members, and also the reliability of the conformity assessment results provided by conformity assessment bodies accredited by the signing members.

Activities of MOLDAC are being consulted with the Accreditation Council – the structure acting on a public basis, which ensures the impartiality, development and compliance with the principles and policies of MOLDAC. The main responsibilities of this structure are to examine and to present some proposals on MOLDAC policies, rules for accreditation, financial aspects or accreditation criteria. All decisions of the Accreditation Council are used as recommendations to the Director of MOLDAC, who takes the final decision.

15. Is there a national plan for the accreditation of conformity assessment bodies and is it being implemented according to plan?

In accordance with the government's activity program⁸³, MOLDAC elaborates a Plan for the development of new accreditation schemes, based on market needs or requests coming from Conformity Assessment Bodies. The plan for accreditation of conformity assessment bodies is being elaborated yearly. Plans are being coordinated with the Head of Departments in charge for each type of conformity assessment bodies, and approved by the Director of MOLDAC. The fulfillment of the plans is monitored and registered by the end of the year. MOLDAC has already established and is working on the further development of the following new accreditation schemes, which are included in the Mid-term Budget plans:

- Accreditation of Certification Bodies for Persons, according to provisions of SM EN ISO/IEC 17024 standard,
- Accreditation of Validation and Verification bodies, according to requirements of SM EN ISO/IEC 17029 standard,
- Accreditation of Certification bodies of environmental management systems, according to SM EN ISO 14001 standard;
- Accreditation of medical laboratories performing Point-of-care-testing (POCT) according to SM EN ISO 22870 standard.

In accordance with the Government Decision No.1065/2017 on the approval of the National Action Plan in the field of trade facilitation for the period 2018–2020⁸⁴, the development of new accreditation schemes and the strengthening of MOLDAC capacities were foreseen.

Thus, MOLDAC has initiated the appropriate activities to expand the areas of accreditation for:

- Testing laboratories in forensic area according to SM EN ISO/IEC 17025
- Proficiency testing providers according to SM EN ISO/IEC 17043
- Reference materials producers according to SM EN ISO 17034.

⁸³Government's activity program, available in Romanian at:

https://gov.md/sites/default/files/document/attachments/programul_de_activitate_al_guvernului_moldova_vremu_rilor_bune.pdf

⁸⁴Government Decision No. 1065/2017 on the approval of the National Action Plan in the field of trade facilitation for the period 2018–2020 available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=102401&lang=ro

B. Market Surveillance

16. How is it ensured that products on the market throughout the country meet standard requirements? Alternatively, is there a reliable and standardized system of pre-marketing authorization?

Compliance with the requirements for products on the national market is ensured by applying the legal framework - Law No.7/2016 on market surveillance of the marketing of non-food products⁸⁵, which entered into force in 2017 and Law No.422/2006 on general product safety⁸⁶.

Market surveillance authorities take measures to ensure that products introduced and made available on the market comply with the requirements of the applicable technical regulations and do not present a danger to health and safety in general, health and safety at work, consumer protection, environmental protection and other issues of public interest. All market surveillance authorities constitute a market surveillance system.

The Ministry of Economy is the main coordinator for market surveillance activities, according to the Law No.7/2016 through Council for Consumer Protection and Market Surveillance as an advisory body.

The main tasks of the Ministry of Economy are:

- to develop State policy in the field of market surveillance;
- to evaluate the results of the activities carried out by the market surveillance authorities and the effects activities on the market;
- to develop and approve the market surveillance programme on the basis of the sectoral programmes;
- to publish the annual general market surveillance programme on its official website and, where appropriate, make it available to the public by other means of communication; establish appropriate mechanisms for communication and coordination between market surveillance authorities;
- to organize and coordinate the exchange of information between the market surveillance authorities and the customs body.

The coordination of market surveillance activity is conducted on the basis of the Regulation of the Council, approved by Government Decision No.964/2016⁸⁷. The Council is composed of designated representatives of central public authorities,

⁸⁵Law No. 7/2016 on market surveillance of the marketing of non-food products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

⁸⁶Law No. 422/2006 on general product safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro

⁸⁷Government Decision No.964/2016 on the Coordinating Board for Consumer Protection and Market Surveillance, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102589&lang=ro

market surveillance authorities, the customs authority, consumer associations and sectoral professional associations.

The Council has the following tasks:

- it shall analyze and/or propose mechanisms to coordinate the work of market surveillance authorities operating in the regulated areas;
- regularly assess the conduct of market surveillance activities by the relevant authorities;
- establish the framework for the preparation and updating, as appropriate, of the annual overall market surveillance programme;
- establish the appropriate framework for the training of staff specialized in the control of products made available on the market;
- participate in consultations on the legal, regulatory and institutional framework in the field of market surveillance.

Government Decision No. 1076/2016 approving the Regulation on the procedures for cooperation between the market surveillance authorities and the Customs Service sets⁸⁸ out the procedures and mechanisms for cooperation between the market surveillance authorities and the customs body with a view to establishing the control mechanism of non-food products for their release for free circulation.

Also, the legal framework for market surveillance is represented by the following laws and government decisions:

- Law No. 7/2016 on market surveillance of the marketing of non-food products⁸⁹
- Law of metrology No. 19/2016⁹⁰
- Law No.131/2012 on state control of entrepreneurial activity⁹¹
- Customs Code⁹²
- Government Decision No. 1054/2016 on risk grades for non-food products and their award criteria⁹³

⁸⁸ Government Decision No.1076/2016 approving the Regulation on the procedures for cooperation between the market surveillance authorities and the Customs Service sets, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=95324&lang=ro

⁸⁹ Law No.7/2016 on market surveillance of the marketing of non-food products, available in Romanian at

https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

⁹⁰ Law of metrology No.19/2016 available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106060&lang=ro

⁹¹ 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

⁹² Customs Code available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130520&lang=ro

⁹³ Government Decision No.1054/2016 on risk grades for non-food products and their award criteria, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110667&lang=ro

- Government Decision No. 1116/2016 approving the Regulation on the operation of the Rapid Information System for dangerous products⁹⁴
- Government Decision No.1212/2016 on the approval of the Methodology for risk assessment of non-food products intended for consumers and selection of corrective measures⁹⁵
- Government Decision No. 1096/2017 approving the unified requirements for the development of market surveillance programmes⁹⁶
- Government Decision No. 637/2018 on the approval of the Technical Concept of the National Automated Information and Communication System for Market Surveillance⁹⁷.

17. Do market surveillance authorities control products on their national market (domestic products or products coming from third countries)?

According to Art.7 para. (1) of the Law no.7/2016 on market surveillance of the marketing of non-food products, the competence of the market surveillance authorities includes the types (categories) of products subject to technical regulations.

The list of authorities responsible for market surveillance by regulated areas, regulatory authorities and regulated areas (product groups) are set out in the Annex to Law no.7/2016 on market surveillance in respect of the marketing of non-food products, which provides the following provisions:

Regulated area (product group)	Applicable technical regulations
Agency for Consumer Protection and Market Surveillance	
Low voltage equipment	Government Decision No. 745/2015 approving the Technical Regulation for the placing on the market of electrical equipment designed for use within certain voltage limits ⁹⁸

⁹⁴Government Decision No.1116/2016 approving the Regulation on the operation of the Rapid Information System for dangerous products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=102598&lang=ro

⁹⁵Government Decision No.1212/2016 on the approval of the Methodology for risk assessment of non-food products intended for consumers and selection of corrective measures, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=96091&lang=ro

⁹⁶Government Decision No.1096/2017 approving the unified requirements for the development of market surveillance programmes, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=102441&lang=ro

⁹⁷Government Decision No.637/2018 on the approval of the Technical Concept of the National Automated Information and Communication System for Market Surveillance, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108768&lang=ro

⁹⁸Government Decision No.745/2015 approving the Technical Regulation for the placing on the market of electrical equipment designed for use within certain voltage limits, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110263&lang=ro

Electromagnetic Compatibility	Government Decision No 807/2015 approving the Technical Regulation on Electromagnetic Compatibility of Equipment ⁹⁹
Toys	Government Decision No.808/2015 approving the Technical Regulation on the safety of toys ¹⁰⁰)
Non-automatic weighing machines	Government Decision No. 267/2014 approving the Technical Regulation on non-automatic weighing machines ¹⁰¹
Means of measurement	Government Decision No. 408/2015 on the approval of the Technical Regulation on making available on the market of measuring instruments ¹⁰²
Gaseous fuel burners	Government Decision No. 109/2022 approving the Technical Regulation on appliances burning gaseous fuels ¹⁰³
Hot water boilers	Government Decision No.428/2009 on the approval of the Technical Regulation Efficiency requirements for new hot water boilers fired by liquid or gaseous fuels ¹⁰⁴
Energy labeling	Government Decision No. 1003/2004 approving the regulations on energy labeling requirements for certain energy-related products ¹⁰⁵
Personal protective equipment	Government Decision No. 108/2022 approving the Technical Regulation on personal protective equipment ¹⁰⁶
Agency for Technical Supervision	
Industrial machinery	Government Decision No. 130/2022 on the approval of the Technical Regulations for Industrial Machinery ¹⁰⁷
Lifts	Government Decision No. 8/2016 on the approval of the Technical Regulation on lifts and safety components for lifts ¹⁰⁸
Potentially explosive environments	Government Decision No. 1407/2016 approving the Technical Regulations on equipment and protective systems intended for use in potentially explosive environments ¹⁰⁹

⁹⁹Government Decision No.807/2015 approving the Technical Regulation on Electromagnetic Compatibility of Equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110320&lang=ro

¹⁰⁰Government Decision No.808/2015 approving the Technical Regulation on the safety of toys, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110321&lang=ro

¹⁰¹Government Decision No.267/2014 approving the Technical Regulation on non-automatic weighing machines, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109737&lang=ro

¹⁰² Government Decision No.408/2015 on the approval of the Technical Regulation on making available on the market of measuring instruments, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110038&lang=ro

¹⁰³Government Decision No.109/2022 approving the Technical Regulation on appliances burning gaseous fuels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130430&lang=ro

¹⁰⁴Government Decision no.428/2009 on the approval of the Technical Regulation Efficiency requirements for new hot water boilers fired by liquid or gaseous fuels, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=103391&lang=ro

¹⁰⁵Government Decision No.1003/2004 approving the regulations on energy labeling requirements for certain energy-related products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128814&lang=ro

¹⁰⁶Government Decision No.108/2022 approving the Technical Regulation on personal protective equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130459&lang=ro

¹⁰⁷Government Decision No.130/2022 on the approval of the Technical Regulations for Industrial Machinery, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109660&lang=ro

¹⁰⁸Government Decision No.8/2016 on the approval of the Technical Regulation on lifts and safety components for lifts, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109570&lang=ro

¹⁰⁹Government Decision No.1407/2016 approving the Technical Regulations on equipment and protective systems intended for use in potentially explosive environments, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=96923&lang=ro

Cableway installations designed to carry persons	Government Decision No. 744/2015 approving the Technical Regulation on cableway installations designed to carry persons ¹¹⁰
Simple pressure vessels	Government Decision No. 368/2015 approving the technical regulation on the placing on the market of simple pressure vessels ¹¹¹
Pressure equipment	Government Decision No.1333/2016 approving the Technical Regulation on making pressure equipment available on the market ¹¹²
Transportable pressure equipment	Government Decision No.1094/2017 approving the Technical Regulation on transportable pressure equipment ¹¹³
Explosives for civil use	Government Decision No. 1324/2016 approving the Technical Regulation on essential safety requirements for civil explosives, making available on the market and control of civil explosives ¹¹⁴ Government Decision No. 1236/2016 approving the Technical Regulation on the establishment of a system for the identification and traceability of explosives for civil use ¹¹⁵
Pyrotechnic articles	Law No.143/2014 on the regime of pyrotechnic articles ¹¹⁶
Construction products	Government Decision No. 913/2016 approving the Technical Regulation on minimum requirements for the marketing of construction products ¹¹⁷
National Agency for Electronic Communications Regulation and Information Technology	
Radio equipment	Government Decision No.34/2019 on the approval of the Technical Regulation on the placing on the market of radio equipment ¹¹⁸
Environmental Protection Inspectorate	
Packaging and packaging waste	Government Decision No.561/2020 approving the Regulation on packaging and packaging waste ¹¹⁹
Medicines and Medical Devices Agency	
Medical devices	Government Decision No.702/2018 on the approval of the Technical Regulation Efficiency requirements for new hot water boilers fired by liquid or gaseous fuels ¹²⁰

¹¹⁰Government Decision No.744/2015 approving the Technical Regulation on cableway installations designed to carry persons, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110261&lang=ro

¹¹¹Government Decision No.368/2015 approving the technical regulation on the placing on the market of simple pressure vessels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109915&lang=ro

¹¹²Government Decision no.1333/2016 approving the Technical Regulation on making pressure equipment available on the market, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110443&lang=ro

¹¹³Government Decision No.1094/2017 approving the Technical Regulation on transportable pressure equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102439&lang=ro

¹¹⁴Government Decision No.1324/2016 approving the Technical Regulation on essential safety requirements for civil explosives, making available on the market and control of civil explosives, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102623&lang=ro

¹¹⁵Government Decision No.1236/2016 approving the Technical Regulation on the establishment of a system for the identification and traceability of explosives for civil use, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102604&lang=ro

¹¹⁶Law no.143/2014 on the regime of pyrotechnic articles, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106094&lang=ro

¹¹⁷Government Decision No.913/2016 approving the Technical Regulation on minimum requirements for the marketing of construction products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110395&lang=ro

¹¹⁸Government Decision no.34/2019 on the approval of the Technical Regulation on the placing on the market of radio equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130653&lang=ro

¹¹⁹Government Decision no.561/2020 approving the Regulation on packaging and packaging waste, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122773&lang=ro

¹²⁰Government Decision no.702/2018 on the approval of the Technical Regulation Efficiency requirements for new hot water boilers fired by liquid or gaseous fuels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103391&lang=ro

	<p>Government Decision No.703/2018 approving the Regulation on the conditions for placing on the market of in vitro diagnostic medical devices¹²¹</p> <p>Government Decision No.704/2018 approving the Regulation on the conditions for placing active implantable medical devices on the market¹²²</p>
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Market surveillance is carried out in accordance with sectoral programmes approved annually by 1 December for the following year by the market surveillance authorities in their areas of responsibility and placed on the authorities' websites. The sectoral programme I includes the implementation of market surveillance activities for a product category, taking into account the risks they present. The unified requirements for the elaboration of the general and sectoral market surveillance programme are laid down in Government Decision No.1096/2017 on the approval of the unified requirements for the elaboration of market surveillance programmes. Based on the sectoral programmes, the Ministry of Economy prepares the general market supervision programme for the following year and places the information on the website of the coordinating authority.

The control of the safety and conformity of imported products according to the provisions of the Law No.7/2016 chapter VI, is carried out by the Customs Service. The Service checks on the characteristics of products before their release for free movement with the aim of preventing the introduction into the customs territory of the Republic of Moldova of products which present a serious risk to health, safety, the environment or any other public interest.

The Customs Service has the following main tasks in the verification of imported products:

- participates in the implementation of the state policy in the field of market surveillance;
- contributes, within the limits of its competences, to ensure the economic security of the State;
- carries out control of documents and/or identification of products before they are put for free movement on the customs territory of the Republic of Moldova;
- decides on the suspension of the release for free movement of products presented for customs control and customs clearance;

¹²¹Government Decision no.703/2018 approving the Regulation on the conditions for placing on the market of in vitro diagnostic medical devices, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108837&lang=ro

¹²²Government Decision no.704/2018 approving the Regulation on the conditions for placing active implantable medical devices on the market, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108838&lang=ro

- allows the destruction of the products under customs supervision, in compliance with the provisions of the Customs Code, Law and other normative acts in force.

The Customs Service verifies the products based on the risk analysis, according to the information provided by the market surveillance authorities.

The Customs Service exchanges the necessary information in electronic format with the market surveillance authorities, which are used for customs purposes, but also for effective monitoring of products and market surveillance.

If the market surveillance authorities have taken corrective measures concerning the introduction into the customs territory of the Republic of Moldova of a product which does not meet the essential requirements, they shall inform the Customs Service about the product in question.

18. How is the independence and impartiality of market surveillance authorities ensured?

In addition to the role and duties of the market surveillance authorities and the Customs Service established by the Law No.7/2016. The mentioned law expressly defines the basic principles of market surveillance in the Republic of Moldova, namely:

- objectivity, impartiality and competence of market surveillance authorities and customs body in conducting market surveillance;
- the non-admission of duplication of functions of market surveillance authorities;
- when applying sanctions for non-compliance with the essential requirements, respect for the principle of proportionality between the size of the sanction and the damage caused by the infringement admitted.

19. How often is testing done? Please provide statistics for the last year.

Sampling and laboratory testing of products is carried out on the basis of a reasoned written decision by the head of the market surveillance authority. The method of sampling and the quantity of the sample shall correspond to the requirements of the applicable standards or technical specifications for the product concerned. Tests of samples of products shall be carried out in accredited testing laboratories on the basis of contracts between laboratories and market surveillance authorities. The parameters tested are determined by the market surveillance authorities according to the field of competence of the testing laboratory. Testing of samples of products taken in accredited testing laboratories involved in the conformity assessment of products and held by producers of these products is not allowed.

The costs of the samples and laboratory tests (analyses and measurements) are borne by the market surveillance authorities. If results of laboratory tests (analyses and measurements) show that the product is dangerous, presents a risk and/or does not meet the essential requirements, the costs of taking samples and carrying out laboratory tests shall be borne by the economic operator subject to inspection.

Statistical data on sampling and testing results for the year 2021 are presented in the table below:

Domain (product)	Number of controls	Number of taken samples	Number of tests performed	Number of non- compliant products found after testing
Low voltage equipment	149	6	6	6
Toys	61	10	10	-
Pyrotechnic articles	28	5	-	-
Construction products	30	3	3	3

20. Do market surveillance authorities take restrictive measures which could include, for example, prohibition of their marketing or their withdrawal for reasons of health/safety, environmental risk or any other risk to public interests, incomplete labeling, inadequate consumer information, or failure to comply with EU legal requirements?

