

GOVERNMENT OF THE REPUBLIC OF MOLODVA

RESOLUTION No. 423

of 3 May 2000

Chisinau

**On approval of Regulations on state sanitary-epidemiological supervision
in the Republic of Moldova**

The Government of the republic of Moldova RESOLVES:

1. To approve the Regulations on state sanitary-epidemiological supervision in the Republic of Moldova (attached).
1. The Ministry of Health Care, prefectures, judet local public administration, UTA Gagauzia, town municipalities jointly with the state sanitary-epidemiological supervision authorities, as well as services and departments interested in implementation of prophylactic and anti-epidemic measures, shall exercise permanent control of the execution of the regulations of on state sanitary-epidemiological supervision in the Republic of Moldova.
2. To abrogate the Resolution of the Government of the Republic of Moldova NR 816 as of December 12, 1995 "On approval of Regulations on state sanitary-epidemiological supervision in the Republic of Moldova".

Prime Minister
the Republic of Moldova

Dumitru Braghis

**REGULATIONS
on state sanitary-epidemiological supervision in the Republic of Moldova**

1. Regulations on state sanitary-epidemiological supervision in the Republic of Moldova was developed in compliance with provisions of the Constitution of the Republic of Moldova, the law on Health Care and the Law on sanitary – epidemiological safeguarding of the population. The main objective of the state sanitary-epidemiological supervision is to protect and implement public health by highlighting factors impacting it, through developing recommendations and exercising control over execution of sanitary – hygienic and sanitary – epidemiological measures oriented towards:

- accomplishing prophylactic and anti-epidemic measures, extension of immunization of population against certain infectious diseases;
- ensuring food safety;
- improving working, training, education, leaving and leisure conditions of population;
- prevention, elimination or reducing the level of environmental pollution;
- minimization of consequences of natural calamities and other exceptional conditions for public health;
- promoting health education and healthy lifestyle;
- complete, objective and continuous reporting to the government officials and population about sanitary-epidemiological condition nationwide;

2. Definitions

(a) *Sanitary measure* – any measure taken to:

- protect, within the country, life or health of people against risks caused by polluters, contaminates, additives, toxins, toxic components of natural origin, pathogenic and conditionally pathogenic organisms present in raw materials, semi-finished goods, final consumer goods, environmental factors, food (drinks inclusively), as well as risks determined by indecent practice of some legal entities or individuals;
- protect the territory of the country against risks of penetrating conventional and extremely dangerous diseases for human beings.

(b) *Harmonization* – establishing, acknowledging and enforcement of sanitary or anti-epidemic measures jointly with other nations members of the World Health Organization, World trade organization, other international bodies.

(c) *Risk evaluation* – evaluation of probability of penetration, deep-rooting and spreading of a disease on the territory of the country, compliant with sanitary measures which might be taken and related possible biologic and economic consequences, or evaluation of likely adverse effects on health resulting from exposure to noxious factors.

- (d) *International standards, guidelines and recommendations* - standards, guidelines and recommendations set forth by World Health Organization, Codex Alimentarius Commission, other international structures for maximum admissible values of different harmful, toxic and potentially toxic substances, contents of pathogenic and conditionally pathogenic agents and products of their vital activities, natural factors with harmful effects on human beings, etc., methods of analysis and sampling, and codes and guidelines for hygienic subjects.
 - (e) *Adequate level of sanitary protection* – level of protection deemed adequate by the Ministry of Health of the Republic of Moldova, which establishes the necessary sanitary extent to protect life and health of the nation.
 - (f) *Disease free area* – an area, either the entire territory of the country, or part of it, or a number of countries, identified by competent authorities, free of specific diseases.
 - (g) *Slight spread disease area* - an area, either the entire territory of the country, or part of it, or a number of countries, identified by competent authorities, developing specific disease with slight intensity, which is efficiently monitored, controlled or eradicated.
 - (h) *Sanitary – hygienic authorization for facility operation* – represents a state sanitary authorization act which provides for operation of businesses and social-cultural agencies from hygienic and sanitary standpoint.
 - (i) *Hygienic certification* – survey procedure effected by the State Sanitary-Epidemiological Service, which reveals compliance of control systems with current requirements, allows production (importing) and marketing of goods and confirms their safety for population.
3. State sanitary –epidemiological supervision in the republic of Moldova is being carried out by the State Sanitary-Epidemiological Service of the Ministry of Health in the form of continuous supervision of the environmental factors quality, food flow, working, training, education, living, leisure, etc. conditions which can impact health or life; current and preventive supervision of execution of sanitary–hygienic and sanitary-epidemiological regulations and norms by ministries, departments, institutions, organizations, business agents, legal entities and individuals.
 4. State sanitary –epidemiological Service is an integral system of institutions and organizations under the Ministry of Health including:
 - National Scientific-practical Center for Preventive Medicine
 - Centers of Preventive medicine at judet level, in towns and UTA Gagauzia, with their territorial branches.
 5. Management of facilities and institutions of the State sanitary –epidemiological Service is assigned, respectively, on:
 - Vice-minister of Health, head sanitary doctor of state of the Republic of Moldova and his/her deputies;
 - head sanitary doctor of state at judet level, in towns and UTA Gagauzia, Directors of Preventive Medicine Centers and their deputies at judet level, in towns and UTA Gagauzia;
 - chief specialists of the Ministry of health in the field of preventive medicine.

