

INTERNATIONAL AND EUROPEAN PUBLIC HEALTH OBLIGATIONS VS CHEMICAL TERRORISM THREATS: THE ROMANIAN CONTRIBUTION TO PREVENT THE USE OF WEAPONS OF MASS DESTRUCTION

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SUMMARY: 1.- Introduction; 2.- International obligations and cooperation; 3.- International criminal law framework; 4.- Public health regulations under national law; 5.- Chemicals management legislation under national law; 6.- International responses to chemical terrorism threats; 7.- Conclusion.

1.- Introduction

The current tensions in the global struggle for power, hegemony and resources encourage the proliferation of international conflicts between states, this should increase attention to wars involving the use, evaluation, control, commercialization, import and export of chemical and biological weapons and from the legal point of view attention should be focused on the protection of the fundamental right to health, both in internal and external regulations.

The core principles of the right to health are availability, accessibility, acceptability and quality, or the AAAQ framework, adopted by national courts and UN treaty monitoring bodies to evaluate the obligations of UN members in respect of the right to health.²

Regarding the activity involving biological or chemical laboratories, which are by their very nature dangerous, particular attention must be paid to practical regulations for the authorization, establishment, operation, safety, security, supervision of the activity and the level of potential risk to human life in order to ensure effective protection of citizens whose lives could be endangered by the inherent risks focusing on the right to information of the public.³ The obligation also applies to dangerous activities with a focus on specific regulations and the level of potential risk to human life to ensure effective protection of citizens whose lives could be endangered by inherent risks.⁴ The relevant regulations should provide for appropriate procedures, taking into account the technical aspects of the activity in question, to identify deficiencies in the processes concerned and any errors made by those responsible at different

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² Committee on Economic, Social and Cultural Rights (ESCR Committee), General Comment No. 14: The right to the highest attainable standard of health (Art. 12), (22nd Sess., 2000), in *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, at XX, para. XX, U.N. Doc. HRI/GEN/1/Rev.9 (Vol. I) (2008).

³ European Court of Human Rights, *Case of Budayeva and others v. Russia* (Applications nos. 15339/02, 21166/02, 20058/02, 11673/02 and 15343/02), pt. 132;

⁴ See the *Case of Öneriyıldız v. Turkey* (Application no. 48939/99), pt. 90.

levels.⁵

Romania is contributing to the international efforts to prevent the use of weapons of mass destruction, to promote global peace and security, and to general and complete disarmament through the prohibition and elimination of all types of weapons of mass destruction, chemical and bacteriological (biological) weapons under international control, therefore acceded on November 5, 1929 to the Geneva Protocol,⁶ signed on April 10, 1972 and ratified on June 25, 1979, the Biological Weapons Convention⁷ and signed on January 13, 1993 and ratified on February 15, 1995 the Chemical Weapons Convention.⁸

The obligation to protect people against biological and chemical disasters is, in principle, a matter for the discretion of the Contracting State. The European Court of Human Rights in evaluating the fulfillment of the obligation to protect must take into account the particular circumstances of the case, the origin of the threat, the extent to which the risk is likely to be mitigated having particular regard, inter alia, to the internal legality of the acts or omissions of the authorities, the domestic decision-making process, including appropriate investigations and studies, and the complexity of the issue, in particular where conflicting interests of the Convention are involved.⁹ A toxic chemical means any chemical substance which, by its chemical action on biological processes, is capable of causing death, temporary incapacity or permanent harm to humans or animals. This includes any such chemical substances, regardless of their origin or method of production and regardless of whether they are produced in facilities, contained in munitions or elsewhere.¹⁰

2.- International obligations and cooperation

Regulations in the field of public health in the international context, including in the case of biological laboratories, biological and chemical weapons, through public international law are contained in acts such as the Charter of Fundamental Rights of the European Union,¹¹ the Treaty

⁵ See the *Case of Kolyadenko and others v. Russia* (Applications nos. 17423/05, 20534/05, 20678/05, 23263/05, 24283/05 and 35673/05), pt. 159.

⁶ Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare from 1925 which does not prohibit the development, production or stockpiling of these weapons but only their use in war.

⁷ Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BWC) signed in London, Moscow and Washington which introduces a commitment by States Parties to destroy all biological agents and toxins, weapons, equipment and means of delivery specified in the convention without including a robust verification regime.

⁸ Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (CWC) from 1993 which finally introduces an inspection, verification and monitoring regime for the destruction of chemical weapons stockpiles to ensure compliance with its provisions.