Depending on the level of risk that is present or may occur to the health and safety of consumers, the market surveillance authority selects the corrective measures provided in Law No.7/2016, Law No. 422/2006 and the Methodology on risk assessment of non-food products for consumers and selection of corrective measures (Methodology), approved by Government Decision No. 1212/2016. It should be noted that the Methodology partially transposes Commission Decision 2010/15/EU of 16 December 2009 establishing a guide for the use of the Community Rapid Information System “RAPEX”.

- The market surveillance authority shall, as appropriate, take one of the following measures:
- In the case a product presents a serious risk, i) prohibition on placing on the market of the product; ii) withdrawal or recall of the product and warning the public of the subsequent risk, iii) destruction of the product permanently banned from sale, in case this is measure of removing the hazard, or other measures rendering it unusable.
- In the case a product may present a serious risk: i) temporary prohibition on placing the product on the market during the period needed to assess safety, checks and controls.
- In the case a product is likely to present a risk only under certain conditions or only to certain persons and when this risk is not covered by

the requirements of EU legislation or technical regulations transposing it, i) applying on the product of appropriate and clearly worded warnings, in the national language, easy for consumers to understand, concerning the risks which it may present; ii) establishing prior conditions to be fulfilled before the product is placed on the market iii) warning persons exposed to risk about it in a timely manner in an appropriate form, including via publication of special warnings.

- In the case of a higher risk product, i) temporary suspension of the product from the market and ii) prohibition of the product on placing on the market.
- In the case of a product presenting a medium risk, temporary suspension of the product from the market
- In the case of a product which does not comply with the requirements set out in EU harmonization legislation or in the technical regulations transposing it or the applicable technical regulations, i) temporary suspension of the product from the market; ii) prohibition of the product on placing on the market; iii) withdrawal from circulation; iv) recall from consumers (users), v) destruction of products posing a serious risk which are permanently banned from the market, in case this is the only means of removing the hazard.

Statistical data on the results of market surveillance activities for the year 2021 are presented in the table below:

Domain	Number of controls		Restrictive measures				Sanctions applied	
	Carried out	Non-compliances	Temporary prohibition	Prohibition on placing on the market	Withdrawal from the market	Non-compliances with technical regulation applied	Number of sanctions	Amount of fines, MDL
Low voltage equipment	149	81	10	10	1	29	50	496050 (≈ EUR 24805,5)
Electromagnetic compatibility	41	13	7	-	-	8	10	92000

								(≈ EUR 4600)
Toys	61	49	17	8	-	8	18	19960 0 (≈ EUR 9980)
Non- automatic weighing machines	1	1	-	-	-	-	2	10000 (≈ EUR 500)
Burning gaseous fuels	28	20	10	-	-	12	12	95500 (≈ EUR 4475)
Hot water boilers	21	8	2	-	-	3	4	-
Energy Labeling	103	79	28	8	-	-	14	-
Pyrotechnic articles	28	5	-	-	-	-	-	-
Construction products	30	22	3	3	3	-	58	48000 (≈ EUR 2400)
Radio equipment	46	-	-	-	-	-	-	-
Packaging and packaging waste	422	-	-	-	-	-	148	14990 0 (≈ EUR 7495)
Materials and articles intended to come into contact with food	27	-	-	-	-	-	-	-
Cosmetic products	10	-	-	-	-	-	-	-

C. Metrology

21. Does Moldova have a metrology system and an official metrology body? If so, is the metrology body adequately staffed and equipped?

Republic of Moldova has a regulated national metrology system, headed by the Ministry of Economy of Republic of Moldova, as a central authority which is the founder of National Metrology Institute (INM-MD). INM-MD is a Public Institution which implements, at the national level, the policy in the field of metrology, by assuring the uniformity, legacy, accuracy and traceability of measurements in the Republic of Moldova.

INM-MD exercises the functions according to the Regulation of organization and functioning of the National Institute of Metrology approved by Government Decision No.976/2016¹²³.

National metrology system includes:

- Central authority for metrology – The Ministry of Economy;
- National Metrology Institute;
- National Measurement Standards;
- National Council of Metrology;
- Metrological services of economic operators;
- Agency for Consumer Protection and Market Surveillance.

The Ministry of Economy, as the Central authority for metrology, develops and coordinates the implementation of state policy in the field of metrology, including on ensuring the measurement traceability.

Following the studying of needs of the national economy in the field of metrology and identifying the priorities of the state policy in this field, the Central authority for metrology elaborates draft legislative and normative acts in view of ensuring metrological traceability of measurement results to the International System of Units (SI).

¹²³Government Decision No.976/2016 regarding the approval of the Regulation on the organization and functioning of the National Institute of Metrology, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=94505&lang=ro

In addition, the Central authority for metrology ensures the harmonization of normative documents in the field of legal metrology, with international and European practice and approves these documents, correlates the activities in the field of metrology with the activities in the field of accreditation, thus designates the legal entities for performing metrological verifications of measuring instruments subject to legal metrological control and for performing measurements in areas of public interest, monitors the designated legal entities.

The National Measurement Standards, which respond to the needs of the national economy are managed by INM-MD. The management of the National Measurement Standards represents the continuous realization of measurements and evaluation of results, their interpretation and improvement of measurement techniques.

Currently, INM-MD is adequately staffed and equipped. INM-MD manages 19 National Measurement Standards, which cover 80% of national market needs.

The institutional and administrative capacities of the National Metrology Institute (INM-MD)
The institutional and administrative capacities of NM-MD are provided in the table below.

Institutional and administrative capacities of INM-MD

Institution level/institution/ organizational unit in the institution	Staff number		
	Professional staff	Administrative staff	Technical staff
Office of Director and Deputy Director	1	1	-
Administrative Department	8	1	8
Applied Metrology Department	27	2	-
Legal Metrology Department	7	2	-
Quality manager	1	-	-
Total	58		

INM-MD currently employs 58 employees, including 29 acting in the field of scientific metrology department, 9 acting in the field of legal metrology department, 17 acting in the administrative department. From all employees 90% completed higher education, 2 employees currently do their PhD studies.

The responsibilities and functions of INM-MD are described in the Law of metrology No. 19/2016¹²⁴ which is focusing on two main directions: legal metrology and general (scientific) metrology.

Legal metrology involves the control of measuring instruments in the field of legal metrology in accordance with the Official List of measuring instruments and

¹²⁴Law of metrology No. 19/2016, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=106060&lang=ro

measurements subject to legal metrology control approved by Government Decision No.1042/2016¹²⁵.

The activities performed within the field of legal metrology include the legal metrological control by type approval and metrological verification of measuring instruments, in special situations, when only INM-MD is technically equipped to perform such verifications.

In addition, the responsibilities of INM-MD include, among others:

- metrological expertise and expertise to draft normative documents in the field of legal metrology;
- develop draft training programs in the field of metrology;
- develop draft normative documents in legal metrology, harmonized with international and regional practice, and
- manage the National database of normative documents in the field of legal metrology and the process of elaboration of legal metrological norms, legal metrological procedures. Economic operators and other stakeholders have the opportunity to access the National database of normative documents in the field of legal metrology on the institution's website.¹²⁶

General (scientific) metrology is focused on the maintenance, research and development of the components of the National Measurement Standards. The purpose of these activities is the assurance of traceability and uniformity of measurements conducted on the territory of the Republic of Moldova.

For achieving this objective, are approved the Annual Program¹²⁷, which have three main directions:

- undertaking traceable measurement units
- preserving the measurement units
- disseminating the measurement unit.

All activities are realized according to the Quality Management System of INM-MD, which ensures their conformity with the standard SM ISO/CEI 17025.

Quality Management System includes the calibration procedures, through which it ensures the dissemination of the measurement units to all stakeholders, and these procedures are continuously developing.

¹²⁵Government Decision No. 1042/2016 regarding approval Official list of measuring instruments and of measurements subject to metrological control legal available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122681&lang=ro

¹²⁶Available in Romanian at: <https://inm.md/rom/fondul-national-de-documente-normative-in-domeniul-metrologiei-legale-1>

¹²⁷Available in Romanian at: <https://inm.md/rom/programe-de-dezvoltare-si-activitate>

Additionally, INM-MD organizes interlaboratory comparisons in public interest areas. The comparisons have the mission to demonstrate the capability of laboratories to realize correct testing and to generate trustworthy measurement results.

Thus, INM-MD supports the implementation of European practices in the Republic of Moldova, the transposition of accurate measurement techniques and the protection of consumers in the country from possible effects of wrong measurements.

The National Standards System is the technical basis, which ensures the taking over, preservation and dissemination of measurement units.

National Metrology Council is a consultative body under the central authority for metrology, in which all stakeholders are represented and which submits proposals of policies in the field of metrology. The setting up and organization of the National Metrology Council, the composition, the members' selection mode and their functions, are defined in the Rules of organization and functioning of the National Metrology Council, which are developed and approved by the central authority for metrology.¹²⁸

The metrological services of economic operators ensure the uniformity and the accuracy of measurements in different measurement fields. Today, in Republic of Moldova, a total 12 conformity assessment bodies were accredited:

- 3 calibration laboratories (in accordance with SM EN ISO/IEC 17025)
- 9 metrological verification laboratories (in accordance with SM EN ISO/IEC 17020).

Measuring instruments in the field of legal metrology control are subject to metrological verification carried out by metrological verification laboratories. These laboratories are accredited and designated by the Central Metrology Authority. The designation is made in accordance with Government Decision No 1118/2018 on the approval of the General Regulation of legal metrology on designation for metrological verification of measuring instruments and for conducting measurements in areas of interest.¹²⁹

Consumer Protection and Market Surveillance Agency performs, on behalf of the state, the metrological surveillance under Law No.7/2016 on market surveillance relating to the marketing of non-food products, as well as Law No.131/2012 on state control of entrepreneurial activity. It is subordinate to the central authority for metrology and performs without charging tariffs or fees, the metrological

¹²⁸Order No.3/2022 on the approval of the Regulation organization and functioning of the National Metrology Council it available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129602&lang=ro

¹²⁹Government Decision No. 1118/2018 on the approval of the General Regulation of legal metrology on designation for metrological verification of measuring instruments and for conducting measurements in areas of interest available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109884&lang=ro

surveillance of compliance by economic operators of the regulations on legal metrology.

22. Is there a national programme for the development of the metrology structure? Please provide details.

The Ministry of Economy draws up an annual plan¹³⁰ of activities covering all areas under its control, one of which is the quality infrastructure, of which the field of metrology is also a part. The INM-MD takes the program of the central authority for metrology as bases for developing its own annual activity plan¹³¹. This plan is harmonized with strategies of EURAMET, in the area of scientific metrology, and with WELMEC, in the field of legal metrology.

In addition, there is a valid and updated sectoral spending strategy for quality infrastructure (SSC) for period 2022-2024¹³². These SSCs are approved by the Government and include a spending strategy that includes the core costs of INM-MD activities as metrology. For the development of metrology structure are planned objectives as maintain the membership of EURAMET, WELMEC, OIML and continual activity based on CIPM-MRA Arrangement, development of National Measurement Standards, participation in regional/international comparisons and obtaining of international recognition by publication of best calibration measurement capabilities (CMC) into BIPM KCDB. In addition, in the SSC are established indicators of achievements that refer to the developments and cover with traceable measurements the needs of the national market.

23. Are scientific metrology and legal metrology treated differently? How is cooperation and coordination ensured?

Scientific metrology is completely within the INM-MD and accredited calibration laboratories.

Scientific metrology implies development of laboratories implementing National Measurement Standards and providing traceability of international measurement standards through calibration systems carried out within the INM-MD. National Measurement Standards are held by the INM-MD.

Traceability of international measurement standards in Republic of Moldova is ensured through the laboratories of INM-MD, i.e. through calibration using

¹³⁰Activity plan of Ministry of Economy, available in Romanian at:
https://me.gov.md/sites/default/files/planul_de_activitate_al_me_2022.pdf

¹³¹Activity plan of INM-MD, available in Romanian at:
<https://inm.md/rom/programe-de-dezvoltare-si-activitate>

¹³²Sectoral spending strategy for quality infrastructure (SSC) for period 2022-2024 available in Romanian at:
https://me.gov.md/sites/default/files/proiectul_strategiei_sectoriale_de_cheltuieli_pe_sectorul_infrastructura_calitatii_si_protectia_consumatorilor_pentru_anii_2022-2024.pdf

national measurement standards of other national metrology institutes from other country that are signatories to the CIPM MRA Agreement and have published calibration and measurement capabilities in the KCDB database of the International Bureau of Weights and Measures in Paris (BIPM).

Lower level measurement standards in Republic of Moldova ensure traceability using the standard of the INM-MD, calibration laboratories accredited according to SM EN ISO/IEC 17025 standard by the MOLDAC and national metrology institutes from other country that are signatories to the CIPM MRA Agreement and have published calibration and measurement capabilities in the KCDB database of the International Bureau of Weights and Measures in Paris (BIPM) or calibration laboratories accredited according to EN ISO/IEC 17025 standard by other accreditation body (MLA signatories within the EA in the area of calibration).

Laboratory for chemistry analysis ensures traceability of results by using certified reference materials. Certified reference materials are recognized if they are prepared in accordance with SM EN ISO 17034 standard General requirements for the competence of reference materials producers.

Internationally recognized competence of the national measurement standards obtained through the registration of Calibration and Measurement Capabilities (CMC) in the Key Comparison Database (KCDB BIPM) within the CIPM MRA. CMS are maintained by the INM-MD and published in the Appendix C¹³³, have been achieved for the following areas:

- Ionizing radiation – 2 entries of 15 November 2016;
- Dimensional – 1 CMC entry of 29 October 2017;
- Electricity – 4 CMC entries of 28 March 2020;
- Temperature – 69 CMC entries of 31 March 2020;

INM-MD of the brings the EU best practice in the field of scientific metrology by participating into EMPIR (European Metrology Programme for Innovation and Research) projects¹³⁴ and implements this knowledge by linking national stakeholders needs to the project, from one hand, and transfers this knowledge by training of legal metrology representatives from other hand.

Legal metrology implies control of measuring instruments in the areas of public interest (regulated areas) according to the Law on Metrology No 19/2016. List of measuring instruments and measurements, subject to legal metrological control, is approved by the Government and specifies:

¹³³Database (KCDB BIPM) at:

<https://www.bipm.org/kcdb/cmc/quick-search?keywords=Republic+of+Moldova>

¹³⁴EMPIR projects at: <http://dosetrace-empir.eu/>; <https://rholiq.org/>; <https://metfortc-empir.org/home-en>; <https://www.ptb.de/empir2021/smart-phora/home/>; <https://projectcefton.com/>

- the categories and the range of measuring instruments used in measurements of sizes, such as acoustic, chemical, ultrasound and vibration, electricity and magnetism, flow, ionizing radiation, lengths, mass and derived quantities, photometry and radiometry, thermometry, frequency and time;
- methods of metrological control applicable to each assortment of measuring instruments, the maximum permissible range between two successive metrological verifications;
- the categories of measurements performed in the areas of public interest specified in paragraph
- Traceability of measuring instruments used in metrological verification laboratories is ensured through the laboratories of INM-MD.

D. Standardization

24. Is there an independent standardization body able to implement European and international standards with adequate staff resources and financing?

The Republic of Moldova has an established and operational standardization system, compatible with the rules and practices of international and European standardization. The national standardization rules are based on TBT/WTO rules and principles and CEN/CENELEC guides and Internal Regulations. The national standardization body of the Republic of Moldova is the Institute for Standardization of Moldova, which is a public institution subordinated to the Ministry of Economy of the Republic of Moldova as a specialized body of central public administration, responsible for quality infrastructure. ISM was founded in 2013 as an independent and the only state body responsible for the area of standardization, established pursuant to the Law on standardization No20/2016¹³⁵ and Government Decision No 969/2016 on the Regulation for organization and operation Institute of Standardization of Moldova¹³⁶.

According to the Article 7 on the Law on standardization No 20/2016, the Standardization Council of the National Standardization Body is a consulting body in problems of strategy and development in the field of national standardization. The Standardization Council consists of representatives of the stakeholders (from economic area, scientific, educational, and similar institutions, state administrative bodies, non-governmental organizations, professional associations, consumers,

¹³⁵Law No. 20/2016 on standardization, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106043&lang=ro

¹³⁶Government Decision No. 969/2016 on the Regulation for organization and operation Institute of Standardization of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127659&lang=ro

etc.). The permanent member of the Standardization Council is a representative of the central body of the public administration, responsible for quality infrastructure.

The activity of the standardization is financed from two sources. ISM participates in the medium and short term strategic financial planning and has the annual possibility to present proposals regarding the activities carried out and their financing from the state budget. At the same time, ISM offers paid services, such as training courses and standardization consultancy, which is an additional source of funding. This type of budget consists of two different sources of financing, allows the realization of investments in increasing the institutional capacities of ISM and offers to ISM the possibility to take decisions independently and transparently.

The budget of the Institute for Standardization of Moldova was planned for 29 staff, and it currently provides conditions for performing the planned activities. The main organizational units of the ISM are the Standardization Department, the Communication and External Relations Department, the Center for Business Support in Standardization, and the Certification body. The current number of staff of the Institute for Standardization of Moldova is 29, out of which 28 hold a university degree and 1 a secondary education qualification.