6. The Head sanitary doctor of state of the Republic of Moldova is appointed and relieved from office by the government, at the request of the Ministry of Health.

The deputies of the Head sanitary doctor of state of the Republic of Moldova and head sanitary doctors at judet level, in towns and UTA Gaguzia are appointed and relieved from office by the Ministry of Health after coordination with territorial prefects.

7. Ministry of health of the Republic of Moldova is responsible for managing the activity of the State Sanitary-Epidemiological Service, for which purpose, directly, or through the subordinate institutions:
 - a) conducts scientific research in the field of hygiene, epidemiology, protection of public health, for the purpose of working out of measures for control or prevention of diseases, and establishing main guidelines for the Service's activities;
 - b) reveals and keeps record of environmental and living factors which have a negative impact on public health, develops and submits, in established order, recommendations on health protection and strengthening;
 - c) works out and approves, in established order, regulations and sanitary-hygienic and sanitary-epidemiological norms, other normative documents mandatory for all individuals and legal entities, regardless of ministerial subordination and form of property;
 - d) works out and submits to the Government of the Republic of Moldova for approval drafts and legal normative acts regarding the issues of sanitary-epidemiological safeguarding of population, proposals on establishing or abolishing special conditions and orders of living and economic activity oriented towards prevention of aggravation of sanitary-epidemiological situations and liquidation of epidemics and mass intoxication and, if necessary, sets forth the manner of repairing damages caused to groups of population as a result of violation of sanitary legislation;
 - e) exercises control over execution of national programs of sanitary-epidemiological safeguarding of population, implementation of technical and scientific accomplishments in the field of diseases prophylaxis, drafting state policy in the field of immunological prophylaxis;
 - f) co-works with counterpart international organizations and services abroad in the field of preventive medicine and sanitary-epidemiological safeguarding of population, with government services in the issues of common interest;
 - g) develops and approves sanitary-hygienic requirements and standards for normativ-technical documentation for specifications of projects, state commission envisaging imports of foods, agricultural raw materials, cosmetics, perfumery, household goods, toxic substances, including agricultural chemicals, equipment, packaging, other consumer and housekeeping articles likely to have a harmful impact on public health;
 - h) supervises execution of sanitary-hygienic and sanitary - anti-epidemic norms and regulations in construction or re-construction projects;