⁹ See the *Cases of Brincat and Others v. Malta*, Applications nos. 60908/11, 62110/11, 62129/11, 62312/11 and 62338/11, pt. 101 and *Vilnes and Others v. Norway*, Applications nos. 52806/09 and 22703/10, pt. 220.

¹⁰ Art. 2 pt. (2) of the Chemical Weapons Convention (CWC).

¹¹ Art. 35 ensures the definition and implementation of all Union policies for preventive healthcare and the right to receive healthcare.

on the Functioning of the European Union,¹² The European Social Charter (Revised),¹³ the Charter of the United Nations,¹⁴ the International Covenant on Economic, Social and Cultural Rights (ICESCR),¹⁵ the European Convention on Human Rights (ECHR),¹⁶ the Biological and Toxin Weapons Convention (BTWC)¹⁷ and the Chemical Weapons Convention (CWC).¹⁸

The European Union includes in its regulatory framework restrictive measures to combat the proliferation and use of chemical weapons¹⁹ by introducing humanitarian exceptions for those acting for exclusively humanitarian purposes to facilitate the work of states and impartial humanitarian organizations.²⁰ The amendments reflect the EU's commitment to balance security concerns with humanitarian needs under the Treaty on the Functioning of the European Union and are consistent with international standards set out in instruments on chemical arms control.²¹ The Universal Declaration of Human Rights (UDHR), although non-binding, has served as a reference for international acts in the field of health,²² having been adopted by the United Nations General Assembly on 10 December 1948. The UDHR underlines the importance of human rights for freedom, justice and peace in the world and the need for human rights to be protected by the rule of law.

¹² Art. 168 outlines the role of the European Union (EU) and its institutions in protecting human health, complementing national policies to improve public health, prevent diseases and combat epidemics by coordinating health policies with the European Commission, which proposes initiatives to promote coordination and the European Parliament and the Council adopt measures to set quality and safety standards to combat cross-border threats and protect public health.

¹³ Art. 11 and 13 by which Romania is committed to take measures adequate, aimed at preventing, as far as possible, the spread of epidemic, endemic and other diseases and accidents by using a social security system under which every person may benefit from appropriate assistance in accordance with the obligations of the European Convention on Social and Medical Assistance.

¹⁴ Art. 13 pt. (1) letter (b), art. 55 letter (b), art. 57 pt. (1) and art. 62 pt. (1) promotes international cooperation and problem-solving in the health field for the equal protection of human rights and fundamental freedoms, where the Economic and Social Council may conduct or initiate studies and reports in the health domain.

¹⁵ Art. 12 by which Romania recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

¹⁶ Art. 2 and 14 by which establishes the protection of the life of every person by law against unlawful violence, violent disturbances, insurrection regardless of national or social origin or affiliation.

¹⁷ Art. 1 by which Romania commits that it shall never, under any circumstances, refine, produce, stockpile, acquire or possess microbial agents, biological agents, toxins, weapons, auxiliary equipment and means of delivery to the target of such agents or toxins from any source or method of production of the type and in the quantities that cannot be justified for prophylactic, protective or other peaceful purposes.

¹⁸ Art. 1 by which Romania commits that it will never, under any circumstances, develop, produce, otherwise acquire, stockpile, use or retain chemical weapons or transfer, directly or indirectly, chemical weapons to others or engage in any military training for the use of chemical weapons and that it commits to destroy those it possesses, together with any chemical weapons production facilities under its jurisdiction, for the purpose of combating public disorder as a method of warfare.

¹⁹ Council Regulation (EU) 2024/1965 of July 15, 2024 amending Regulation (EU) 2018/1542 concerning restrictive measures against the proliferation and use of chemical weapons.

²⁰ Revisions to Decision (CFSP) 2018/1544 and Regulation (EU) 2018/1542 to facilitate humanitarian action for the Union's humanitarian partners.

²¹ Chemical Weapons Convention (CWC).

²² Art. 25 establishes the right to a standard of living adequate for health, including health care and necessary social services.

Since 1980 the frequency and intensity of epidemics²³ caused by new types of bacteria and viruses has increased significantly, a risk that has caused the States Parties to the Biological and Toxin Weapons Convention to strengthen surveillance and the implementation of national and international surveillance and response measures in the event of a new epidemic, accidental or controlled, with the capability to rapidly detect a biological weapons attack. Similar recommendations have been made by the international institution the World Health Organization (WHO)²⁴ on international cooperation.