Institutional and administrative capacities of the Institute for Standardization of Moldova

Institution level/institution/ organizational unit in the institution	Staff number	
	Professional staff	Administrative staff
Office of Director and Deputy Director	1	3
Certification body	1	1
Standards Department	11	1
Communication and External Relations Department	4	1
Center for Business Support in Standardization	2	1
Accountant	-	1
Integrated management system	1	
Building administrator	1	
Total	29	

ISM is a correspondent member at the International Organization for Standardization (ISO), associate member at the International Electrotechnical Commission (IEC), companion member at the European Committee for Standardization (CEN) and European Committee for Standardization in Electrical Engineering (CENELEC), observer member at European Telecommunications Standards Institute (ETSI). The status of members within above-mentioned organizations offer to the ISM the right to adopt European and international standards as Moldovan standards. At the same time, being a member of European

and international standardization organizations, ISM has the right and possibility to be involved in the process of drafting standards at European and international level. At the same time, by taking the good practices ISM improved the basic documents for the national standardization system-National Standardization Rules, which was developed based on TBT/WTO rules and principles and CEN/CENELEC guides and Internal Regulations.

The National Standardization Rules reflect the basic standardization principles:

- standards are voluntary;
- standardization is industry-initiated and market-driven;
- openness to every interested stakeholder to join a TC;
- balance of interests within a TC;
- TC decisions based on consensus;
- separation of standardization from technical regulation.

All the standards are voluntary. However, there are cases when authorities make direct (dated and undated) references to standards and these become mandatory.

For an efficient planning and development of the standardization system, ISM has developed a number of strategic documents, such as ISM Activity Strategy 2021-2023, ISM Communication strategy 2020-2022, Annual Activity Plan and Annual National Standardization Programme and is under development the National Standardization Strategy. The National Standardization Strategy will be developed with the support of international experts and will consider the further strategic development of the standardization segment in the light of the priorities of the national economy of the Republic of Moldova.

One of the strategic objectives of the ISM activity is obtaining the status of full member at CEN and CENELEC. In this context, since 2017, ISM annually performs the assessment of the national standardization activities to establish the degree of compliance with the requirements of the Guide 22 of CEN/CENELEC.

The ISM evaluates the needs assessments for investment and the expertise and technical knowledge of its staff required for participating in the European system of standards, which are the basis for the annual activity and budget planning.

Additionally, the status of membership offers ISM the possibility to take over good practices in the standardization field and become a modern, progressive, and efficient NSB. In this context, ISM has been implemented 4 management systems in its activity: Quality management system (QMS), according to ISO 9001:2015, Anti-bribery management system (ABMS), according to ISO 37001:2016, Information Security management system (ISMS), according to ISO/IEC 27001:2017, Business Continuity management system (BCMS), according to ISO 22301:2020, which was integrated and two of them are certified - QMS and ABMS.

Adequate information and advisory support to the interests of SMEs, as potential but also as most users of standards, will promote their access to modern information (modern requirements set by modern standards) and would facilitate the understanding of the process, but and the benefits of implementing the standards would implicitly condition the development of these enterprises and the increase of their turnover. For this reason, ISM has created the Center Business Support in Standardization, whose primary purpose is to provide information support to standard users. Also ISM has developed an online platform for standards dissemination¹³⁷, to facilitate stakeholder access to standards. The platform allows the commercialization of standards in electronic format, the protection of copyright on standards. The platform is a useful tool for standards selling but also an effective tool in identifying the required standard.

These achievements contribute to resource optimization, risk management, and as result to the progress of the standardization field in the Republic of Moldova.

25. Has the standardization body started to withdraw national standards that conflict with European Standards?

With the signing of the Association Agreement between the European Union and the Republic of Moldova, the Republic of Moldova is committed to implementing and promoting European principles and practices, including in the field of quality infrastructure. Alignment with European experience and practices aims to adopt the full body of European standards and the abolition of conflicting Moldovan standards.

Once the European standards are adopted, ISM has to withdraw the national conflictual standards. In this regard ISM established clear criteria and procedure, with a transparent and inclusive process, involving main stakeholders via project national TC (*when relevant*).

The number and period of withdrawal of conflictual standards

No.	Year	Number of national standards canceled
1.	2015	315
2.	2016	2 200
3.	2017	1 594
4.	2018	1 742
5.	2019	944
6.	2020	1 132

¹³⁷Moldovan Standards Catalogue, available in English at: <https://shop.standard.md/en>

7.	2021	1 142
Total		9069

26. What percentage of national standards has been adopted that (in the opinion of the standardization body) are in full conformity with the European standards (CEN, CENELEC and ETSI standards)? Are they full standards aligned to EU ones, or adopted by "cover page" methods¹³⁸?

Starting with 2015, ISM aims to increase the share of European and international standards adopted as Moldovan standards. This objective was achieved considering economic priorities and stakeholder demands.

The National Standardization Programme yearly provides for adoption of more than 3000 of European and international standards. The rate of international standards is low as these are adopted at the request of stakeholders.

As of 2019 100% of European standards, published at European level, are adopted as Moldovan standards, this rate being maintained annually by the consistent adoption of standards published by CEN/CENELEC.

During the period 2015-2021, over 29 723 of European standards were adopted as Moldovan standards.

All the EU standards are adopted by “cover page” methods.

All the adoptions of EN standards are notified to CCMC via iprojex tool.

All new draft standards under development are notified to CCMC (published in CCMC monthly notification register).

The total number of national found of standards of Moldova is 36679, of these 29723 (approximately 81%) are European standards, 3101 (approximately 8.45%) are international standards, 1049 (approximately 2.85%) are interstate GOST standards and 2806 (approximately 7.65%) are original Moldovan standards.

27. Is there a timetable for the standardization body to become a full member of CEN and CENELEC?

The Activity Plan of the Ministry of Economy for 2022 adopted by the Ministry Decision No. 27 from 02.03.2022, p. 5.2.1 establishes the *Strengthening the ISM*

¹³⁸The "cover page" method is a method whereby the national standards body adopts European standards in an EU language version with a cover page in the national language (s).

in order to meet the requirements for full members of CEN/CENELEC, the KPI are:

- External evaluation according to CEN / CENELEC Guide 22 performed;
- The improvement actions resulting from the self-assessment carried out in 2021 implemented;
- 97% of the requirements of the CEN / CENELEC Guide 22 met.

Since 2017, ISM annually carried out the self-assessment process, based on the requirements of the CEN / CENELEC Guide 22 to understand the level of compliance of the national standardization body with requirements established for the full member.

Between 20-30 December 2021, ISM carried out the process of self-assessment of the activity according to the requirements of the CEN / CENELEC Guide 22, which is the basic action of a national standardization body (ONS) aspiring to full membership in European standardization organizations CEN and CENELEC. The result of the self-assessment exercise is 95.49% and represents the degree of compliance with the requirements of the 5th edition of CEN/CENELEC Guide 22.

As the next step, for becoming a member of CEN/CENELEC, ISM in 2022 is planning to organize an assessment of ISM on Guide 22 requirements, carried out by an external expert which could evaluate the degree of compliance based on the European experience and provide recommendations to align the national standardization practices to the level required by the CEN/CENELEC toward the full members.

Based on the results of the self-assessment exercise, ISM established a to do list to improve its institutional capacity, such as: knowledge of English, development of IT infrastructure, including mechanisms for managing the activities of technical committees, training of ISM experts and increase its technical knowledge necessary to participate in the European standardization system but also to strengthen the involvement of technical committee members in European standardization, aspect ISM faces certain challenges, such as their low interest in standardization work, limited number of experts in certain fields, low knowledge of English and use of IT tools by TC members.

3. SECTORAL LEGISLATION (non-exhaustive list of relevant *EU acquis*)

Describe the current situation per sector (as defined in each piece of the *EU acquis* listed below) in terms of a) your self-assessment of the degree of alignment to the *EU acquis*, i.e it has not started, or it is partly aligned (and – in which case – what elements are not aligned), or it is designed to be fully aligned; b) whether, for each piece of the *EU acquis* listed below, notably for *EU acquis* in the new approach/new legislative framework, each element of the quality infrastructure (standardization, conformity assessment, accreditation, metrology, and market surveillance) is able to implement the *acquis* to EU levels in each sector in terms of both legal competence and competent human and financial capacity. Complementary information should be provided as necessary.

A. New Approach & New Legislative Framework

28. Lifts (Dir. 2014/33/EU)

a) Directive 2014/33/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.8/2016 on the approval of the Technical Regulation relating to lifts and safety components for lifts, which entered into force in 2018¹³⁹.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities; conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example the identification of notified bodies, delegated and implementing acts).

b) For the purpose of establishing compliance, Order No.394/2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to lifts and safety components for lifts¹⁴⁰ was approved.

The list contains 18 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Technical Surveillance is appointed as the market surveillance authority, which is the administrative authority subordinated to the Ministry of

¹³⁹Government Decision No. 8/2016 on the approval of the Technical Regulation relating to lifts and safety components for lifts available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=109570&lang=ro

¹⁴⁰Order No.394/2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to lifts and safety components for lifts available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110823&lang=ro.

Infrastructure and Regional Development. The financing and the technical-material support of the Agency are made from the state budget.

The conformity assessment of lifts is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is performed according to Law No.235/2011 on accreditation and conformity assessment activities¹⁴¹ and Government Decision No.8/2016 on the approval of the Technical Regulation relating to lifts and safety components for lifts.

There are 2 conformity assessment bodies in the Republic of Moldova that are accredited and recognized (1 certification body and 1 inspection body). The legal form of these bodies is a limited liability company (private).

29. Machinery (Dir. 2006/42/EC)

a) Directive 2006/42/EC is transposed into the Republic of Moldova legislation by Government Decision No.130/2014 on the approval of the Technical Regulation on machinery, which entered into force in 2016¹⁴².

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

b) For the purpose of establishing compliance, Order No. 4 of 20.01.2015 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on machinery¹⁴³ has been approved.

The list contains 913 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Technical Surveillance is appointed as the market surveillance authority, which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material support of the Agency are made from the state budget.

The conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is performed according to Law

¹⁴¹Law No. 235/2011 on accreditation and conformity assessment activities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

¹⁴²Government Decision No.130/2014 on the approval of the Technical Regulation on machinery, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109660&lang=ro

¹⁴³Order No.4 of 20.01.2015 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on machinery, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112158&lang=ro#

No.235/2011 on accreditation and conformity assessment activities¹⁴⁴ and Government Decision No.130/2014 on the approval of the Technical Regulation on machinery.

There are 3 accredited conformity assessment bodies in the Republic of Moldova (1 certification body and 2 testing laboratories). The legal form of these bodies is state-owned enterprises.

30. Cableways (Reg. (EU) 2016/424)

a) Regulation (EU) 2016/424 is currently in the process of being transposed by the draft Government Decision approving the technical regulation on cable installations number 142 / ME / 2022).

The draft Government decision is currently subject to public consultation and is due for approval in May this year¹⁴⁵.

The degree of alignment is compatible (fully aligned). The provisions in the process of being transposed are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

Once approved, the draft Government Decision will repeal Government Decision No. 744/2015 for the approval of the Technical Regulation on cableway installations designed to carry persons¹⁴⁶, transposing Directive 2000/9/EC of the European Parliament and of the Council relating to cableway installations designed to carry persons.

b) For the purpose of establishing compliance, Order No. 420 of 17.08.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation on cableway installations¹⁴⁷ was approved.

¹⁴⁴Law No. 235/2011 on accreditation and conformity assessment activities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

¹⁴⁵Draft Government Decision, available in Romanian at: <https://particip.gov.md/ro/document/stages/hotarare-de-guvern-pentru-aprobarea-reglementarii-tehnice-privind-instalatiile-pe-cablu/8941>

¹⁴⁶Government Decision No. 744/2015 for the approval of the Technical Regulation on cableway installations designed to carry persons, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110261&lang=ro#

¹⁴⁷Order No. 420 of 17.08.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation on cableway installations, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110836&lang=ro

The list contains 24 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Technical Surveillance is appointed as the market surveillance authority, which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material support of the Agency are made from the state budget.

There are no conformity assessment bodies in the Republic of Moldova.

31. Personal Protective Equipment (PPE) (Reg. (EU) 2016/425)

a) Regulation (EU) 2016/425 is transposed into the legislation of the Republic of Moldova by Government Decision No.108/2022 for the approval of the Technical Regulation on personal protective equipment ¹⁴⁸, which will enter into force in 2023.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

The Government Decision No. 102/2022 repeals the Government Decision No.1289/2016 for the approval of the Technical Regulation on personal protective equipment ¹⁴⁹, transposing the Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment.

b) The degree of adoption of harmonized European standards as Moldovan standards for technical regulation for the approval of the Technical Regulation on personal protective equipment is 100%. The Order on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation on personal protective equipment will be approved until the entry into force of the Government Decision No.108/2022.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance

¹⁴⁸Government Decision No. 108/2022 for the approval of the Technical Regulation on personal protective equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130459&lang=ro

¹⁴⁹Government Decision No. 1289/2016 for the approval of the Technical Regulation on personal protective equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130515&lang=ro

authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

The conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is carried out according to Law No.235/2011 on accreditation and conformity assessment activities and Government Decision 108/2022 for the approval of the Technical Regulation on personal protective equipment.

Three conformity assessment bodies are accredited in the Republic of Moldova (1 certification body and 2 testing laboratories). The legal form of these bodies is the limited liability company (private) and the state-owned enterprise.

32. Electromagnetic Compatibility (EMC) (Dir. 2014/30/EU)

a) Directive 2014/30 / EU is transposed into the legislation of the Republic of Moldova by Government Decision No.807/2015 for the approval of the Technical Regulation for the approval of the Technical Regulation Electromagnetic compatibility of equipment¹⁵⁰.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

b) In order to establish compliance, Order No. 421 of 17.08.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation electromagnetic compatibility of equipment¹⁵¹ has been approved.

The list contains 201 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance

¹⁵⁰Government Decision No. 807/2015 for the approval of the Technical Regulation for the approval of the Technical Regulation Electromagnetic compatibility of equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110320&lang=ro

¹⁵¹Order No. 421 of 17.08.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation electromagnetic compatibility of equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110837&lang=ro

authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

The conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is carried out according to Law 235/2011 on the activities of accreditation and conformity assessment and Government Decision 807/2015 for the approval of the Technical Regulation electromagnetic compatibility.

Three conformity assessment bodies are accredited in the Republic of Moldova (2 certification bodies and 1 testing laboratory). Its legal form is a public institution.

33. Low Voltage (LVD) (Dir. 2014/35/EU)

a) Directive 2014/35/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.745/2015 for the approval of the Technical Regulation the making available on the market of electrical equipment intended for use within certain voltage limits¹⁵².

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) In order to establish compliance, Order No. 555 of 28.11.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation making available on the market of electrical equipment designed for use within certain voltage limits¹⁵³ has been approved.

The list contains 1010 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

¹⁵²Government Decision No.745/2015 for the approval of the Technical Regulation the making available on the market of electrical equipment intended for use within certain voltage limits available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110263&lang=ro

¹⁵³Order No. 555 of 28.11.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation making available on the market of electrical equipment designed for use within certain voltage limits, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110866&lang=ro

Three conformity assessment bodies are accredited in the Republic of Moldova (testing laboratories). The legal form of these bodies is limited liability companies (private) and state-owned enterprises

34. Radio Equipment (RED) (Dir. 2014/53/EU)

a) Directive 2014/53/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.34/2019 for the approval of the technical regulation Making available on the market of radio equipment.¹⁵⁴

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) In order to establish compliance, there has been approved the Order No. 244 of 10.12.2020 on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation Making available on the market of radio equipment¹⁵⁵.

The list contains 165 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The National Regulatory Agency for Electronic Communications and Information Technology is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out on the basis of the principles of self-management and self-financing.

The conformity assessment is carried out by recognized conformity assessment bodies.

Recognition for the purpose of notification is carried out according to Law 235/2011 on the activities of accreditation and conformity assessment and Government Decision 34/2019 for the approval of the technical regulation Making available on the market of radio equipment.

¹⁵⁴Government Decision No. 34/2019 for the approval of the technical regulation making available on the market of radio equipment, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=130653&lang=ro

¹⁵⁵Order No. 244 of 10.12.2020 on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation Making available on the market of radio equipment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125266&lang=ro

Two conformity assessment bodies are accredited in the Republic of Moldova (1 certification body, 1 testing laboratory). The legal form of these bodies is state-owned enterprises.

35. Gas Appliances (GAR) (Reg. (EU) 2016/426)

a) Regulation 2016/426 is transposed into the legislation of the Republic of Moldova by Government Decision No.109/2022 for the approval of the Technical Regulation on appliances burning gaseous fuels¹⁵⁶, which will enter into force in 2023.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

The Government Decision repeals the Government Decision No.1329/2016 on the approval of the Technical Regulation Appliances consuming gaseous fuels, which transposes Directive 2009/142/CE ¹⁵⁷.

b) In order to establish compliance, the Order No. 411 of 15.08.2018 has been approved, with the list of Moldovan standards adopting harmonized European standards to technical regulation on appliances burning gaseous fuels¹⁵⁸.

The list contains 131 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

¹⁵⁶Government Decision No. 109/2022 for the approval of the Technical Regulation on appliances burning gaseous fuels available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130430&lang=ro

¹⁵⁷Government Decision No. 1329/2016 on the approval of the Technical Regulation Appliances consuming gaseous fuels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130439&lang=ro.

¹⁵⁸Order No. 411 of 15.08.2018 on the approval of the list of Moldovan standards adopting harmonized European standards to technical regulation on appliances burning gaseous fuels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110833&lang=ro

The conformity assessment is carried out by recognized conformity assessment bodies.

Recognition for the purpose of notification is carried out according to Law No.235/2011 on the activities of accreditation and conformity assessment and Government Decision 109/2022.

Two conformity assessment bodies are accredited in the Republic of Moldova (1 certification body and 1 testing laboratory). The legal form of these bodies is a limited liability company (private).