- i) authorizes usage of chemical substances, radioactive sources, production means, technologically new methods of processing, manufacturing, transportation, storing, marketing of food products, cosmetics, perfumery, personal hygiene things, detergents, pest control chemicals, plastic materials, polymers and other chemical products, using of plants and animals growth stimulators;
 - j) examines the drafts of national standards, technical prescriptions and other normative documents related to food flow, consumer goods, construction and packaging materials, synthetic materials and new polymers and articles made of them, cosmetics, perfumery, personal hygiene things submitted for approval;
 - k) examines the drafts of new technological processes, new types of equipment, machinery and working tools likely to have a harmful impact on public health;
 - l) issues sanitary authorizations for facilities operation and hygienic certificates for goods and services;
 - m) examines and develops recommendations for educational programs in terms of educational and work task stipulated in the programs, educational methods in schools and children and teenagers institutions;
 - n) works out the draft of the national standard for drinking water and submits it for approval in the established order;
 - o) effects accreditation of Preventive Medicine Centers at judet level, in towns and UTA Gagauzia;
 - p) develops and implements measures of ensuring sanitary-epidemiological safety of the population and sanitary protection of the territory from importing and spreading conventional infections and other contagious or parasitic dangerous diseases;
 - q) works out and submits for implementation measures regarding ensuring radiological protection of population;
 - r) carries out sanitary-hygienic inspection of advertisements for food products, goods and services which are likely to have a negative impact on health due to untrue advertising;
 - s) provides management of health education and healthy life style promotion, training of specialists within the Service and other branches of national economy in the issues of medical-hygienic problems and current sanitary legislation;
 - t) organizes production and procurement of vaccines, serums and bacterial substances (for diagnostic and curative purposes), nutritional milieu and exercises control over their quality;
 - u) organizes supply, repairs and metrologic testing of laboratory equipment and apparatuses in the preventive medicine centers;
8. The State Sanitary-Epidemiological Service, as a structure of the Ministry of health of the Republic of Moldova, is appointed as a Central Notification Authority responsible for notification the Secretariat of the World Trade Organization (WTO) about sanitary measures and providing information about sanitary activities.

For the purpose of harmonization of sanitary measures on a scale as large as possible, the State Sanitary-Epidemiological Service shall:

- base its sanitary measures on international standards, guidelines and recommendations, if any at all, aiming at protection of life and public health;
 - take decision to introduce or maintain certain sanitary measures on a higher sanitary protection level than the one which might be achieved by measures based on relevant international standards, guidelines and recommendations, if such decision is scientifically justified, or this is a consequence of a sanitary protection level deemed appropriate;
 - represent the Government's interests regarding sanitary quarantine in international bodies and fully participate in the activities of the competent international organizations and their subsidiary authorities, in particular the World Health Organization, Codex Alimentarius Commission, to promote periodic development and examination of standards, guidelines and recommendations pertaining to all aspects of sanitary measures.
9. In case of absence of an international standard, guideline or recommendation, or in case the content of any suggested standard, guideline or recommendation does not correspond to the contents of an international standard, guideline or recommendation and can have a significant effect on the trade of other countries members of the WTO, the ministry of health shall:
- publish an early notice in such a way as to allow countries members of the WTO to take a first hand view of the suggested modifications and adjustments;
 - through the secretariat, notify other members about the adjustments related products, accompanying the notice with a brief description of the purpose and motif of the suggested adjustment;
 - at the request of other members provides copies of the suggested adjustments, and any time possible, identify the elements basically different from the international standards, guidelines and recommendations;
 - in a timely manner, as requested, provide other members of the WTO with written comments, to take into consideration comments and results of discussions.
10. The National Scientific Practical Center of Preventive Medicine of the Ministry of health is appointed responsible for providing, through a single informational outlet, of answers to all reasonable questions coming from the WTO members, as well as for furnishing pertinent documents on:
- any sanitary adjustment approved or suggested in the country;
 - the procedures of determining the risk and relevant level of sanitary protection;
 - membership or participation of the Republic of Moldova or national competent authorities in the international organizations or sanitary systems, as well as the texts of the agreements and commitments.
11. The State Sanitary-Epidemiological Service of the Republic of Moldova makes decisions on sanitary measures:
- based on assessment of sanitary-epidemiological situation, public life or health risks, taking into consideration techniques of risks assessment developed by competent international organizations;