The principal objective of the World Health Organization (WHO) "shall be the attainment by all peoples of the highest possible level of health";²⁵ all Member States of the European Union are members of WHO which acts as the directing, coordinating, collaborating, technical assistance, service and facilities authority for international health work, at the request of Governments with a role in strengthening health services or in technical, social or administrative cooperation with other specialized agencies or scientific groups for international health problems and informing public opinion.²⁶

The World Health Organization (WHO) has initiated an international cooperation effort to strengthen global capacities to deal with future pandemics in the areas of alert systems, data sharing, research, production and distribution of vaccines, medicines, diagnostics, personal protective equipment, biological materials, genetic sequences genetic sequence data²⁷ with pandemic potential under the PABS system²⁸ and biosafety, biosecurity and public health biological risk management in connection with laboratories, research, accidental release or misuse of pathogens in accordance with applicable international and national rules, regulations, standards and guidelines.²⁹

The European Convention on Human Rights applies in environmental cases, both where the pollution is caused directly by the state and where the state's liability arises from the absence of

²³ Global AIDS pandemic caused by the HIV virus, Creutzfeldt-Jakob Disease (BSE), Swine Influenza Pandemic (H1N1), Middle East Respiratory Syndrome (MERS), Avian Influenza (H5N1), Ebola epidemic in West Africa, Zika virus epidemic, Severe Acute Respiratory Syndrome (SARS), COVID-19 epidemic caused by SARS-CoV-2 and Monkeypox (monkeypox)

²⁴ United Nations specialized agency in the field of health, established in accordance with art. 57 of the Charter of the United Nations.

²⁵ Art. 1 of the Constitution of the World Health Organization.

²⁶ Art. 2 letters (a), (b), (d), (h), (j), (k), (p) and (r) of the Constitution of the World Health Organization.

²⁷ Art. 1 letters (a), (b) and (c), *Ninth Meeting Of The Intergovernmental Negotiating Body To Draft And Negotiate A Who Convention, Agreement Or Other International Instrument On Pandemic Prevention, Preparedness And Response A/inb/9/3*.

²⁸ Multilateral mechanism through which Romania, as a member of PABS (Pathogen Access and Benefit Sharing), exchanges "biological materials" and "sharing of pathogen samples and associated genetic sequence data for pathogens of pandemic potential" within the meaning of art. 4 of the *Nagoya Protocol*. See *Pathogen access and benefit-sharing system: where do the negotiations stand? April 3, 2024, NUS Center for International Law, Dr. Ayelet Berman and Kriti Sharma, p. 3-6 and Ninth Meeting Of The Intergovernmental Negotiating Body To Draft And Negotiate A Who Convention cit. art. 12*.

²⁹ Art. 4 pt. 3 letter (f) and art. 6 pt. 2 letter (d), *Ninth Meeting Of The Intergovernmental Negotiating Body To Draft And Negotiate A Who Convention cit.*

regulation,³⁰ and, given the subject matter of the paper, the application of the rules is relevant to both chemical and biological weapons.³¹

3.- International criminal law framework

The Charter of Fundamental Rights of the European Union (CFREU) establishes the right to the protection of health, as well as a broad spectrum of rights and requires a high level of human health protection in the implementation of all Union policies and activities. The UN Treaties tend to cover more rights than those listed in national constitutions or the Charter of Fundamental Rights of the European Union.³²

The obligations of the CFREU require Member States and EU institutions to adopt regulations to manage public health risks associated with biological and chemical dangers. The Charter of Fundamental Rights, adopted in 2000 and binding since the end of 2009, plays an essential role in settling human rights disputes, with the Court of Justice of the European Union (CJEU) and the General Court increasingly citing the Charter in their judgments. The CJEU has integrated human rights expertise and the evolution of its approach to dispute resolution due to the CJEU's broader jurisdiction under the Lisbon Treaty. The intersection between public health and fundamental rights is increasingly significant in the regulation of biological laboratories and the prohibition of dangerous weapons.³³

The Treaty on the Functioning of the European Union (TFEU) is the legal basis for EU competences in the field of public health, it also requires Member States to coordinate their health policies and align them with EU standards in order to effectively manage threats to public health from the risks of biological and chemical agents.³⁴ The TFEU is intended to shape the EU's public health strategy, emphasizing the need for harmonized approaches to address cross-border health threats,³⁵ and Romania's obligations under the TFEU involve not only compliance with EU directives, but also the implementation of strict national measures to ensure public health security. The European Social Charter (revised) complements the EU legal framework by emphasizing the positive obligations of the state in terms of health protection, thus requiring states to take measures to prevent disease and protect health and regulate activities involving biological and