36. Explosive Atmospheres Equipment (ATEX) (Dir. 2014/34/EU)

a) Directive 2014/34/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.1407/2016 for the approval of the Technical Regulation on equipment and protective systems intended for use in potentially explosive atmospheres¹⁵⁹.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

The Government Decision No. 1407/2016 repeals the Government Decision No.138/2009 on the approval of technical regulations¹⁶⁰ transposing the Directive 94/9 CE.

b) In order to establish compliance, the Order No. 56 of 17.05.2012 has been approved, with the list of Moldovan standards adopting harmonized European standards to Technical Regulation on equipment and protective systems intended for use in potentially explosive atmospheres.¹⁶¹

¹⁵⁹Government Decision No.1407/2016 for the approval of the Technical Regulation on equipment and protective systems intended for use in potentially explosive atmospheres available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=96923&lang=ro

¹⁶⁰Government Decision No. 138/2009 on the approval of technical regulations, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103383&lang=ro

¹⁶¹Order No.56 of 17.05.2012 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on equipment and protective systems intended for use in potentially explosive atmospheres available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=4578&lang=ro

The list contains 79 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Technical Surveillance, which is subordinated to the Ministry of Infrastructure and Regional Development, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

The conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is carried out according to Law No. 235/2011 on the activities of accreditation and conformity assessment and Government Decision No. 1407/2016.

There are no conformity assessment bodies in the Republic of Moldova.

37. Pressure Equipment (PED) (Dir. 2014/68/EU)

a) Directive 2014/68/EU is transposed into the legislation of the Republic of Moldova by Government Decision No. 1333/2016 for the approval of the Technical Regulation on making available on the market of pressure equipment¹⁶², which entered into force in 2018.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) In order to confer the presumption of conformity, the Order No.332 of 11.12.2019 has been approved, with the list of Moldovan standards adopting harmonized European standards to Technical Regulation on pressure equipment¹⁶³.

The list contains 229 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The market surveillance authority is the Agency for Technical Supervision which is the administrative authority subordinated to the Ministry of Infrastructure and

¹⁶²Government Decision No.1333/2016 for the approval of the Technical Regulation on making available on the market of pressure equipment available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=110443&lang=ro

¹⁶³Order No. 332 of 11.12.2019 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on pressure equipment available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=119485&lang=ro

Regional Development. The financing and the technical-material insurance of the Agency are carried out from the state budget.

The conformity assessment of pressure equipment is carried out by the producer, who, depending on the module applied, may reach out to accredited and recognized conformity assessment body. Recognition for the purpose of subsequent notification is performed according to Law No.235/2011 on the activities of accreditation and conformity assessment¹⁶⁴ and Government Decision No. 1333/2016 for the approval of the Technical Regulation on making available on the market of pressure equipment.

Currently 1 certification body is accredited and recognized. The legal form of this body is a limited liability company (private).

38. Simple Pressure Vessels (SPVD) (Dir. 2014/29/EU)

a) Directive 2014/29/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.368/2015 for the approval of the Technical Regulation on making available on the market of simple pressure vessels¹⁶⁵, which entered into force in 2017.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) With the aim of conferring the presumption of conformity, Order No.333 of 11.12.2019 has been approved, with the list of Moldovan standards adopting harmonized European standards to Technical Regulation on simple pressure vessels.¹⁶⁶

The list contains 7 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

¹⁶⁴Law No. 235/2011 on the activities of accreditation and conformity assessment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

¹⁶⁵ Government Decision No. 368/2015 for the approval of the Technical Regulation on making available on the market of simple pressure vessels, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109915&lang=ro

¹⁶⁶Order No. 333 of 11.12.2019 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on simple pressure vessels available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119487&lang=ro

The market surveillance authority is the Agency for Technical Supervision which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material insurance of the Agency are carried out from the state budget account.

The conformity assessment of the simple pressure vessels is carried out by the producer. There are currently no accredited conformity assessment bodies.

39. Outdoor Equipment Noise Emissions (Dir. 2000/14/EC)

Have you taken the measures necessary to ensure that manufacturers send to the responsible authorities copies of the EC declarations of conformity for equipment placed on the market, according to Article 16 of the Directive on Outdoor Equipment Noise Emissions?

The process of transposition has not yet started, as Directive 2000/14/EC is not the subject of Chapter 3, Title V of the Association Agreement RM-UE. However, the Outdoor Equipment Noise Emissions sector is covered by the provisions of Law No.235/2011¹⁶⁷ (position 26 of Annex No.3). Law 7/2016¹⁶⁸ designates the regulatory authority, as well as the market surveillance authority, which will subsequently ensure the elaboration of the national legal framework and ensure the implementation of this specific sector.

40. Construction Products (CPR) (Reg. 305/2011)

a) Regulation 305/2011 is transposed into the legislation of the Republic of Moldova by Government Decision No. 913/2016 for the approval of the Technical Regulation on the minimum requirements for the marketing of construction products¹⁶⁹, which entered into force in 2018.

The degree of alignment is compatible (partly aligned). The transposed provisions are the following: subject matter; definitions; free movement; basic requirements for construction works and essential characteristics of construction products; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of performance; general principles of the CE marking; market surveillance, with the

¹⁶⁷Law No. 235/2011 on the activities of accreditation and conformity assessment, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127061&lang=ro

¹⁶⁸Law No. 7/2016 on market surveillance of the marketing of non-food products, available in Romanian at https://www.legis.md/cautare/getResults?doc_id=106105&lang=ro

¹⁶⁹Government Decision No.913/2016 for the approval of the Technical Regulation on the minimum requirements for the marketing of construction products available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110395&lang=ro.

exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

b) With the aim of conferring the presumption of conformity Order No.20 of 08.02.2021 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on minimal condition for the marketing of construction products¹⁷⁰ has been adopted.

The list contains 444 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The market surveillance authority is the Agency for Technical Supervision which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material insurance of the Agency are carried out from the state budget account.

The conformity assessment of construction products is carried out by the producer who, depending on the evaluation system chosen, may call upon accredited and recognized conformity assessment body. Recognition for the purpose of subsequent notification is performed according to Law No.235/2011 on the activities of accreditation and conformity assessment and Government Decision No 913/2016.

Currently, 7 certification bodies and 12 testing laboratories are accredited and recognized. The legal form of these conformity assessment bodies is limited liability company (private) or a state-owned enterprise whose founder is the Public Property Agency.

41. Recreational Craft (Dir. 2013/53/EU)

Even though Republic of Moldova has not yet transposed EU Directive 2013/53/EU, it has ensured that the current legislation in force is compliant with existing provisions at the EU level. In this regard, Law No. 235/2011 and Law No. 7/2016 has ensured that the following provisions are aligned with the EU acquis: free movement; making available on the market and putting into use; obligations of economic operators, authorities, conformity assessment body; general principles of the CE marking; market surveillance.

¹⁷⁰Order No. 20 of 08.02.2021 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on minimal condition for the marketing of construction products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125463&lang=ro

42. Civil Explosives (Dir. 2014/28/EU)

a) Directive 2014/28/EU is transposed into the legislation of the Republic of Moldova by Government Decision No. 1324/2016 for the approval of the Technical Regulation on the essential security requirements for civil explosives, the making available on the market and the control of civil explosives¹⁷¹, which entered into force in 2018.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

b) With the aim of conferring the presumption of conformity, Order No.156 of 17.05.2012 (Annex nr. 1) has been approved, with the list of Moldovan standards adopting harmonized European standards related to Technical Regulation on explosives for civil uses¹⁷².

The list contains 57 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The market surveillance authority is the Agency for Technical Supervision which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material insurance of the Agency are carried out from the state budget.

The conformity assessment of civil explosives is carried out by the producer who, depending on the compliance procedure applied, may call upon accredited and recognized conformity assessment body.

There are currently no accredited conformity assessment bodies.

¹⁷¹Government Decision No.1324/2016 for the approval of the Technical Regulation on the essential security requirements for civil explosives, the making available on the market and the control of civil explosives available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102623&lang=ro

¹⁷²Order No.156 of 17.05.2012 (Annex No.1) on the approval of the list of Moldovan standards adopting harmonized European standards related to Technical Regulation on explosives for civil uses available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=4578&lang=ro

43. Pyrotechnic Articles (Dir. 2013/29/EU)

a) Directive 2013/29/EU has been partially transposed into the legislation of the Republic of Moldova by Law No.143/2014 on the pyrotechnic articles regime¹⁷³, which entered into force in 2015.

The degree of alignment is compatible (partly aligned). The provisions transposed are the following: scope; definitions; free movement; conditions regarding making available on the market; essential security requirements; obligations and requirements to economic operators; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other labeling; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts). In addition, the law provides for the licensing of activities in the field of pyrotechnic products and the authorization of pyrotechnicians.

b) The market surveillance authority is the Agency for Technical Supervision which is the administrative authority subordinated to the Ministry of Infrastructure and Regional Development. The financing and the technical-material insurance of the Agency are carried out from the state budget.

The conformity assessment of pyrotechnic articles is carried out by the producer who, depending on the compliance procedure applied, may call upon accredited and recognized conformity assessment body. There is currently 1 accredited conformity assessment body from the private sector.

44. Toys (Dir. 2009/48/EC)

a) Directive 2009/48/EC is fully transposed into the legislation of the Republic of Moldova by Government Decision No. 808/2015 for the approval of the Technical Regulation on the safety of toys¹⁷⁴, which entered into force in 2017.

The degree of alignment is compatible (fully aligned). The transposed provisions are: scope; definitions; free movement; conditions regarding placing and making available on the market; essential requirements; obligations and requirements to economic operators, authorities, conformity assessment body; conformity assessment procedures; warnings and presumption of conformity; declaration of conformity and principles of the CE marking; market surveillance, with the

¹⁷³Law No.143/2014 on the pyrotechnic articles regime available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106094&lang=ro

¹⁷⁴Government Decision No.808/2015 for the approval of the Technical Regulation on the safety of toys available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110321&lang=ro

exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) With the aim of conferring the presumption of conformity the Order No.39 of 31.03.2021 has been approved, with the list of Moldovan standards adopting harmonized European standards to Technical Regulation on toys¹⁷⁵

The list contains 16 harmonized European standards. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The market surveillance authority is the Agency for Consumer Protection and Market Surveillance which is the administrative authority subordinated to the Ministry of Economy. The financing and the technical-material insurance of the Agency are carried out from the state budget account.

The conformity assessment of toys is carried out by the producer who, depending on the module applied, may call upon accredited and recognized conformity assessment bodies. Recognition for the purpose of subsequent notification is performed according to Law No.235/2011 on the activities of accreditation and conformity assessment and Government Decision No. 808/2015 for the approval of the Technical Regulation on toys.

Currently, there are 2 accredited and recognized certification bodies. The legal form of these is limited liability company (private) or a state-owned enterprise whose founder is the Public Property Agency.

45. Eco-design (Dir. 2009/125/EC)

Directive 2009/125/EC is partially transposed into the legislation of the Republic of Moldova by Law No.151/2014 on the eco-design requirements applicable to energy impact products¹⁷⁶, which entered into force in 2015.

Additionally, by adopting the Government Decision No.750/2016, approving the eco-design requirements applicable to energy-related products¹⁷⁷, the 17 Commission Regulations were transposed which are establishing eco-design requirements applicable to 17 types of energy-related products.

The degree of alignment is compatible. The transposed provisions refer to: free movement of products with energy impact, competens of authorities, responsibilities of economic operators, eco-design requirements, presumption of

¹⁷⁵Order No. 39 of 31.03.2021 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation on toys available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=119487&lang=ro

¹⁷⁶Law No.151/2014 on the eco-design requirements applicable to energy impact products available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106031&lang=ro

¹⁷⁷Government Decision No.750/2016 on approving the eco-design requirements applicable to energy-related products available in Romanian at:https://www.legis.md/cautare/getResults?doc_id=102520&lang=ro

conformity and conformity assessment procedures; the declaration of conformity and the rules of applying the EC marking and market surveillance.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget. The Energy Efficiency Agency is responsible for distribution of information to manufacturers and importers on requirements for energy impact products and ensures the organization of information campaigns for the end users of products. Moldova is in the process of implementing these Regulations, which are planned to be fully implemented by 2024.

The conformity assessment is carried out by the producer. The producer shall ensure that the conformity assessment of the product is done in accordance with all relevant requirements.

46. Energy labeling (Dir. 2010/30/EU)

a) Directive 2010/30/EU has been fully transposed into the legislation of the Republic of Moldova by Law No.44/2014 on the labeling of products with energy impact¹⁷⁸.

The degree of alignment is compatible (fully aligned). The transposed provisions refer to: scope; definitions; responsibilities; information requirements; distance selling and free movement, except for the EU rules relating to the competences of the European Commission.

Government Decision No.1003/2014 for the approval of the regulations regarding the energy labeling requirements of some products with energy impact¹⁷⁹ transposes the following EU norms:

Delegated Regulation (EU) No 392/2012 supplementing Directive 2010/30/EU with regard to energy labeling of household tumble driers; Delegated Regulation (EU) No 626/2011 supplementing Directive 2010/30/EU with regard to energy labeling of air conditioners;

Delegated Regulation (EU) No 65/2014 supplementing Directive 2010/30/EU with regard to the energy labeling of domestic ovens and range hoods; Delegated Regulation (EU) No 812/2013 supplementing Directive 2010/30/EU with regard

¹⁷⁸Law No.44/2014 on the labeling of products with energy impact available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106000&lang=ro

¹⁷⁹Government Decision No. 1003/2014 for the approval of the regulations regarding the energy labeling requirements of some products with energy impact available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128814&lang=ro

to the energy labeling of water heaters, hot water storage tanks and packages of water heater and solar device.

Delegated Regulation (EU) No 811/2013 supplementing Directive 2010/30/EU with regard to the energy labeling of space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device.

Additionally, the Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labeling of tyres with respect to fuel efficiency and other essential parameters was transposed by Government Decision No. 685/2018 on the labeling of tyres with respect to fuel efficiency and other essential parameters¹⁸⁰.

Moreover, following the approval by EU of the new regulations on energy labeling, applicable from 1 March 2021, the Moldovan Government, in order to protect the energy related equipment distributors and importers, adopted Government Decision No.362/2021 on the amendment of the Government Decision No.1003/2014¹⁸¹ in order to temporarily suspend the existing energy labeling requirements for the 5 categories of products . The Ministry of Infrastructure and Regional Development is currently invested in transposing the new Energy Labeling Regulation 2017/1369, which replaces the former Energy Labeling Directive 2010/30/EU, in order to fully align to the EU requirements.

b) The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget. The Energy Efficiency Agency is responsible for distribution of information to manufacturers and importers on requirements for energy impact products and ensures the organization of information campaigns for the end users of products. The understaffing of the Agencies, the amount of tasks and the complexity of these Regulations are hampering the implementation of these Regulations.

There are no conformity assessment bodies in the Republic of Moldova.

¹⁸⁰Government Decision 685/2018 on the labeling of tyres with respect to fuel efficiency and other essential parameters available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108817&lang=ro

¹⁸¹Government Decision No.362/2021 on the amendment of the Government Decision No.1003/2014 available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128754&lang=ro

47. Measuring Instruments (Dir. 2014/32/EU)

a) Directive 2014/32/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.408/2015 for the approval of the Technical Regulation on the making available on the market of measuring instruments¹⁸².

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

b) In order to establish compliance, Order No.129 of 28.06.2016 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to the making available on the market of measuring instruments¹⁸³ has been adopted.

The list contains 25 harmonized European standards and 16 OIML regulations. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

Conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is performed according to Law No.235/2011 on the activities of accreditation and conformity assessment and Government Decision 408/2016.

1 conformity assessment body is accredited in the Republic of Moldova. Its legal form is a public institution.

¹⁸²Government Decision No.408/2016 for the approval of the Technical Regulation on the making available on the market of measuring instruments available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110038&lang=ro

¹⁸³Order No.129 of 28.06.2016 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to the making available on the market of measuring instruments, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112181&lang=ro

48. Non-automatic Weighing Instruments (Dir. 2014/31/EU)

a) Directive 2014/31/EU is transposed into the legislation of the Republic of Moldova by Government Decision No.267/2014 for the approval of the Technical Regulation on non-automatic weighing devices¹⁸⁴.

The degree of alignment is compatible (fully aligned). The transposed provisions are the following: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (for example identification of notified bodies, delegated and implementing acts).

b) In order to establish compliance, Order No.08 of 17.01.2017 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to the making available on the market of non-automatic weighing instruments¹⁸⁵ has been adopted.

The list contains 1 harmonized European standard - SM EN 45501 Metrological aspects of non- automatic weighing instruments. The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The Agency for Consumer Protection and Market Surveillance, which is subordinated to the Ministry of Economy, is appointed as the market surveillance authority. The financing and the material-technical supply of the Agency are carried out from the state budget.

The conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is carried out according to Law No.235/2011 on accreditation and conformity assessment activities and Government Decision 267/2014 for the approval of the Technical Regulation on non-automatic weighing instruments.

1 conformity assessment body is accredited in the Republic of Moldova. Its legal form is a public institution.

¹⁸⁴Government Decision No. 267/2014 for the approval of the Technical Regulation on non-automatic weighing devices available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=109737&lang=ro

¹⁸⁵Order No. 08 of 17.01.2017 on the approval of the list of Moldovan standards adopting harmonized European standards to Technical Regulation relating to the making available on the market of non-automatic weighing instruments, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112161&lang=ro

49. Medical devices (Dir. 93/42/EEC, Regulation (EU) 2017/745 and Regulation (EU) 2017/746)

a) Directive 93/42/EEC is transposed into the legislation of the Republic of Moldova by Government Decision No.702/2018 for the approval of the Regulation on the conditions for placing on the market of the medical devices¹⁸⁶.

The degree of alignment is compatible (fully aligned). The provisions transposed are: subject matter; definitions; free movement; making available on the market and putting into use; essential requirements; obligations of economic operators, authorities, conformity assessment body; conformity assessment procedures; presumption of conformity; declaration of conformity; general principles of the CE marking and other inscriptions; market surveillance, with the exception of EU rules relating to the powers of the European Commission (e.g.: identification of notified bodies, delegated and implementing acts).

The transposition of the Regulation (EU) 2017/745 has not yet started, but is included in the Government Action Plan for the years 2021-2022, approved by Government Decision No.235/2021¹⁸⁷.