- in risks assessment will take into account available scientific proofs; pertinent techniques and methods of work, pertinent inspection, sampling and testing methods, disease prevalence, existence of disease free areas, relevant environment conditions or other treatments, potential damage caused by the spreading of the disease, expenditures incurred to control or eradicate it, relative efficiency of costs incurred to support other approaches to risks limitation.
 - to appreciate or support certain sanitary measures to accomplish the due level of sanitary protection, the State Sanitary-Epidemiological Service shall provide for application of such measures only to the extent necessary to implement the level of sanitary protection, in conformity with the Laws on Health Care NR 411-XIII as of march 28, 1995, NR 1513-XII as of June 16, 1993 “On sanitary-epidemiological safeguarding of population”, other current normative documents of the Republic of Moldova;
 - ensures implementation of resolutions and decisions of the Government of the Republic of Moldova aimed at public health protection and sees that they be scientifically reasoned. In case of insufficient scientific reasoning, the ministry of health is entitled to take temporary sanitary measures based on available information, including information provided by competent international organizations and sanitary measures applied in other countries members of the WTO. In these cases, it is necessary to have additional information for a more efficient risk assessment and analysis of sanitary measures in respective order and with a favorable and reasonable timing;
 - ensures that sanitary measures shall not generate unjustified discrimination between countries members of the WTO having similar or identical conditions, including the Republic of Moldova and other countries members of the WTO. Sanitary measures shall not be enforced in a manner likely to be interpreted as a disguised restriction to international trade.
12. Ministry of Health of the Republic of Moldova accepts sanitary measures of other countries members of the WTO as equivalent, even they differ from the Moldovan ones, if the country exporter can objectively prove to the country importer that sanitary measures proposed ensure a sanitary level adequate to the one accepted by the Republic of Moldova. In such cases the Ministry of Health of the Republic of Moldova, at the request, shall be granted access for inspection, testing and other procedures.
13. The State Sanitary-Epidemiological Service:
- shall ensure that sanitary measures be adjusted to the local sanitary characteristics. While assessing local sanitary characteristics, one should take into account the extent of specific disease spreading, availability of programs aimed at disease eradication or control, and adequate criteria or guidelines which can be developed by international competent organizations;
 - shall acknowledge the concepts of disease free areas or slightly prevalent disease areas. Establishing of such zones shall be based on factors, as well as geographically, epidemiological supervision, ecosystems, and efficiency of sanitary control;

- shall declare the territory of the country free of disease providing proof satisfactory to objectively demonstrate this. With this purpose, at the request, grants reasonable access to the country importer.
14. For any procedure related to verification and implementation of sanitary measures, the State Sanitary-Epidemiological Service shall:
- ensure that relevant procedures be effected without unjustified delay and in a manner no less favorable for imported goods than for similar home produced goods;
 - ensure that standard period for carrying out each procedure shall be made public or, as requested, communicated to the person concerned. The State Sanitary-Epidemiological Service shall thoroughly examine the documentation for completeness and informs the person concerned about any deficiencies;
 - shall ensure that confidentiality of all information regarding imported goods which resulted from or were provided in connection with the control, inspection or approval be observed in a manner no less favorable for imported goods than for similar home produced goods, and in such a way as to protect legal commercial interests;
 - ensure that any requests for a specimen of a product for the purpose of control, inspection and approval are limited to what is deemed reasonable and necessary;
 - ensure that any fees charged for procedures pertaining to imported products be equivalent in ratio to any other fees charged for similar locally produced products, or products originating from any country member of the WTO, and that such fees can not exceed the cost of the service provided;
 - ensure that in location of institutions involved in the procedures and selection of samples, the same criteria be applied for imported products, as the ones applied for locally produced goods, so that maximally reduce all inconveniences caused to the applicants, importers, exporters or their agents;
 - ensure that any time specifications of a product are changed as a result of the effected control or inspection, in the light of applicable regulations, the procedure for the modified product shall limit to what is necessary to state whether there is enough trust to believe that the product still complies with the said regulations, and there is a procedure for examining claims on enforcement of such procedures, including correction measures, when the claim is justified.
 - provide necessary assistance to facilitate control from the other country member in cases when sanitary measures stipulate control on production level and this happens on the territory of the Republic of Moldova.
15. The institutions of the State Sanitary-Epidemiological Service which are its internal subdivisions, have a Great Seal, bank account, etc., shall effect sanitary-epidemiological supervision of:
- a) enforcement of legislation of the Republic of Moldova, resolutions of central and local public administration authorities, as well as of regulations and ordinances issued by the Ministry of Health pertaining to ensuring of sanitary-epidemiological safeguarding of population by ministries and departments,