³⁰ Consult the cases with relevance to environmental pollution by chemical processes, chemical factories, exploitation of the environment, lack of information of the local population, collection, treatment and disposal of waste in *Case of Giacomelli v. Italy* (Application no. 59909/00) pts. 78, 97, 98, *Case of Tătar v. Romania* (Application no. 67021/01) pt. 97, *Case of Guerra and others v. Italy* (116/1996/735/932) and *Case of Di Sarno and others v. Italy* (Application no. 30765/08) pt. 112.

³¹ *Guide to Article 8 of the European Convention on Human Rights*, updated on 9 April 2024, p. 50.

³² *Bringing rights to life: The fundamental rights landscape of the European Union*, FRA Annual Report: *Fundamental rights: challenges and achievements in 2011, 2012*, p. 25.

³³ De Búrca, G., *After the EU Charter of Fundamental Rights: The Court of Justice as a human rights adjudicator?*, *Maastricht Journal of European and Comparative Law*, 20(2), 2013, p.2-4.

³⁴ Peers, S., Hervey, T., Kenner, J., & Ward, A. (2014). *The EU Charter of Fundamental Rights: A Commentary*. Hart Publishing, 2021, p. 402-403.

³⁵ Hervey, Tamara K., and Jean V. McHale. "European Union health law." *European Union Health Law: Themes and Implications*, 2015. p. 7-16.

chemical hazards.³⁶ The Charter's impact on public health policies has been noted for its role in promoting social rights, essential in the context of health protection³⁷ which require proactive social rights measures.

The United Nations Charter outlines the global commitment to promote higher standards of health, alongside other social goals, and is essential for member states to implement robust measures to prevent and respond to biological and chemical threats. The UN Charter has a role in shaping international health law by influencing the development of global health governance frameworks. The United Nations Organization has viewed health and human rights as two interlinked social movements, with the UN Charter, the Universal Declaration of Human Rights and the WHO Constitution as defining instruments.³⁸ The WHO Constitution emphasizes the vital interaction between national and international law.³⁹ Romania's obligations under the UN Charter are an integral part of its participation in international efforts to maintain global peace and security through health regulation.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) is a treaty that stresses the need for States to take measures to prevent, treat and control disease, ensuring the availability of health care.⁴⁰ The role of the ICESCR was to expand the scope of the right to health and the obligations of States to protect public health in various contexts: the use and testing of weapons and environmental pollution, ESC Committees - European Society of Cardiology explaining that the scope of the right to health included the obligation to refrain from the testing of weapons harmful to human health and illegal pollution;⁴¹ the use or testing of nuclear, biological or chemical weapons, if such testing results in the release of substances harmful to human health.⁴²

The European Convention on Human Rights (ECHR) has been interpreted to include the protection of public health under the right to life and the prohibition of torture, with the European Court of Human Rights judging cases of states failure to comply with their obligation to protect public health as violations of these provisions; risks caused by participation in nuclear testing and failure to monitor radiation dose.⁴³ The Court's case law increasingly recognizes states obligations to mitigate health risks, including those posed by biological and chemical agents, crucially for Romania, which must ensure that its public health regulations comply with ECHR standards to avoid potential human rights violations.⁴⁴

³⁶ Council of Europe, European Social Charter (Revised), In European Social Charter (Revised), 1996, (Art. 11).

³⁷ Harris, D. *The European Social Charter: The Protection of Economic and Social Rights in Europe* (Vol. 25). BRILL., 2021 p. 149-152, 265.

³⁸ Gostin, Lawrence O., Devi Sridhar, and Daniel Hougenobler. "The normative authority of the World Health Organization." *Public Health* 129, no. 7, 2015, p. 858.

³⁹ Gostin, Lawrence O., cit. p. 857.

⁴⁰ United Nations. (1966). International Covenant on Economic, Social and Cultural Rights. In ICESCR (Art. 12).

⁴¹ Tobin, John. *The right to health in international law*. Oxford University Press, USA, 2012, p. 107.

⁴² Tobin, J., cit., p. 186.