Directive 98/79/EC is transposed into the legislation of the Republic of Moldova by Government Decision No.703/2018 for the approval of the Regulation on the conditions for placing on the market of medical devices for in vitro diagnosis.¹⁸⁸

The transposition of the Regulation (EU) 2017/746 has not yet started, but is included in the Government Action Plan for the years 2021-2022, approved by Government Decision No.235/2021.

Directive 90/385/EEC is transposed into the legislation of the Republic of Moldova by Government Decision No.704/2018 for the approval of the Regulation on the conditions for placing on the market of active implantable medical devices¹⁸⁹.

b) In order to establish compliance, the Order No.53 of 19.02.2018 has been adopted, with the list of national standards related to the technical regulations of

¹⁸⁶Government Decision No. 702/2018 for the approval of the Regulation on the conditions for placing on the market of the medical devices available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=108836&lang=ro

¹⁸⁷Government Action Plan for the years 2021-2022, approved by Government Decision No.235/2021, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128407&lang=ro

¹⁸⁸Government Decision No.235/2021 available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108837&lang=ro

¹⁸⁹Government Decision No.704/2018 for the approval of the Regulation on the conditions for placing on the market of active implantable medical devices available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108838&lang=ro

medical devices; in vitro diagnostic medical devices; active implantable medical devices¹⁹⁰

The degree of adoption of harmonized European standards as Moldovan standards is 100%.

The National Agency for Public Health, together with the Agency for Medicines and Medical Devices, which are administrative authorities subordinated to the Ministry of Health, are appointed as the authority for market surveillance. The financing and the material-technical supply of the Agencies are carried out from the state budget.

Conformity assessment is carried out by recognized conformity assessment bodies. Recognition for the purpose of notification is performed according to Law No.235/2011 on the activities of accreditation and conformity assessment and Government Decision No. 702/2018.

There are no conformity assessment bodies in the Republic of Moldova.

B. Old Approach

50. Tractors (Agriculture, Forestry) (Reg. (EU) 167/2013)

Regulation (EU) 167/2013 is not yet transposed into the legislation of the Republic of Moldova.

51. Motor Vehicles (Reg. (EU) 2018/858)

Regulation (EU) 2018/858 is not yet transposed into the legislation of the Republic of Moldova.

Directive 2007/46 was partially transposed into the legislation of the Republic of Moldova, in the part regarding the registration and vehicle records, by Government Decision No.588/2017 on the amendment of Annex No.2 to Government Decision No.1047/1999¹⁹¹.

¹⁹⁰Order No.53 of 19.02.2018 on the approval of the list of national standards related to the technical regulations of medical devices; in vitro diagnostic medical devices; active implantable medical devices available in Romanian at: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=374555>

¹⁹¹Government Decision No.588/2017 on the amendment of Annex No.2 to Government Decision No.1047/1999 available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=101383&lang=ro

52. Motor vehicles (2/3 wheels) (Reg. (EU) 168/2013)

Regulation (EU) 168/2016 was partially transposed into the legislation of the Republic of Moldova, in the part regarding the registration and vehicle records, by Government Decision No.588/2017 on the amendment of Annex No.2 to Government Decision No.1047/1999¹⁹².

53. Non-road Mobile Machinery Emissions (Reg. (EU) 2016/1628)

Regulation (EU) 2016/1628 is not yet transposed into the legislation of the Republic of Moldova. The Regulation is not subject to the Association Agreement RM-UE.

54. Chemicals (REACH) (Reg. 1907/2006)

Regulation 1907/2006 is partially transposed into the legislation of the Republic of Moldova by:

- Law No.277/2018 on chemicals¹⁹³. The national act transposes Art.1-3, 5-7, 14, 31, 32, 34, 35, 56, 60-62, 68, 118, 119, 121, 123, 125 and 126, Annex IV and point 18a (Mercury) of the Annex XVII of the Regulation;
- Government Decision No.535/2020 for approval of Technical Concept of Informational automated system Registry of chemicals placed on the market of the Republic of Moldova¹⁹⁴;
- the draft Government Decision aiming to create the legal framework for the establishment of the national authority on chemicals, which is National Regulatory Agency of Nuclear, Radiological and Chemical Activities.
- 1 European standards have been adopted as Moldovan standards, which represents 100% of the total number of European standards complementary to the Regulation 1907/2006.

¹⁹²Government Decision No.588/2017 on the amendment of Annex No.2 to Government Decision No.1047/1999 available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=101383&lang=ro

¹⁹³Law No.277/2018 on chemicals available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112668&lang=ro

¹⁹⁴Government Decision No.535/2020 for approval of Technical Concept of Informational automated system Registry of chemicals placed on the market of the Republic of Moldova available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122470&lang=ro

55. Chemicals CLP (Reg. 1272/2008)

Regulation 1272/2008 is partially transposed into the legislation of the Republic of Moldova by Law No.277/2018 on chemicals¹⁹⁵. The national act transposes Art.1, 2, 4-6, 8, 35, 43, 46, 47 and 49 of the Regulation.

In order to implement the provisions of Law No.277/2018, the following legal acts have been approved:

- Government Decision No.505 of 15.07.2020 for the approval of the Regulation on the export and import of dangerous chemicals¹⁹⁶; and Government Decision No.535/2020 approving the Technical Concept of the Automated Information System Registry of chemicals placed on the market of the Republic of Moldova¹⁹⁷.

Government Decision No.505/2020 establishes the notification procedure for the export of dangerous chemicals that are prohibited or restricted in the Republic of Moldova, as well as provisions related to the notification and cooperation in the field of international transport of dangerous chemicals.

Government Decision No.535/2020 provides rules that ensure the management of chemical registration processes and the creation of automated information resources for the process of management and monitoring of chemicals.

The Ministry of Environment is in the process of developing the draft Government Decision on the approval of the Regulation on classification, labeling and packaging of substances and mixtures (CLP Regulation), due to be approved in 2023.

56. Good Laboratory Practice (GLP) (Dirs. 2004/10/EC & 2004/9/EC)

Directives 2004/10/EC and Directive 2004/9/EC are partially transposed into the legislation of the Republic of Moldova by Law No.277/2018 on chemicals. The national act transposes Article 1 and the notion of "good laboratory practice", section I of Annex 1 to Directive 2004/10 / EC.

The principles of good laboratory practice are contained in Art. 20 of Law No.277/2018 on chemicals. Under this article, testing of chemicals is performed

¹⁹⁵ Law No.277/2018 on chemicals available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=112668&lang=ro

¹⁹⁶ Government Decision No.505 of 15.07.2020 for the approval of the Regulation on the export and import of dangerous chemicals available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122468&lang=ro

¹⁹⁷ Government Decision No.535/2020 approving the Technical Concept of the Automated Information System Register of chemicals placed on the market of the Republic of Moldova available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=122470&lang=ro

by laboratories accredited by the national accreditation body which respects the principles of good laboratory practice established by the Government. Thus, Directives 2004/10/EC and Directive 2004/9/EC will be transposed into the legislation of the Republic of Moldova in 2023.

57. Fertilizers (Reg. 2019/1009)

The transposition process has not yet started.

The Government Decision No.268/2012¹⁹⁸ on approving the Regulation "Mineral fertilizers. Essential requirements" has transposed fully the Regulation (EC) No.2003/2003 repealed by the Regulation 2019/1009.

The following provisions are transposed : the scope and definitions; the requirements regarding the introduction and making available on the market; safety requirements, packaging and labeling requirements; conformity assessment; rules on the application of the conformity marking SM and market surveillance.

The conformity assessment of fertilizers is carried out by the accredited conformity assessment bodies. Currently there is an accredited certification body which legal form is a private limited liability company.

The National Agency for Food Safety is designated as the national authority responsible for market surveillance,,which is an administrative authority subordinated to the Ministry of Agriculture and Food Industry. The financing and technical-material insurance of the agency is performed from the state budget.

58. Detergents (Reg. 648/2004)

Art.1, 2, 4-6 and 10 of Regulation 648/2004 are transposed into the legislation of the Republic of Moldova through Law No.277/2018 regarding chemical substances¹⁹⁹, which entered into force in 2019.

The alignment with the Regulation (EC) No.648/2004 is partly compatible in terms of definitions, restrictions on the content of surfactants, as well as conditions on authorization.

¹⁹⁸ Government Decision No.268/2012 on the approval of the Technical Regulation Mineral fertilizers, Essential requirements, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=75654&lang=ro

¹⁹⁹Law No. 277/2018 regarding chemical substances available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112668&lang=ro

At the same time, through the Government Decision No.996/2003 were approved the Rules on labeling of household chemical products²⁰⁰.

59. Drug Precursors (Reg. 273/2004)

The Regulation was partially transposed by the Law No. 193/2016 on modification of some laws²⁰¹ in the Law No.382/1999 regarding the circulation of narcotic and psychotropic substances and precursors²⁰².

To ensure the implementation of the provisions of Law No.382/1999 through the Government Decision No.1088/2004 are approved the tables and lists of the narcotic and psychotropic substances and their precursors²⁰³, subject to control. The lists are periodically updated and adjusted to the international acts to which the Republic of Moldova is part.

Government Decision No.128/2006 regarding the approval of the technical requirements concerning the locations and objectives in which narcotic, psychotropic and/or precursor²⁰⁴ are preserved which determine the basic principles of creating multi-alignment systems of signaling and anti-incendiary for the protection of locations and objectives in which activities are carried with drugs, psychotropic and/or precursors.

The Government Decision No.216/2006²⁰⁵ establishes the rules regarding the transit on the territory of the Republic of Moldova of narcotic substances, psychotropic substances, and precursors.

60. Aerosol Dispensers (ADD) (Directive 75/324/EEC)

The transposition process has not yet started. Directive 75/324/EEC is not the subject of the Association Agreement.

²⁰⁰Government Decision No. 996/2003 were approved the Rules on labeling of household chemical products available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110618&lang=ro

²⁰¹Law No. 193/2016 on modification of some laws, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=95138&lang=ro

²⁰²Law No. 382/1999 regarding the circulation of narcotic and psychotropic substances and precursors, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108388&lang=ro

²⁰³Government Decision No.1088/2004 are approved the tables and lists of the narcotic and psychotropic substances and their precursors available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=97918&lang=ro

²⁰⁴Government Decision No.128/2006 regarding the approval of the technical requirements concerning the locations and objectives in which narcotic, psychotropic and/or precursor available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=97920&lang=ro

²⁰⁵Government Decision No. 216/2006 on the transit of narcotic drugs, psychotropic substances and precursors on the territory of the Republic of Moldova available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=97921&lang=ro

61. Pre-packaging (Dir. 75/107/EEC 76/211/EEC & 2007/45/EC)

Directive 75/107 / EEC is transposed into the legislation of the Republic of Moldova through the Government Decision No.881/2014 regarding the approval of the General Regulation of legal metrology to establish the requirements for bottles used as measuring containers²⁰⁶, which entered into force in 2016 and is fully aligned.

The transposed provisions concern subjects such as : scope and notions, technical requirements for bottles used as measuring containers, competences of the authorities, responsibilities of the producers, the statistical verification procedure for bottles used as measuring containers, as well as the sign reversed epsilon.

In order to ensure the implementation of the rules on metrological legal control of the bottles used as measuring containers, PML 14-02: 2016 Legal measurement procedure was approved through Order No.234/2016 ²⁰⁷ which adopts the verifications by measurement and statistical analysis of bottles used as measuring containers.

Directives 76/211 / EEC and Directive 2007/45 / EC are transposed into the legislation of the Republic of Moldova through the Government Decision No.907/2014 General Regulation of Legal Metrology concerning the pre-packaging, depending on mass or volume, of certain pre-packages²⁰⁸ , which entered into force in 2015.

The rank of alignment is compatible. The transposed provisions concern subjects such as : scope and definitions, inscriptions and markings, responsibilities of the packer and the importer, and the reference verification method.

In order to ensure the implementation of the rules on nominal quantities of prepacked products, the following Orders have been approved: through:

- Order No.233 of 19.12.2016 adopting PML 14-01: 2016 Legal measurement procedure. Verifications by measurement and statistical analysis of pre-packaged lots²⁰⁹;

²⁰⁶ Government Decision No.881/2014 regarding the approval of the General Regulation of legal metrology to establish the requirements for bottles used as measuring containers available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110367&lang=ro

²⁰⁷ Order No.234/2016 was approved PML 14-02: 2016 Legal measurement procedure. Verifications by measurement and statistical analysis of bottles used as measuring containers. available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=97989&lang=ro

²⁰⁸ Government Decision No.907/2014 General Regulation of Legal Metrology concerning the pre-packaging, depending on mass or volume, of certain pre-packages available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110392&lang=ro

²⁰⁹ Order No.233 of 19.12.2016 was approved PML 14-01: 2016 Legal measurement procedure. Verifications by measurement and statistical analysis of pre-packaged lots available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=97988&lang=ro

- Order No.232 of 19.12.2016 adopting PML 14-03: 2016 Legal measurement procedure. Measuring the density of pre-packages²¹⁰
- The Agency for Consumer Protection and Market Surveillance is designated as the national authority in charge of metrological surveillance, which is an administrative authority subordinated to the Ministry of Economy. The financing and technical-material insurance of the agency is performed from the state budget.

62. Units of Measurement (Dir. 80/181/EEC Dir. 2009/3/EC)

Directive 80/181/EEC and Directive 2009/3/EC are transposed into the legislation of the Republic of Moldova through the Government Decision No.909/2014 on the approval of legal units of measurement²¹¹.

Law of metrology No.19/2016²¹² establishes that in the Republic of Moldova the legal units of measurement are the units of measurement of the International System of Units (SI), their decimal multiples and submultiples.

C. Procedural Measures

63. Firearms (Dir. 91/477/EEC)

The transposition process has not yet started. Directive 91/477/EC is not subject to the Association Agreement RM-UE.

Anyway, some elements of Directive 91/477 / EEC are presented in the Law No.130/2012 on the regime of weapons and ammunition for civilian use²¹³.

Moreover, Moldova holds a comprehensive national legislation in the field, namely Decision of the Parliament No.283/1999 for the approval of the Regulation

²¹⁰ Order No.232 of 19-12-2016 was approved PML 14-03: 2016 Legal measurement procedure. Measuring the density of pre-packages available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=97986&lang=ro

²¹¹ Government Decision No.909/2014 on the approval of legal units of measurement available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=122677&lang=ro

²¹² Law of metrology No.19/2016 available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=106060&lang=ro

²¹³ Law No.130/2012 on the regime of weapons and ammunition for civilian use available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=129076&lang=ro

on the marketing of military equipment, armaments and other military technical means available to the Armed Forces of the Republic of Moldova.²¹⁴

64. Crystal Glass (Dir. 69/493/EEC)

Some elements of Directive 69/493 / EEC are transposed in Order No.73/2006 for the approval of technical regulations regarding crystal glass²¹⁵. Directive 69/493/EEC is not subject to Chapter 3, Title V of the Association Agreement.

65. Defense Products & Defense Procurement (Dir. 2009/43/EC & Dir. 2009/81/EC)

Some elements of the Directive are listed in the Law No. 131/2015 on public procurement.²¹⁶ Directive 2009/43/EC is not subject to the Association Agreement RM-UE.

66. Footwear (Dir. 94/11/EC)

Some elements of Directive 94/11/EC are transposed in Order No.147/2007 on technical Regulation Establishing the labeling conditions of the materials used in the production of the main components of footwear for sale to consumers²¹⁷.

Conformity assessment is performed by accredited conformity assessment bodies. Currently, there are 3 conformity evaluation bodies (2 certification bodies and 1 testing laboratory). Its legal form is a private limited liability company and state-owned enterprise. Directive 94/11/EC is not subject to Chapter 3, Title V of the Association Agreement.

67. Textile Labeling & Mixtures (Reg. 1007/2011)

²¹⁴ Decision of the Parliament No.283/1999 for the approval of the Regulation on the marketing of military equipment, armaments and other military technical means available to the Armed Forces of the Republic of Moldova, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=105969&lang=ro

²¹⁵ Order No.73/2006 for the approval of technical regulations regarding crystal glass available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=43730&lang=ro

²¹⁶ Law No.131/2015 on public procurement available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=131046&lang=ro

²¹⁷ Order No.147/2007 on technical Regulation Establishing the labeling conditions of the materials used in the production of the main components of footwear for sale to consumers available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=50856&lang=ro

Even though Moldova has not yet aligned the national provisions in the field of textile labeling and mixtures with the current EU requirements (Reg. 1007/2011), the country has transposed the provisions of Directive 96/73/CEE, which repeals the EU Regulation 1007/2011. The current applicable legislation in the field, Order No. 154/2007 approving the Technical Regulation Establishing the methods of analysis used to determine and verify the fibrous composition of textiles²¹⁸ and Order No 61/2007 approving the Technical Regulation name, marking of fibrous composition and labeling of textile products²¹⁹, has aligned the national provisions with the EU ones (in Directive 96/73/CEE), concerning for example (definitions, principle, methods of samples, methods for quantitative analysis of certain binary fiber mixtures, labeling for consumers). Given the fact that the nominated orders, established by Order No. 154/2007 are partially compatible with the provisions of Regulation No.1007/2011, one could state that Moldova is partially compliant with the current applicable provisions in this sector.

Conformity assessment is carried out by accredited conformity assessment bodies. Currently, there are 3 conformity assessment bodies (2 certification bodies and 1 testing laboratory). Its legal form is a private limited liability company and state-owned enterprise.

68. Medicinal Products Pricing (Dir. 89/105/EEC)

Approval procedure and criteria for medicines price registration

- *The decision of price registration adopted within 90 days*, is a legal provision fully transposed into the national normative framework and regulated by Government Decision No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines²²⁰.
- *The decision-making process regarding the non-registration of the price of a medicine as well as its ways of appeal* is partially transposed through the provisions of Government Decision No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines.
- *Development, maintenance and updating of the National Catalog of Manufacturer Prices of Medicines*, is fully transposed into the national normative framework and regulated by Government Decision

²¹⁸ Order No.154/2007 available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=65165&lang=ro

²¹⁹ Order No. 61/2007, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=80033&lang=ro

²²⁰ Government Decision No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=110111&lang=ro

No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines and into Periodic Orders of the Agency for Medicines and Medical Devices regarding the registration of manufacturer prices for medicines

- *The decision-making process regarding the increase of the price of a medicine as well as its ways of appeal* is partially transposed in accordance with the regulatory norms indicated in Government Decision No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines.
- *Freeze pricing for all medicines or certain categories of medicines* is a non-aligned element of the Directive 89/105/EEC. This procedure is to be implemented following the potential EU accession.