- businesses, institutions, organizations, other business agents regardless of the form of property, as well as individuals;
- b) implementation of measures and observance of regulations and sanitary-hygienic norms when allotting plots of land for construction, systematization and building of localities, construction and reconstruction of enterprises, changing the enterprise profile and technology of production processes, commissioning of homes, public buildings, and other constructions;
 - c) implementation of measures and observance of sanitary-hygienic and sanitary-anti-epidemiological regulations in the process of production, cooking, storing, transportation, and marketing of food products, food additives, technological equipment for producing and cooking of food products, equipment for producing packaging, packaging materials containers for storing food products, cosmetics, perfumery and personal hygiene;
 - d) implementation of measures and observance of sanitary-hygienic and sanitary-anti-epidemiological regulations during processing, transportation, storing, using and stocking of radioactive substances and sources of ionizing radiation, as well as of toxic substances from industrial production, application of pesticides, mineral fertilizer and other agricultural chemicals;
 - e) implementation of measures aimed to prevention and liquidation of professional or infectious diseases, sanitary protection of the country's territory from penetration and spreading of conventional infections and other infectious and parasitic diseases;
 - f) implementation of measures to prevent, liquidate or reduce pollution of surface waters used as sources of drinkable water and in purposes of health improving, leisure and other human needs, of soil and air with wastes, residual substances, harmful exhausts from industrial enterprises and public facilities;
 - g) implementation of measures for prevention, reducing and elimination of noise;
 - h) observing the norms of sanitary maintaining of localities and out of town leisure zones;
 - i) accomplishment of public health education and training of national economy specialists in medical-hygienic issues.
16. The State Head Sanitary Doctor of the Republic of Moldova and its deputies, head state sanitary doctors at judet level and in towns, UTA Gagauzia and their deputies are entitled to:
- a) development and submitting for approval drafts of activity programs (at the national level inclusively) aimed to settle certain problems of public health of major importance;
 - b) to submit to central and local public administration authorities proposals pertaining to problems of sanitary legislation enforcement , drafts of plans of the social-economic development of territories, complex programs of public health protection, environment, of improving working, training and living conditions, oriented towards ensuring sanitary-epidemiological well-being of population;
 - c) notify government authorities and business agents, regardless the form of property, on:

- drafts of technical specifications standards, drafts of systematization projects and building of localities, long term projects for placing business activities, public facilities and other projects;
 - sanitary-hygienic and epidemiological condition of plots of land allotted for construction, identifying sources of drinking water and places of setting water outlets, admissible exhausts in the air;
 - technical specifications and execution instructions for building enterprises, buildings, constructions and other erections in case of partial deviation from the current rules and norms, or in cases of non-existence of approved regulations and sanitary-hygienic norms;
- d) examine the drafts of the normative documents: national and other standards, technical prescriptions, technologic instructions, new raw material recipes, food products, construction materials, packaging and packaging materials, synthetic materials, polymers and polymer articles, cosmetics, perfumery, personal hygiene articles, as well as the drafts of new technological processes, types of equipment, working tools likely to have a negative influence on public health;
 - e) carry out hygienic inspection of food products, materials and articles which come into any contact with the latter during the production, storing, transportation and marketing, packaging, synthetic products, polymers, construction materials, cosmetics, perfumery, articles of personal hygiene, and to issue hygienic certificate;
 - f) issue sanitary authorizations, notification on compliance of business agents, public catering and trade facilities, public facilities, homes and other constructions and premises with sanitary-hygienic and sanitary-anti-epidemic norms and regulations;
 - g) forbid or suspend, until sanitary and anti-epidemic measures are enforced, operation of industrial business facilities, agricultural, transportation, telecommunications enterprises, hydro-technical and utilities buildings, public catering, trade premises, other buildings with public meaning, as well as putting into operation of vessels and aircraft if they are under working condition and using them is hazardous for passengers' health, to stop certain construction works if sanitary-hygienic and sanitary-anti-epidemic norms and regulations stipulated in technical specifications are not observed;
 - h) ban the use of chemical substances, means and technologies in producing and treating of food products, use of growth stimulators on plants and animals, as well as of pesticides, plastic masses, polymers and other chemical products if their application causes hazards to public health;
 - i) ban the use of food products identified as improper for using as food;
 - j) to bind on scientific institutions and laboratories, regardless of their departmental affiliation, the task of effecting hygienic inspection aimed at identifying factors presenting risks to public health;
 - k) temporarily suspend from work persons bearers pathogenic agents of infectious diseases, who due to the specific character of their job or production process in which they are involved can serve a source of disease dissemination;
 - l) request mandatory hospitalization of patients with catching diseases and persons suspected to be infected, who present clear danger to the surrounding people;