⁴³ European Court of Human Rights. (1998). Case of L.C.B. v. the United Kingdom, Application No. 14/1997/798/1001, pts. 24, 27, 36, 38, 40, 41 and 46.

⁴⁴ Mowbray, A., *The development of positive obligations under the European Convention on Human Rights by the European Court of Human Rights*, Hart Publishing., 2004.

The Biological and Toxin Weapons Convention (BTWC) mandates states to destroy existing weapons and prevent their proliferation.⁴⁵ The BTWC is critical in preventing bioterrorism and protecting public health globally, it also addresses the need for a legally binding instrument that includes declarations on relevant activities, routine on-site inspections and verification inspections⁴⁶ to ensure compliance as advances in biotechnology have made the task of implementing a verification protocol more complicated.⁴⁷

The Chemical Weapons Convention (CWC) prohibits the production, stockpiling and use of chemical weapons and requires States to adopt national measures to implement these prohibitions, including criminal sanctions for violations.⁴⁸ The CWC's verification regime includes inspections and investigations to strengthen global security by eliminating chemical weapons with a focus on national implementation.⁴⁹

The international and European legal frameworks collectively establish a regime to protect public health against the threats posed by biological and chemical agents, Romania being obliged to adopt national legislative measures to prevent the misuse of biological and chemical substances.

4.- Public health regulations under national law

Constitutional provisions, laws and ordinances containing dispositions on the rights and freedoms of citizens shall be interpreted and applied in accordance with the Universal Declaration of Human Rights, the Covenants and other international treaties to which Romania is a party; international regulations shall take precedence, unless the Constitution or domestic laws contain more favorable provisions.⁵⁰

Romania is a member state of the Organization for the Prohibition of Chemical Weapons (OPCW), established under the terms and for the implementation of the Chemical Weapons Convention (CWC) with the aim of the complete elimination of the chemical weapons stockpile, as well as to prevent the proliferation of chemical weapons and to verify the implementation by States Parties of the CWC provisions through inspections of companies with declarable activities under the terms of the Convention.⁵¹

In order to implement the requirements of the CWC, Romania had the obligation to establish a National Authority, create and implement the specific legal framework for the development, production, import and export of certain chemicals in the field of export, import and other export

⁴⁵ United Nations Office for Disarmament Affairs. (1972). Biological and Toxin Weapons Convention. In BTWC, Art. 1.

⁴⁶ Pearson, Graham S. "The threat of deliberate disease in the 21st century." Biological Weapons Proliferation: Reasons for Concern, Courses of Action 31, 1998, p. 35.

⁴⁷ Pearson, Graham S., cit. p. 13.

⁴⁸ Organisation for the Prohibition of Chemical Weapons. (1993). Chemical Weapons Convention. In CWC, Art. 1.

⁴⁹ Kgarebe, Boitumelo V., and Cristina B. Rodrigues. "27 The Chemical Weapons." Chemicals, Environment, Health: A Global Management Perspective, 2011, p. 391.

⁵⁰ Title II - Fundamental Rights, Freedoms and Duties, Art. 20 - International Human Rights Treaties of the Romanian Constitution republished in 2003.

⁵¹ Romania signed the Convention on January 13, 1993 and ratified it on December 9, 1994 by Law No. 125/1994. Romania submitted its instruments of ratification to the UN Secretary-General on February 15, 1995.

control operations with military and dual-use items to improve trade in chemicals and technologies not prohibited by the CWC.⁵²

The Romanian Constitution⁵³, Law 95/2006⁵⁴ and Law 46/2003⁵⁵ establish the domestic legislation governing the right to health. The Ministry of Health is the central public authority in the field of public health, which ensures public health through technical and methodological guidance, supervises the state of public health, evaluates and monitors it through the National Institute of Public Health⁵⁶, a specialized body subordinated to the Ministry.⁵⁷

Public health is the state of health of the population in relation to socio-economic, biological, environmental, lifestyle, health service provision, quality and accessibility of health services.⁵⁸

The Ministry of Health, in situations of biological and epidemiological risk,⁵⁹ according to Law no. 136/2020, develops rules for the organization and operation of centers providing vaccination, diagnostic, evaluation and treatment services approved by order of the Minister of Health, in the event of a pandemic, public health emergencies or imminent epidemiological and biological risk.⁶⁰

The constitution, development and coordination of the national statistical system for the formulation, implementation, modernization and evaluation of national policies in accordance

⁵² The national authority is the Department for Export Control (ANCEX), subordinated to the Ministry of Foreign Affairs, which controls the compliance with the obligations and commitments assumed by international treaties, agreements and agreements in accordance with Law no. 56/1997 for the implementation of the provisions of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction.