State control over the price of medicines

- *Direct or indirect control of the profit made as a result of the sale of medicines*, the mentioned legal provisions have been partially transposed in the following normative acts:
 - Law No.1456/1993 on the pharmaceutical activity²²¹;
 - Law No.1409/1997 on medicines²²²;
 - Government Decision No.603/1997 on the approval of the Regulation on the formation of prices for medicines and other pharmaceutical and parapharmaceutical products²²³;
 - Government Decision No.525/2010 for the approval of the Regulation on the approval and registration of manufacturer prices for medicines.
- Price control system for certain types of medicines that are excluded from the scope of the profit control system, is partially transposed into the following normative acts:
 - Law No.1456/1993 on the pharmaceutical activity;
 - Law No.1585/1998 regarding the compulsory health insurance²²⁴;

²²¹ Law No.1456/1993 on the pharmaceutical activity available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128121&lang=ro

²²² Law No.1409/1997 on medicines, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=115116&lang=ro

²²³ Government Decision No.603/1997 on the approval of the Regulation on the formation of prices for medicines and other pharmaceutical and parapharmaceutical products available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100955&lang=ro

²²⁴ Law No.1585/1998 regarding the compulsory health insurance, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128122&lang=ro#

- Government Decision No.105/2022 on the approval of the negotiation mechanism for the inclusion of medicines and / or medical devices for compensation from the funds of the compulsory health insurance²²⁵;
- Government Decision No.106 of 23.02.2022 on the prescription and release of reimbursed medicines and medical devices for the outpatient treatment of persons registered at the family doctor²²⁶
- Government Decision No.71 of 23.01.2013 on the approval of the Regulation, structure and staff of the Agency of Medicines and Medical Devices ²²⁷;
- Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance²²⁸.

Reimbursement of medicines in the national health insurance system

- ***Procedure and criteria for inclusion / non-inclusion of the medicine in the national health insurance system*** is fully transposed through the provisions of Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance
- ***The decision-making process regarding the non-inclusion of a medicine in the list of products comprised in the national health insurance system as well as its ways of attack*** is partially aligned in conformity with the provisions of Joint Order of the Ministry of Health and the National Health Insurance Company No. 600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance and of the Joint Order of the Ministry of Health and the National Health Insurance Company No.492/139 of 22.04.2013 regarding

²²⁵ Government Decision No.105/2022 on the approval of the negotiation mechanism for the inclusion of medicines and / or medical devices for compensation from the funds of the compulsory health insurance available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130160&lang=ro

²²⁶ Government Decision No.106 of 23.02.2022 on the prescription and release of reimbursed medicines and medical devices for the outpatient treatment of persons registered at the family doctor available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130165&lang=ro

²²⁷ Government Decision No.71 of 23.01.2013 on the approval of the Regulation, structure and staff of the Agency of Medicines and Medical Devices, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128144&lang=ro#

²²⁸ Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128338&lang=ro#

the reimbursed medicines from the funds of the compulsory health insurance²²⁹.

- ***The procedure for excluding certain medicines or categories of medicines from the list of products covered by the national health insurance system*** fully transposes the legal provisions of Directive 89/105/EEC, based on the Joint Order of the Ministry of Health and the National Health Insurance Company No. 600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance.
- ***The decision-making process regarding the exclusion of a medicine from the list of products included in the national health insurance system as well as its ways of attack*** is fully aligned to EU acquis based on the following normative acts:
 - Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance;
 - Joint Order of the Ministry of Health and the National Health Insurance Company No.492/139 of 22.04.2013 regarding the reimbursed medicines from the funds of the compulsory health insurance ;
 - Order of the National Health Insurance Company No.78-A of 18.04.2022 regarding the updating of the list of trade names of medicines ²³⁰.
- Criteria for the therapeutic classification of medicinal products used by the competent authorities within the national social insurance system, are partially transposed into national law in the following normative acts:
 - Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320 of 24.07.2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance;
 - Order of the Ministry of Health No.1033 of 11.11.2021 regarding the approval of the National List of Essential Medicines ²³¹;

²²⁹ Order of the Ministry of Health and the National Health Insurance Company No.492/139 of 22.04.2013 regarding the reimbursed medicines from the funds of the compulsory health insurance available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129700&lang=ro

²³⁰ Order of the National Health Insurance Company No.78-A of 18.04.2022 regarding the updating of the list of trade names of medicines available in Romanian at: http://cnam.md/httpdocs/editorDir/file/MedicamenteCompensate/farmacii/2022/78-A%20din%2018_04_2022%20actualizarea%20Listei%20de%20denumiri%20comerciale%20de%20medicamente%20compensate%20din%20FAOAM.pdf

²³¹ Order of the Ministry of Health No.1033 of 11.11.2021 regarding the approval of the National List of Essential Medicines available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128625&lang=ro

- Order of the Ministry of Health No.321 of 28.03.2013 on the rational use of medicines²³²;

Currently, a Government Decision was drafted to regulate the way of forming and updating the National List of essential medicines, that will fully transpose the mentioned provisions from the element of therapeutic classification of medicines and verifying the correctness and transparency of their prices. The approval of this Government Decision is included in the Government Action Plan for 2022.

- Removal of obstacles to the free movement of patented medicinal products or any distortion thereof, elements partially transposed in the national legislation in the following normative acts:
 - Law No.1409/1997 on medicines;
 - Law No.50/2008 on the protection of inventions²³³.

Currently, the draft amendment of the Law No.50/2008 on the protection of inventions is under the procedure of elaboration, which will fully transpose the legal provisions on the elimination of obstacles to the free movement of patented medicinal products. The approval of these amendments to Law No.50/2008 are included in the Government Action Plan for 2022.

69. Cultural Goods (Dir. 2014/60/EU)

Directive 2014/60/EU of the European Parliament and of the Council of 15 May 2014 on the return of cultural objects unlawfully removed from the territory of a Member State and amending Regulation (EU) No 1024/2012 (Recast) has not been yet transposed into national law. At the same time, there are no planned actions for its transposition in the Government Action Plan for 2021-2022, approved by Government Decision No.235/2021.

²³² Order of the Ministry of Health No.321 of 28.03.2013 on the rational use of medicines available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinul_321_din_28_martie_2013-fft.pdf

²³³ Law No.50/2008 on the protection of inventions available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107070&lang=ro

4. SECTORAL LEGISLATION & PROCEDURAL MEASURES (SPECIFIC QUESTIONS)

A. Medical Products Pricing

70. Are the conditions for the refusal of products to be added to the reimbursement list fully aligned to the conditions laid down in the *EU acquis*?

The procedure and criteria for inclusion / non-inclusion of the medicines in the national health insurance system is regulated by the Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320/2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance²³⁴. This joint order fully transposes the provisions of Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

The decision-making process regarding the non-inclusion of a medicine in the list of products comprised in the national health insurance system as well as its ways of appeal is regulated by the provisions of the Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320/2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance and of the Joint Order of the Ministry of Health and the National Health Insurance Company No.492/139/2013 regarding the reimbursed medicines from the funds of the compulsory health insurance²³⁵. The document partially transposes the provisions of Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

The procedure for excluding certain medicines or categories of medicines from the list of products covered by the national health insurance system is regulated by the provisions of the Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320/2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance, which fully transposes the provisions of Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

The decision-making process regarding the exclusion of a medicine from the list of products included in the national health insurance system, as well as its ways of appeal is regulated by the following normative acts:

²³⁴Order of the Ministry of Health No.600/320/2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128338&lang=ro#

²³⁵Order of the Ministry of Health No. 492/139/2013, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129700&lang=ro

- Joint Order of the Ministry of Health and the National Health Insurance Company No.600/320/2015 on the mechanism of inclusion of medicines for compensation from the funds of the compulsory health insurance;
- Joint Order of the Ministry of Health and the National Health Insurance Company No.492/139/2013 regarding the reimbursed medicines from the funds of the compulsory health insurance;
- Order of the National Health Insurance Company No.78-A of 18.04.2022 on updating the list of trade names of medicines²³⁶.
- Above-mentioned regulations fully transpose the provisions of Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

B. Civil Explosives

71. Is there a specific licensing and registration system for economic operators in the civil explosive sector?

In accordance with the provisions of pt.7 of Annex No.1 to Law No.160/2011 on Regulation of Entrepreneurial Activity by Authorisation²³⁷, type of activity "production, import, export, re-export, trade, storage of explosive materials and/or performing works with explosives for civil use" shall be subject to regulation by licensing.

72. Are economic operators in the civil explosive sector required to keep track of explosives so they can be tracked at any time?

According to the Government Decision No.1236/2016²³⁸ on the approval of the Technical Regulation on the establishment of a system for the identification and traceability of explosives for civil use, businesses must comply with the following obligations regarding the record-keeping of explosive materials:

²³⁶Order of the National Health Insurance Company No.78-A of 18.04.2022 on updating the list of trade names of medicines, available in Romanian at:
http://cnam.md/httpdocs/editorDir/file/MedicamenteCompensate/farmacii/2022/78-A%20din%2018_04_2022%20actualizarea%20Listei%20de%20denumiri%20comerciale%20de%20medicament e%20compensate%20din%20FAOAM.pdf

²³⁷Law No. 160/2011 on Regulation of Entrepreneurial Activity by Authorisation available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro

²³⁸Government Decision No. 1236/2016^[1] on the approval of the Technical Regulation on the establishment of a system for the identification and traceability of explosives for civil use available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=102604&lang=ro

- keeping a register of all explosives identifications as well as all relevant information, including the type of explosive, the name of the company or the name of the person in custody;
- recording the location of each explosive when in their possession or custody until it is transferred to another company or used;
- submitting regular tests of the data collection system in order to ensure its efficiency and the quality of the recorded data;
- recording and retaining data collected, including unique identifications, for a period of 10 years from delivery or from the last known date after the expiration of the life of the explosive, even if the undertaking concerned has ceased its commercial activity;
- protecting data collected against accidental or deliberate damage or destruction;
- providing the control body, upon request, with information on the place of origin and location of each explosive during its lifetime and supply chain;
- providing to the control body the name and contact details of the person who can provide the required information outside the normal working hours.

73. Are there specific controls on the transit of explosives and ammunition through the country?

Concerning the ammunition related to civilian weapons, transit control is carried out by the following authorities:

- Customs Service,
- the Interdepartmental Commission, which is the permanent body of the Government of the Republic of Moldova at the level of state secretaries of the authorities with competence in the field of national defense, state security and public order, and
- the Ministry of Internal Affairs, which according to Law No.130/2012²³⁹ on the regime of weapons and ammunition for civilian use, and Government Decision No.293/2014²⁴⁰ for the approval of the Regulation on the regime of arms and ammunition for civilian use, is the competent authority that exercises authorization, record-keeping, control and supervision over the possession, carrying and use of arms and ammunition, as well as their operation, being the only competent authority representing

²³⁹Law No.130/2012 on the regime of weapons and ammunition for civilian use, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129076&lang=ro#

²⁴⁰ Government Decision No.293/2014 for the approval of the Regulation on the regime of arms and ammunition for civilian use, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=48385&lang=ro

the Republic of Moldova in transfers and notifications concerning arms and ammunition.

74. Are there mechanisms in place to detect smuggled explosives?

Over the last few years, the Customs Service of the Republic of Moldova benefited from external assistance, which aimed to strengthen the operational and technical capacities.. Therefore, thanks to technical assistance, the Customs Service was equipped with customs control equipment, in particular with scanners and smuggling equipment, means of transport for mobile teams, as well as the customs laboratory.

In terms of the mechanisms to detect smuggled explosives, the Customs Service has special means of control, such as X-Ray - scanning means, metal detectors, hazmat ranger, customs laboratory with mobile laboratories, chemPro100i, k900 buster, in addition to canine teams.

C. Drug Precursors

75. Is the national list of controlled substances compliant with the *EU acquis*, and are they grouped into exactly the same categories (e.g. category 1, 2, & 3) as the *EU acquis*?

The national lists of narcotic precursors and psychotropic substances correspond to the lists and categories of precursors in the United Nations Single Convention on Narcotic Drugs of 1961; The Convention on Psychotropic Substances of 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, including the EU acquis.

In accordance with the provisions of Law No.382/1999 on the circulation of narcotic substances, psychotropic substances and precursors²⁴¹, with the subsequent amendments and completions, the following notions are provided:

- *narcotic substances* – substances listed in the Annexes to the United Nations Single Convention on Narcotic Drugs of 1961²⁴², as amended by the Protocol of 1972, and provided for in the normative acts of the Government.

²⁴¹ Law No.382/1999 on the circulation of narcotic substances, psychotropic substances and precursors, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108388&lang=ro

²⁴² United Nations Single Convention on Narcotic Drugs of 1961, available in English at: https://www.incb.org/incb/en/narcotic-drugs/1961_Convention.html

- *psychotropic substances* – substances listed in the Annexes to the Convention on Psychotropic Substances of 1971²⁴³ and provided for in the normative acts of the Government.
- Therefore, in accordance with the Government Decision No.1088/2004 on the approval of tables and lists of narcotic substances, psychotropic substances and their precursors, subject to control²⁴⁴, are approved tables and lists of narcotic substances, psychotropic substances and their precursors, subject to control, as follows:
- Table I *narcotics and psychotropic substances not used for medical purposes*, List No.1. Narcotic substances and List No.2 Psychotropic substances;
- Table II *narcotics and psychotropic substances used for medical purposes*, List No.1 Narcotic substances (narcotics) included in lists 2 and 4 of the Single UN Convention on Narcotic Drugs, 1961 and List No.2 Psychotropic substances included in List 2 of the UN Convention on Psychotropic Substances, 1971;
- Table III *narcotics (narcotics), psychotropic substances, used for medical purposes*, List No.1. Narcotic substances (narcotics) included in List 3 of the UN Single Convention on Narcotic Drugs, 1961; List No.2 Psychotropic substances included in List 3 of the UN Convention on Psychotropic Substances, 1971; List No.3 Psychotropic substances included in List 4 of the UN Convention on Psychotropic Substances, 1971.

76. Are there mechanisms in place to detect smuggled Drug Precursors? If so, what are they?

Since 2018, the Standing Committee on Drugs Control within the Agency for Medicines and Medical Devices, based on Law No.382/1999 on the circulation of narcotics, psychotropic substances and precursors²⁴⁵, has access to the PEN Online (Pre Export Notification) platform developed by the International Narcotics Control Board (INCB) which is used by Member States exporting chemical precursors to alert the competent national authorities in the importing country on the details of the export transaction.

Each import of precursors is actively and systematically verified by the Agency for Medicines and Medical Devices through this system. About 100 imports are

²⁴³ Convention on Psychotropic Substances of 1971, available in English at: https://www.incb.org/incb/en/psychotropics/1971_convention.html

²⁴⁴ Government Decision No. 1088/2004 on the approval of tables and lists of narcotic substances, psychotropic substances and their precursors, subject to control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=97918&lang=ro

²⁴⁵ Law No. 382/1999 on the circulation of narcotics, psychotropic substances and precursors, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108388&lang=ro

authorized annually (124 - in 2019, 102 - in 2020, 98 - in 2021). The regulatory authority has the right to defer importation until receipt of the result of the verification of shipped substances included in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.

77. Is there an obligation for economic operators to report suspicious orders or transactions?

The circulation of narcotics, psychotropic substances and precursors is regulated by the Law No.382/1999 on the circulation of narcotic substances, psychotropic substances and precursors²⁴⁶, which provides in Chapter IX, Art. 40¹, para. (11) that operators and users shall promptly notify the Standing Committee on Drugs Control of any circumstances, such as unusual orders or transactions with classified substances to be placed on the market, which suggest that such substances may be used in the illicit manufacture of narcotic or psychotropic substances.

At the same time, illicit actions on narcotics, psychotropic substances and precursors are regulated by Arts. 217-217⁶, 218, 219 of the Criminal Code of the Republic of Moldova²⁴⁷.

D. Good Laboratory Practice (GLP)

78. Do national legislative/regulatory GLP requirements apply to all the following chemical groups (please answer for each group of chemicals): industrial chemicals; pharmaceuticals; veterinary medical products; pesticides; food additives; feed additives; cosmetics; biocides?

Legal bases governing the scope of activity with pesticides

Legal bases governing the scope of activity with pesticides:

- Law No.119/2004²⁴⁸ on phytosanitary products and fertilizers which establishes the legal bases and state policy in the field of activity with phytosanitary products and fertilizers, regulates their conditions of state research, testing, experimentation and approval, manufacture, import,

²⁴⁶Law No.382/1999 on the circulation of narcotics, psychotropic substances and precursors, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108388&lang=ro

²⁴⁷Criminal Code of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130983&lang=ro#

²⁴⁸ Law No. 119/2004 on phytosanitary products and fertilizers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107644&lang=ro

transport, storage, marketing and use harmless to humans, animals, environment, reports on state surveillance and control force, determines the rights and obligations of enterprises, institutions, organizations and citizens, the powers of the competent authorities in the field, actions that are considered violations, as well as the responsibility for their commission.