- m) carry out mandatory disinfecting, fumigation, deratization in the hotbed of the infectious disease, as well as in the premises and territories providing conditions for infection spreading;
 - n) carry out preventive vaccination of the population or of certain groups of people, in conformity with epidemiological instructions;
 - o) pay unhindered visits (with certificate of employment) and inspect enterprises, institutions, organizations, as well as working conditions of persons having private businesses, with the purpose to supervise observance of sanitary legislation and hygienic and anti-epidemic norms and requirements;
 - p) obtain, with no hampers from ministries, departments, legal entities and individuals, documents necessary to accomplish the tasks vested in the State Sanitary-Epidemiological Service;
 - q) collect samples of materials, substances, articles, foods, air, water, and soil for laboratory research and hygienic examination;
 - r) examine cases of violation of sanitary-hygienic and anti-epidemic regulations and impose fines in compliance with articles 42, 42¹, 43 and 53 of the Code of Administrative Contravention and take legal actions against the violators of sanitary legislation.
17. Legal entities and individuals responsible for releasing infectious diseases, non-infectious diseases and massive intoxication of population shall be liable for recovering to medical and sanitary-epidemiological institutions the real costs of providing medical help to the affected people and carrying out hygienic and anti-epidemic activities. In case of any refusal to willingly reimburse the costs, the litigation is taken to court.
18. With the purpose to collect funds for carrying out anti-epidemic activities, Republican Epidemiological Fund shall be created. The Fund shall be replenished with the amounts collected as fines applied for violation of sanitary-hygienic and anti-epidemic norms and regulations, in conformity with current legislation, as well as donations coming from legal entities and individuals from the country and abroad, amounts willingly allotted by beneficiaries. In sanitary-epidemiological emergencies, the Fund shall also receive budgetary funds.
19. The State Head sanitary doctors, other officials and specialists of the State Sanitary-Epidemiological Service shall be regarded as representatives of the state administration authorities and shall be protected by the state. They shall carry out independent activity compliant with the Constitution of the Republic of Moldova, laws of the Republic of Moldova, Presidential Decrees, Government Resolutions and current sanitary legislation.

Any meddling in the activity of officials and specialists exercising state sanitary-epidemiological supervision is against the law. Legal entities and individuals exercising pressures (of any form) on officials and specialists shall be made legally responsible for their actions, in conformity with provisions of current legislation.

20. Officials and specialists exercising state sanitary-epidemiological supervision are entitled to a free ticket (supported by a valid employment certificate) in public transport within the assigned territory.
21. The State Head Sanitary Doctor of the Republic of Moldova, state head sanitary doctors at local level, in towns and UTA Gagauzia, other officials and specialists of the State Sanitary-Epidemiological Service, within the limits of their competence, have the following commitments:
 - a) to make a timely and fully use of powers vested to prevent, reveal and suppress violations of sanitary legislation;
 - b) to coordinate their activity with government authorities and local public administrations, with public organizations interested in civil rights and interests protection, protection and improvement of public health, providing for sanitary-epidemiological well-being of the population;
 - c) to permanently update their professional expertise as stipulated by current legislation.
22. The officials and specialists of the State Sanitary-Epidemiological Service shall provide legal entities and individuals with information about sanitary and sanitary-epidemiological situation, environment condition, morbidity of population in the assigned areas, limited to the needs of the applicant's orienting in prevention measures, as well as current sanitary-hygienic and sanitary-anti-epidemic norms and regulations.
23. The officials and specialists of the State Sanitary-Epidemiological Service shall be liable for inadequate execution of their responsibilities, in conformity with current legislation.