- Law No.228/2010²⁴⁹ on plant protection and phytosanitary quarantine. Its purpose is to strengthen the legal and institutional framework, to create economic conditions suitable and carrount plant protection and phytosanitary quarantine, to ensure the prevention of the mass spread of harmful organisms, to avoid crop loss and to obtain a high agricultural production, especially ecological production.
- The object of the law is to organize and develop plant protection and phytosanitary quarantine in the territory of the Republic of Moldova, to list protection measures and activities against the occurrence or introduction on Moldovan territory from other countries, including via related goods subject to phytosanitary quarantine, of harmful organisms.
- Government Decision No.1045/2005²⁵⁰ for the approval of the Regulation on the import, storage, sale and use of plant protection products and fertilizers. The Decision establishes the conditions and manner of import, storage, sale and use of plant protection products and fertilizers, in order to suppress their illicit import, ensuring the protection of the vital interests and security of citizens, in accordance with the requirements of the legislation in force.
- Government Decision No.1307/2005²⁵¹ regulates the certification, state 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. The Decision also regulates GLP principles for laboratories performing tests on state certification and product approval, including toxicological and hygienic tests, are not regulated.
- Government Decision No.42/2020²⁵² for the approval of the Requirements for the sustainable use of plant protection products.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

²⁴⁹Law No. 228/2010 on plant protection and phytosanitary quarantine, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106744&lang=ro

²⁵⁰Government 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

²⁵¹Government Decision No.1307/2005 on the approval of the Regulation on state attestation 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

²⁵²Government 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

integrated pest management and alternative techniques such as non-chemical methods for plant protection.

- Government Decision No.123/2018²⁵³ on the approval of the National Integrated Plant Protection Program for the years 2018-2027 and the Action Plan on its implementation. The main objective of the Program is to optimize phytosanitary treatments by reducing the quantitative pressure of phytosanitary products at a unit of agricultural area, in order to ensure consumers with quality and safe plant products and a healthy living environment.
- Government Decision No.1191/2010²⁵⁴ (on approving the Sanitary Regulation on the maximum residues allowed for plant protection products in or on food and feed of plant and animal origin) regulates the activity of laboratories for the analysis of samples for the purpose of official control of product residues, which must be accredited in accordance with ISO/IEC 17025 and must use standardized and validated methods of analysis. Currently, there are laboratories in the Republic of Moldova accredited on the basis of ISO/IEC 17025 for the analysis of residues of phytosanitary products, respectively, these laboratories are subject to assessment by the National Accreditation Center MOLDAC.

Legal bases governing the scope of activity with chemicals:

At the national level, in order to regulate chemicals, Law No.277/2018 on chemical substances²⁵⁵ was adopted, which regulates the Principles of good laboratory practice (Chapter VI, Art.20). Important provisions in this law:

(1) Descriptions of good laboratory practices, ie. a quality system that deals with the organization and conditions under which non-clinical health and environmental safety studies are planned, performed, verified, recorded, archived and reported;

(2) The testing of the dangerous properties of chemical substances and chemical mixtures is carried out in laboratories that are accredited by the national accreditation body in accordance with the provisions of Law No.235/2011 on accreditation and conformity assessment activities and respecting the principles of good laboratory practice established by the Government;

²⁵³Government 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/cautare/getResults?doc_id=102113&lang=ro

²⁵⁴Government Decision No.1191/2010 approving the Sanitary Regulation on the maximum residues allowed for plant protection products in or on food and feed of plant and animal origin, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114320&lang=ro

²⁵⁵Law on chemicals No.277/2018 available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112668&lang=ro

(3) Manufacturers and importers of chemicals and chemical mixtures may submit test results for the evaluation of hazardous properties performed in international laboratories that comply with the principles of good laboratory practice.

The Law on chemicals No.277/2018 embraces and partially transposes the key EU chemicals Directives and Regulations, such as REACH, CLP, PIC, BPR, PPP, and GLP.

In accordance with the harmonization clause stipulated in the Law on chemicals, the following European Directives are partially transposed in this Law:

- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version) (Text with EEA relevance), published in the Official Journal of the European Union L 50 of 20 February 2004, which applies to the inspection and verification of the organizational processes and the conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing, carried out according to the rules and regulations, of all chemicals (e.g., cosmetics, industrial chemicals, medicinal products, food additives, animal feed additives, pesticides) in order to assess the effect of such products on man, animals, and the environment;
- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the approximation of the laws, regulations, and administrative provisions relating to the application of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) (Text with EEA relevance), published in the EU Official Journal L 50 of 20 February 2004, which apply to the measures necessary to ensure that laboratories carrying out tests on chemical products comply with the principles of good laboratory practice (GLP), measures necessary for verification of compliance with the principles of GLP, including inspections etc.

According to the Law on Chemicals, the respective normative act will be published by 2024.

Also, at national level, in accordance with the provisions established by the Order of the Ministry of Health No.189/2014, toxicological testing in the field of state surveillance of public health is carried out according to OECD methods as follows:

- OECD 402 Acute Dermal Toxicity: Fixed Dose Procedure
- OECD 404 Acute Dermal Irritation/Corrosion
- OECD 405 In Vivo Eye Irritation/Serious Eye Damage
- OECD 406 Skin Sensitisation Guinea Pig Maximization Test and Buehler Test
- OECD 420 Acute Oral Toxicity – Fixed Dose Procedure

- OECD 423 Acute Oral Toxicity – Acute Toxic Class Method
- OECD 436 Acute Inhalation Toxicity - Acute Toxic Class Method

Biocides

In the context of the regulation of biocidal products at national level based on Art. 6, para.b) of Law No.277/2018 on chemical substances, the Health Regulation on the placing on the market and use of biocidal products²⁵⁶ (according to Annex 2 paragraph 19-22), specifies the following:

- Certification tests must be performed according to standardized methods.
- If a standardized method is inappropriate or not described, other internationally recognized, scientifically appropriate methods should be used.
- The tests performed must comply with the appropriate requirements for the protection of laboratory animals laid down by national and international law.

If testing is not deemed scientifically necessary (Annex 3 II), data on physico-chemical properties from experiments that have not been carried out in accordance with good laboratory practice (GLP) standards or the relevant test methods will be considered equivalent to data obtained by the appropriate test methods, if the following conditions are met:

- are appropriate for classification, labeling and risk assessment purposes,
- adequate and reliable documentation is provided to assess study equivalence;
- are valid for the effect under study, which is performed using an acceptable level of quality assurance.

According to para. 100 of Annex 4, performance tests should be carried out according to national standards, and in their absence, international standards can be used. Currently, the bactericidal and levuricidal efficacy of biocidal preparations is evaluated according to approved international standards (ISO) as national standards:

- SM SR EN 1040:2012 Chemical antiseptics and disinfectants. Quantitative suspension testing for basic bactericidal activity of chemical antiseptics and disinfectants. Test methods and requirements (phase 1)
- SM EN 1276:2020 Chemical antiseptics and disinfectants. Quantitative testing of the suspension to evaluate the bactericidal activity of chemical

²⁵⁶Government Decision No. 344/2020, the Health Regulation on placing on the market and use of biocidal products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122109&lang=ro

antiseptics and disinfectants used in agri-food, industrial, domestic and community. Test method and requirements (Phase 2, Stage 1)

- SM EN 1650:2020 Chemical antiseptics and disinfectants. Quantitative testing of the suspension to evaluate the bactericidal activity of chemical antiseptics and disinfectants used in agri-food, industrial, domestic and community. Test method and requirements (Phase 2, Stage 1)
- SM SR EN 13727+A1:2014 Chemical antiseptics and disinfectants. Quantitative testing of the suspension for the evaluation of bactericidal activity in the medical field. Test method and requirements (Phase 2, Stage 1)
- SM SR EN 13697:2019 Chemical antiseptics and disinfectants. Quantitative testing of the non-porous surface for the evaluation of the bactericidal and / or fungicidal activity of chemical disinfectants used in the food, industrial, household and community fields. Test method without mechanical action and requirements (Phase 2, Stage 2)
- SM SR EN 13624:2014 Chemical antiseptics and disinfectants. Quantitative test of the suspension for the evaluation of fungicidal or levuricidal activity in the medical field. Test method and requirements (Phase 2, Stage 1)

Food additives

The sanitary regulation regarding the food products are approved via the Government Decision No.229/2013²⁵⁷, which sets the rules on food additives used in food products to ensure the efficient functioning of the internal market, a high level of protection of public health and a high level of consumer protection, including the protection of consumers' interests and fair practices in food trade, taking into account, where appropriate, environmental protection.

The mentioned regulation does not provide GLP principles for laboratories which are performing tests on food additives. However, currently in the Republic of Moldova there are laboratories accredited according to ISO / IEC 17025 for testing food additives using international standardized methods.

Cosmetics

According to Chapter III, paragraph 18 of Government Decision No.1207/2016²⁵⁸ for the approval of the *Sanitary Regulation regarding cosmetic products*, the safety assessment of cosmetics, except for those from the Member States of the European

²⁵⁷Government Decision No.229/2013 The sanitary regulation regarding the food products, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=109707&lang=ro

²⁵⁸Government Decision No.1207/2016 for the approval of the Sanitary Regulation regarding cosmetic products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102601&lang=ro

Union, is carried out by accredited bodies in accordance with the relevant EU harmonized standards, and which are accepted as national standards. Currently, there are laboratories in the Republic of Moldova accredited according to ISO/IEC 17025 in the field of cosmetics testing.

The methods referred to para. 26 of Government Decision No.1207/2016 of this Regulation, provide guidelines for the production, approval, testing of cosmetics in accordance with the rules of the Code of Good Manufacturing Practices (GMP), covering aspects related to the manufacturing and verification process of laboratory quality, to confirm that the product meets the acceptance criteria for cosmetics.

The assessments required to verify the composition of cosmetic products (paras. 26 to 27) shall be carried out in accordance with the requirements specified in Annexes 10 to 16 to this Regulation. The determination of the toxicological, sanitary-chemical and bacteriological properties of the harmless indices shall be carried out in accordance with the relevant harmonized standards, the references of which are published in the Official Journal of the European Union and which are adopted as national standards.

Currently, testing laboratories in the fields of pesticides, food additives, cosmetics comply with the requirements of the international standard ISO / IEC 17025 thus, when issuing the test results, the respective laboratories refer to the accreditation, but not to the compliance with the GLP principles.

Pharmaceuticals

EU pharmaceutical legislation refers to GLP in Annex I to Directive 2001/83/EC, which has been transposed into Regulation on the authorization of medicines approved by Order of Ministry of Health No.739/2012²⁵⁹, namely as an obligation to perform non-clinical studies in compliance with GLP guide. This guide is in the process of development by the Agency of Medicines and Medical Devices and will be finalized by the end of 2022.

²⁵⁹Order of Ministry of Health No.739/2012, available in Romanian at: [OMS739/2012 \(legis.md\)](#)

E. Chemicals Classification, Labelling and Packaging (CLP)

79. Is national legislation on CLP aligned with the United Nations Globally Harmonised System of Classification and Labelling of Chemicals?

The Law on chemicals No.277/2018²⁶⁰ embraces and partially transposes the key EU chemicals directives and regulations, such as *REACH*, *CLP*, *PIC*, *BPR*, *PPP* and *GLP*.

In conformity with the harmonization clause stipulated in the Law on chemicals, the Articles 1, 2, 4, 5, 6, 8, 35, 43, 46, 47, 49 of the Regulation (EC) No.1272/2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 „, have been transposed into the Chemicals Law.

For example, the Article 14 of the Law on chemicals establishes provisions for Packaging of Substances and Mixtures, as follows:

- Packaging of substances and mixtures is carried out before placing them on the market to ensure their safe delivery and not endanger humans and other living organisms' environment, life, and health.
- Substances and mixtures are placed on the market only if the packaging is compliant with the Law and the EU Regulation on classification, labeling, and packaging of substances and mixtures, approved by the Government.
- Packages containing hazardous substances and mixtures must comply the following requirements:
 - the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents or liable to form hazardous compounds with the contents.
 - the packaging and fastenings shall be solid throughout their transportation to ensure that they will not loosen and safely meet the normal stresses and strains of handling.
- Packaging containing a hazardous substance or mixture supplied to the general public must not hold a shape or a design which would attract the curiosity of children, or that would mislead consumers. Designs that would mislead the consumer include for example, packaging with similar presentation or design used for food products, for animal feeding products, for medicinal or cosmetic products
- Packaging of hazardous substances or mixtures shall be equipped with a fastening resistant system for children and tactile warning of danger

²⁶⁰ Law on chemicals No. 277/2018, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=112668&lang=ro

according to Regulations on classification, labeling and packaging of substances and mixtures mentioned in para. (2) of this Article.

According to the Law on Chemicals, the Regulation on classification, labeling and packaging of substances and mixtures is in process of development. In this regard, the Draft Government Decision on classification, labeling and packaging of substances and mixtures has been published online, in order to ensure a transparent process of the decision making²⁶¹. The Draft Decision aims to align the national legislation with the CLP Regulation.

Also, the elaborated Informative Note and Regulatory Impact Analysis (RIA) for the Government Decision on classification, labeling and packaging of substances and mixtures have been transferred to the State Chancellery for examination by the Working Group of the State Commission for Regulation of Entrepreneurial Activity. As result, the RIA was examined and supported by the Working Group of the State Commission for Regulation of Entrepreneurial Activity²⁶².

The draft Government Decision on classification, labeling and packaging of substances and mixtures is under development, being planned for approval in 2023.

F. Fertilisers

80. Are any categories of fertiliser regulated outside the scope of Reg. (EC) 2019/1009? If so, please give details.

In the national legislation, the Technical Regulation „Mineral fertilizers. Essential requirements”, approved by Government Decision No.268/2012²⁶³, transposes Regulation (EC) No.2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilizers, which was repealed by Regulation 2019/1009.

²⁶¹ Draft Government Decision on classification, labeling and packaging of substances and mixtures, available in Romanian at:

<https://old.madrm.gov.md/ro/content/anunt-privind-inițierea-elaborării-proiectului-de-hotărîre-guvernului-cu-privire-la-1>

²⁶² RIA https://cancelaria.gov.md/sites/default/files/agenda_08_09_2020.semnat.pdf

²⁶³ Government Decision No.268/2012 on the approval of the Technical Regulation „Mineral fertilizers. Essential requirements”, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=75654&lang=ro

G. Medical Devices

81. Is there a national Agency for Drugs and Medical Devices? If so, does it have adequate resources to ensure the control of the relevant products and of economic operators?

The Agency for Medicines and Medical Devices is the regulatory authority responsible for the registration of:

- certified medical devices in the Republic of Moldova,
- medical devices bearing the CE marking, certified by notifying conformity assessment bodies, published in the Official Journal of the European Community,
- medical devices certified by accredited conformity assessment bodies with which international recognition agreements have been concluded, with their registration in the Register of Certified Medical Devices, in accordance with the provisions of Government Decision No.71/2013 on the approval of the Regulation, structure and staffing of the Agency for Medicines and Medical Devices²⁶⁴.

The function of supervision and control in the field of medical devices is held by the National Agency for Public Health (NAPH), pursuant to provisions of the Law No.102/2017 on Medical Devices²⁶⁵, as well as in accordance with Government Decision No.1090/2017²⁶⁶ on the organization and operation of the National Agency for Public Health, Chapter II, Art. 9, para. b): performing the control of the circulation of medicines, parapharmaceuticals, medical devices, including their radiological and nuclear safety, the control of the services provided by the medical service providers and the pharmaceutical activity.

Overall, there are only 3 pharmaceutical inspectors within NAPH. Due to the limited capacities in trained inspectors in the field of medical devices, only unannounced checks are performed based on petitions received from the population, numbering about 5-6 per year. In this context, the reform of the pharmaceutical inspection is envisioned to assign the function of supervision and control in the field of medical devices to the Agency for Medicines and Medical Devices.

²⁶⁴ Government Decision No.71/2013 on the approval of the Regulation, structure and staffing of the Agency for Medicines and Medical Devices, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=19047&lang=ro

²⁶⁵ Law No.102/2017 on Medical Devices, available in Romanian at:

https://www.legis.md/cautare/getResults?doc_id=128123&lang=ro#

²⁶⁶ Government Decision No.1090/2017 on the organization and operation of the National Agency for Public Health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114711&lang=ro

H. Control of the acquisition and possession of weapons

82. Does national legislation regarding the acquisition and possession of weapons lay down the categories of firearms, which are prohibited to be acquired or in the possession of private persons that are subject to authorisation or declaration? If so, please provide details.

The Law No.130/2012²⁶⁷ on the regime of firearms and ammunition for civilian use, establishes the categories of weapons and ammunition for civilian use, as well as the conditions under which the acquisition, transfer, possession, carrying, use and operations with these weapons and ammunition are allowed on the territory of the Republic of Moldova.

Under the conditions of the above-mentioned Law, Art. 2, the following notions are highlighted:

- *Weapon* means any object or device in the categories in Annex 1, designed or adapted, by means of which projectiles, bullets or other projectiles or noxious substances, regardless of the state of aggregation, can be projected by explosive, gaseous or atmospheric pressure or other propelling agents;
- *Firearm* means any portable barreled weapon that can, is designed to, or can be converted to, expel buckshot, a bullet or a projectile by the action of a propellant. An article shall be considered to be capable of being converted to expel a shot, bullet or projectile by the action of propellant if it has the appearance of a firearm and, by reason of its construction or the material from which it is made, is capable of being so converted.

At the same time, Annex no.1 to Law No.130/2012 expressly indicates the main categories of weapons in civilian circulation: Category A - prohibited firearms and ammunition; Category B - firearms subject to authorization; Category C - weapons subject to declaration; Category D - other weapons not subject to authorization.

For the purposes of Law No.130/2012, the definition of firearms does not include the weapons listed in categories C and D of Annex 1.

Additional, in accordance with the provisions of section 6 of Annex No.1 to Law No.160/2011 on Regulation of Business Activity by Authorisation²⁶⁸ production, assembly, import and / or export, re-export, trade in weapons and ammunition for civilian use and repair of weapons for civilian use" is subject to regulation by licensing. Moreover, if the category of weapons to be imported, transited, exported or re-exported meets the conditions concerning the dual-use strategic goods, authorisation shall also be required.

²⁶⁷Law No.130/2012 on the regime of weapons and ammunition for civilian use, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129076&lang=ro#

²⁶⁸Law No.160/2011 on Regulation of Business Activity by Authorisation, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130211&lang=ro

I. Cultural Goods

83. Is there legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State?

The Republic of Moldova has ratified the Convention on Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, adopted by the UNESCO General Conference in Paris on November 14, 1970, through the Law No.141/2007 with the following statement: „Until the full restoration of the territorial integrity of the Republic of Moldova, the provisions of the Convention shall apply only on the territory effectively controlled by the authorities of the Republic of Moldova”.

In order to return illicitly exported cultural goods, the Republic of Moldova complies with the regulations established by the Convention on Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, adopted by the UNESCO General Conference in Paris on 14 November 1970.

In the Republic of Moldova, the circulation of cultural goods is regulated by Law No.280/2011²⁶⁹ on the protection of the mobile national cultural heritage. According to this normative act, the removal from the country by any means of classified cultural goods without temporary export authorization is illegal. The same is regulated by the Criminal Code of the Republic of Moldova No.985/2002²⁷⁰. Article 27 of Law No.280/2011²⁷¹ contains general provisions on the restitution of movable cultural goods, illegally removed from the territory of a state.

84. If so, what are the legal provisions to ensure this, and what categories of cultural goods are covered?

The following categories of cultural assets fall under the incidence of Law No.280/2011:

- Archaeological and historical-documentary goods (archaeological pieces; inscriptions, separate elements from the dismantling of historical monuments; material and documentary evidence on political, economic, social, military, religious, scientific, artistic, sports or other fields; manuscripts, incunabula, rare and old books, publications of various kinds, with autographs and ex-libris, periodicals, documents and prints of social interest, objects of memorial value, objects and documents of numismatic,

²⁶⁹Law No.280/2011 on the protection of the mobile national cultural heritage, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106379&lang=ro

²⁷⁰Criminal Code of the Republic of Moldova No.985/2002, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=122429&lang=ro

philatelic, heraldic value: coins, medals, decorations, badges, banknotes, seals, patents, postage stamps, flags and banners; epigraphic pieces; photographs, photographic clichés, movies, audio and video recordings; musical instruments; military uniforms and their accessories; clothing);

- Goods of artistic significance (works of art: painting, sculpture, graphics, drawing, engraving, printing; decorative and applied works of art: furniture, tapestries, carpets, pieces of glass, ceramics, metal, wood, textiles and other materials, ornaments; objects of worship; design projects and prototypes; primary materials for artistic, documentary and animated films; public monuments, outdoor art components; postcards and illustrations; decorative pieces for shows);
- Ethnographically significant goods (elements of folk architecture; elements of technical installations; household and household goods; work tools; products of the home textile industry: carpets, wall hangings, towels, folk costumes; furniture; custom props; objects of worship, contemporary handicrafts);
- Goods of scientific importance (rare specimens and collections of zoology, botany, mineralogy, petrology, paleontology, anthropology, speleology, anatomy; hunting trophies);
- Goods of technical importance (unique technical creations; rarities, regardless of brand; prototypes of devices, devices and machines of current creation; watchmaking; achievements of traditional technology; technical documents: projects, plans, sketches, patents; means of transport and telecommunications; CD, CD-ROM, DVD arrays);
- Memorial goods (memorial goods and objects; documents and photographs from the lives of personalities of importance; pieces related to events of national and international importance).
- According to Art. 27 of the above-mentioned legislation, the unlawful removal of movable cultural property from the territory of a State means:
- Removal of a classified good from the territory of a state in violation of the legislation of that state in the field of protection of cultural goods;
- Non-return of the classified goods at the end of a legal temporary export or any violation of any of the conditions of this temporary export.
- Para. 4 stipulates that the Ministry of Culture shall take the necessary measures for the return to the applicant State of the movable cultural goods illegally removed from its territory, as well as for the return to the country of cultural goods illegally removed from the territory of the Republic of Moldova.
- Procedures for the return and recovery of cultural property unlawfully removed from the territory of a State or from the territory of the Republic of Moldova shall be exercised in accordance with the provisions and rules established by international law, in particular the Convention on Means of

Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, adopted by the UNESCO General Conference in Paris on 14 November 1970, which was ratified by Law No.141/2007.

- Para. 6 stipulates that the competent authorities of the Republic of Moldova shall take the necessary measures to prevent any attempt to ignore the procedure for the return of the cultural property illegally removed from the territory of a state and will act as mediators between the possessor or, as the case may be, the holder of the cultural good illegally removed from the territory of the state.

85. Which authority, if any, is responsible for dealing with the return of cultural goods?

Art. 27 of Law No.280/2011, specifies that the Ministry of Culture is the institution responsible for the restitution to the requesting state of the movable cultural goods illegally removed from its territory, as well as for the return to the country of the cultural goods illegally removed from the territory of the Republic of Moldova. In case of situations regarding the return of cultural goods, the Ministry of Culture will request the involvement of the Ministry of Foreign Affairs and European Integration in order to resolve the issue through diplomatic channels.

According to Art.28 of the same normative act, the Ministry of Culture may request any state, through the competent authorities and in accordance with the law, to conduct research in order to find the location of the illegally removed movable cultural goods from the Republic of Moldova and identify its owner. The recovery of the identified cultural assets is carried out according to the legal procedures agreed between the parties.

J. Firearms

86. Are there statistics about legal holders of firearms in Moldova (hunters, marksmen, private persons or companies)? Are there records of illegally possessed arms and are there any plans to seize them?

According to police records, there are currently 61 436 (64,704 - 2021) individuals in possession of 76 159 (77 444 - 2021) weapons, of which:

- with tubular barrel – 22,659
- shotguns - 19145
- with long barrel with bullet - 3514

- with smooth barrel – 46,940
- with smooth long barrel – 44 297
- with rubber balls - 2643
- non-metallic - 5,560
- gas gun - 3568
- pneumatic gun - 1843
- flare pistols - 50
- starter pistols - 14
- flobert cartridge guns - 46
- other weapons subject to declaration – 39.

At the same time, a total of 234 targets of the licensing system are on record, with 4,371 weapons under management.

According to the records of the Society of Hunters and Fishermen of the Republic of Moldova there are currently 13726 registered hunters, 1073 are members of sports' clubs within the shooting sports federations accredited by the Ministry of Education and Research, as well as 493 collectors.

87. Are there any special rules for collectors and bodies concerned with the cultural and historical aspects of weapons? If so, must these collectors and bodies be recognised by the local authorities?

The weapons are subject to a special record, according to Law No.130/2012²⁷² on the regime of weapons and ammunition for civilian use. Under the conditions of the enunciated Law, the following notions are highlighted:

- collector's weapon - a weapon intended to be a museum piece, as well as weapons that may or may not be in working order that constitute rarities or that have historical, documentary, scientific or artistic value;
- old weapon - lethal weapon produced before 1877 or its reproduction to be kept in collections;
- collector of weapons - a person who has acquired, under the law, a collector's certificate, issued by the competent authority, and who is the owner or intends to become the owner of a collection of weapons to be authorized or declared in accordance with this law, for the purpose of historical capitalization of these weapons.

Art. 32 of the Law no.130/2012 mentions that the competent authorities that give the permission for the procurement, possession and use of weapons and

²⁷²Law No.130/2012 on the regime of weapons and ammunition for civilian use, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129076&lang=ro#

ammunition are the authorized service of the Ministry of Internal Affairs or of the police bodies in whose territorial jurisdiction the seat of the legal entity or the place of storage of weapons and ammunition are, under the conditions of this law.

According to Art.7 para.(3) of Law mentioned above, the conditions for the granting of a permit to purchase and, where appropriate, a firearms permit for rifled and smooth-bore weapons, as well as the application for the issuance of a *collector's certificate*, shall be submitted to the authorized service of the Ministry of Internal Affairs, and for smooth-bore weapons - may also be submitted to the police body in whose territorial jurisdiction the applicant is domiciled, and according to the provisions of Government Decision No.293/2014²⁷³ for the approval of the Regulation on the regime of weapons and ammunition for civilian use, **the procedure for granting the collector's certificate is set out in point 54** that Individuals wishing to own collector's weapons may apply to the competent police body for the granting of the collector's certificate, if they meet the conditions specified in Art. 7 of Law No.130/2012, and point 55 of the Government Decision.

In order to obtain the collector's certificate, the applicant must submit an application accompanied by the documents referred to in points 7 (1)- (7) and one of the following documents, as appropriate, justifying the purpose of the application:

- proof of the status of heir to a lethal weapon;
- the act of donation (decoration) from a public institution, a museum, another authorized legal person, as well as from natural persons legally in possession of the weapon to be donated;
- a document issued by a museum or an association of collectors certifying that the weapon to be purchased is a weapon intended as a museum piece or constitutes a rarity or has artistic, scientific or documentary value;
- a certificate issued by a collectors' association, legally established in the Republic of Moldova, certifying the applicant's membership or, where applicable, the fact that the applicant will become a member after the purchase of the collector's weapon.

In the situation where the applicant is the holder of the right to possess or carry and use a lethal weapon, the application may be accompanied only by a valid firearms license and the documents mentioned above.

If the conditions laid down by law are met, the competent police body shall issue the applicant with a collector's certificate and, where appropriate, a firearms license. If the conditions for issuing a collector's certificate are not met, the competent police body shall notify the applicant in writing of the reason for rejecting the application. The collector's certificate confers on the holder, where

²⁷³ Government Decision No.293/2014 for the approval of the Regulation on the regime of weapons and ammunition for civilian use, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=48385&lang=ro

appropriate, the right to keep in the collection weapons which he has inherited or donated before obtaining this right, as well as the right to acquire and keep collector's, hunting or shooting (sporting) weapons. Weapons held in collection may not be used under any circumstances, except in self-defense.

If the collector has made use of the weapon, he is obliged to act under the conditions provided for in Art. 17 of the Law. The collector's certificate shall be endorsed at the same time as the firearms license in which the weapons held in the collection are registered.

Museums may be authorized, under the terms of this law, to procure and possess collectible weapons as well as non-lethal weapons.

Public museums, including those with weapons collections, are registered in the Register of Museums of the Republic of Moldova, managed by the Ministry of Culture. Private gun collectors are not in the records of the Ministry of Culture.

Weapons, which have historical, technical, memorial and artistic value, are part of the category of movable cultural goods.

The evidence of museum goods, including weapons, is made in accordance with Law No.262/2017²⁷⁴ of museums and the Regulation on the evidence and conservation of museum heritage, approved by Government Decision No.604/2020²⁷⁵. Any cultural good entered in the museum / public collection on a permanent basis or in temporary custody, including weapons, is subject to the procedure of evidence, written and computerized and registered in the Register of evidence of the museum heritage.

Special records are kept in the Weapons Register. The weapons register contains such information as: weapon number, caliber, model, type, number of cartridges, material, size, country of manufacture, etc. The register is kept in written and electronic format.

According to Law No.130/2012²⁷⁶ on the regime of weapons and ammunition for civilian use, weapons that can no longer be brought into operation can be deactivated and kept as collectible weapons, panoply, instruction or museum pieces, and those that cannot be sold, put out of use or their components are handed over to the Ministry of Internal Affairs for their scrapping and destruction. Disabled weapons are used only for instruction, panoply, collection and as museum or exhibition pieces. Annex No.3 of the above-mentioned Law states the

²⁷⁴Law No.262/2017 of museums, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=105639&lang=ro

²⁷⁵Government Decision No.604/2020 on the implementation of the Museums Law No.262/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=123059&lang=ro

²⁷⁶ Law No.130/2012 on the regime of weapons and ammunition for civilian use, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=110345&lang=ro

conditions that the storage and storage spaces of weapons and ammunition must meet.

88. Does the legislation, if any, exclude from its scope weapons and ammunition used for hunting or target shooting? If so, what rules are applied?

The conditions for possession of hunting weapons and shooting weapons are laid down in Law No.130/2012 on the regime of weapons and ammunition for civilian use. According to this law, *hunting weapon* is a weapon intended for hunting, with one or more barrels, using ammunition with bullet and/or buckshot, approved or recognized under the law, and *shooting (sporting) weapon* is a weapon intended for sporting shooting, approved or recognized under the law.

The right to own a firearm is granted only for self-defense, shooting, hunting and collector's weapons, giving the holder the possibility to keep the weapon at home. The right to own hunting weapons is granted, under the terms of this Law, to hunters who are members of legally constituted hunting associations, who operate in accordance with the legislation on animal kingdom, who have passed the examination for obtaining the status of hunter, who hold a valid hunter's license, as well as to sportsmen, shooting coaches and gun collectors.

The holder of the right to possess hunting weapons may carry and use the weapons entered on the weapon permit only on hunting grounds for which he is authorized, and in shooting ranges authorized by law.

Hunting weapons as well as long guns may only be purchased by hunters, sportsmen, shooting coaches and gun collectors. The transport of hunting weapons, for which a firearms license with the right to possess has been issued, from the owner's residence to the place where hunting is to be carried out, in accordance with the law, shall be carried out under the following conditions:

- the weapons must be kept in their holsters, unloaded;
- they must be carried at all times only by the possessor and must not be transferred in any form to other persons, except to armorers, competent police bodies, and to personnel authorized by law to keep and temporarily secure weapons when entering public institutions, means of sea or air transport, or other places where the carrying of weapons is prohibited by law;
- weapons must be accompanied by the document certifying the right to possess them.

The carrying of hunting weapons in the hunting area is subject to the following conditions:

- the firearm may be loaded provided that, after loading, it is secured and carried in such a way that it does not present a danger of accident;
- it must be carried at all times only on the person's person and must not be passed on in any form to other persons, with the exception of armorers, the competent police authorities and personnel authorized by law to keep and temporarily secure weapons when entering public institutions, means of sea or air transport or other places where the carrying of weapons is prohibited by law;
- and weapons must be accompanied by the document certifying the right to possess them.

The holder of the right to possess long arms with rifled barrels and collectors' long arms (except those expressly mentioned in the firearms license with the right to carry) may, on request, obtain from the police authority in whose territorial jurisdiction he is domiciled a transport permit for the removal of arms held under the law from their place of storage in the following situations:

- deposit them with a gunsmith;
- change of place of storage;
- transport and use in a firing range specially equipped and authorized by law for the category of weapons in question;
- transporting them to be taken out of the territory of the Republic of Moldova for participation in sporting competitions or hunting.

The holder of the right to possess hunting weapons may apply the weapon registered in the firearm permit only on the game for which he has been authorized, as well as for training purposes in shooting ranges authorized under the law. By exception, hunting weapons may also be applied in self-defense or in a state of extreme necessity, under the terms of the law.

89. Is there an overall obligation to mark firearms at the time of manufacturing? What kind of marking is applied?

No weapons are manufactured in the Republic of Moldova.

According to the Law No.130/2012 on the regime of weapons and ammunition for civilian use, conditions for manufacturers are set as follows: Art. 49. *Marking of arms and ammunition produced by arms manufacturers in the Republic of Moldova*; Art. 50. *Recording of arms and ammunition manufactured in the Republic of Moldova*; Art. 51. *Keeping of records of manufactured arms and ammunition*.

90. Are there record-keeping obligations to trace transfers of firearms when manufactured or sold by dealers? Who has this obligation (the State, the dealers)? For how many years?

No weapons are manufactured in the Republic of Moldova, and Law No.130/2012 stipulates the following: *Article 3. Delimitation of competences*:

(1) The legal regulation of the control of arms and ammunition is a matter for Parliament.

(2) The Government, in accordance with its powers:

a) approves the regulations implementing the Law No.130/2012;

b) carries out State policy in the field of circulation and use of lethal and non-lethal weapons and ammunition for civilian use;

c) decides on the acquisition of arms and ammunition, including civilian arms and ammunition, for the public administration authorities with competence in the field of national defence, state security and public order;

d) draws up and approves the regulations of the State Commission for the evaluation, upgrading and scrapping of weapons.

(3) The Ministry of Internal Affairs is the competent authority exercising authorization, record-keeping, control and supervision over the possession, carrying and use of arms and ammunition, as well as over operations with them, and is the only competent authority representing the Republic of Moldova in transfers and notifications of arms and ammunition under the terms of Law No.130/2012, in the field of authorization, registration, control and supervision of the circulation of arms and ammunition.

91. How are the fire arms tested at the time of manufacturing? Are there state proof-houses?

In the Republic of Moldova there is no laboratory for testing of firearms produced in the country, respectively there is no procedure.

92. What are the main requirements to "deactivate/neutralise" a firearm? Which techniques are used?

The requirements for the deactivation of firearms are stipulated in Law No.130/2012, Article 68. Deactivation of weapons.

Government Decision No.293/2014²⁷⁷ approving the Regulation on the regime of weapons and ammunition for civilian use, Chapter XXXVII. **Deactivation or conversion of lethal weapons into non-lethal weapons**, establishes:

- Lethal weapons may only be converted by gunsmiths licensed to carry out weapons repair operations into deactivated/ panoply weapons or prop weapons.
- The owner of a lethal weapon who wishes to convert it into a non-lethal weapon under the conditions of paragraph 334 must give prior notification to the police body in whose records the weapon is kept, who shall issue him with a certificate stating its identification data and the fact that it is to be converted into a deactivated/panic weapon or, where appropriate, a prop weapon.
- Lethal weapons can be converted into deactivated/panic weapons by piercing the barrels immediately after the cartridge chamber, the diameter of the hole being at least 5mm.
- Lethal weapons can be converted into prop weapons by plugging the barrel channel with two steel pins fixed by pressing or welding to the outside of the barrel and positioned in such a way as to allow the introduction into the chamber of the cartridge only of handling ammunition not loaded with bullet or shot.
- Certification by means of a ballistic technical-scientific report issued by the central or local police service authorized to carry out ballistic examinations shall be carried out in accordance with the recommendations of the „Best practice Guide: minimum standards for national procedures for the deactivation of small arms and light weapons” issued by the OSCE in 2018.

²⁷⁷Government Decision No.293/2014 for the approval of the Regulation on the regime of weapons and ammunition for civilian use, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=48385&lang=ro