⁵³ Art. 22 the right to life, physical and mental integrity; art. 34 the right to health protection and the obligation to take measures to ensure public health; art. 35 the right to a healthy environment and art. 47 the standard of living through social protection.

⁵⁴ Regulating the field of public health, the obligation of public health protection, the authorities of the public health system, health inspection and medical assistance according to art. 1, art. 3 and Chapter III, IV and V of Law 95/2006 on health reform in the field of public health, in order to protect and promote the health of the population.

⁵⁵ It institutes the patients right to medical care without any discrimination according to art. 2 and 3 of Law 46/2003 on patients rights.

⁵⁶ The National Institute of Public Health (INSP) develops public health policies and strategies, collects and analyzes epidemiological data, conducts studies and research to assess the health status of the population and coordinates the implementation of national health programs with the legal basis in Law no. 95/2006 on health reform and Government Decision no. 1414/2009 on the organization and functioning of the National Institute of Public Health. The National Center for Monitoring Risks in the Community Environment (CNMRMC) operates under the authority of the INSP, which monitors the factors that may affect the health of the population, the impact on health, produces reports and studies for the implementation of alert and rapid response systems in inter-institutional cooperation in accordance with Law no. 458/2002 on the quality of drinking water, Law no. 104/2011 on ambient air quality, Government Emergency Ordinance no. 195/2005 on environmental protection and Regulation of June 17, 2024 on the organization and functioning of the National Institute of Public Health.

⁵⁷ Art. 2 pts. (1), (5) and (6) and art. 13 of Law 95/2006

⁵⁸ Art. 4 letter (a) of Law 95/2006

⁵⁹ Art. 25 pt. (3) of Law 95/2006

⁶⁰ Art. 6 of Law 136/2020 on the implementation of public health measures in situations of epidemiological and biological risk

with the fundamental principles of official statistics,⁶¹ has in its composition and structure the National Institute of Statistics (NSI)⁶² which also complies with European regulations on official statistics⁶³ and provides demographic data for the assessment of risks and vulnerabilities, including those of chemical and biological weapons proliferation and collaborates with other national and international institutions to ensure the accuracy and integrity of data, essential in the development of national and international security policies.⁶⁴ The National Institute of Statistics has an indirect role in the non-proliferation of chemical and biological weapons, given that its object of activity is the collection, processing and publication of statistical data.

Under the coordination of the Ministry of Health, policies for the planning, control and prevention of epidemics and diseases are implemented by educating, communicating and informing the public about threats to the life and health of the population, the cause of which may include chemical substances.⁶⁵

Chemical substances, as defined in national health legislation, are elements, natural chemical substances and chemical products obtained by chemical transformation or synthesis.⁶⁶

"The National Agency for Medicines and Medical Devices in Romania" (ANMMDMR) collaborates with the Ministry of Health in the elaboration of policies for medicines, medical devices and technologies by ensuring control, supervision and evaluation of compliance with regulations in the medical field, authorizing the marketing, trade and quality of medicines in the manufacturing and import processes.⁶⁷

In the field of medicines, ANMMDMR conducts studies and laboratory analysis on the quality of medicines, approves the advertising of medicines, communicates and cooperates with national and international bodies, other EU Member States and the European Commission for the marketing of medicines and may decide to suspend, withdraw or amend marketing authorizations for medicinal products for human use.⁶⁸

In the field of medical devices, ANMMDMR elaborates norms in collaboration with national, international organizations and EU bodies with the lists of Romanian standards compliant with European directives; evaluates and approves the establishments with marketing and service activities in the field of medical devices and supervises the medical devices market by registering them from manufacturers or importers, classifying medical devices and authorizing the placing

⁶¹ The principles ensure professional independence in data collection, adequate resources, quality, confidentiality, impartiality, objectivity of statistics carried out through robust methodologies and appropriate statistical procedures to provide relevant, accurate, reliable and timely results that are accessible, clear, consistent and comparable according to *art. 5* of Law no. 226/2009 on the organization and functioning of official statistics in Romania and the principles of Council Regulation (EC) No 322/1997 of 17 February 1997 on Community Statistics and the European Statistics Code of Practice for National Statistical Authorities and Eurostat.

⁶² Art. 6 of Law No 226/2009.

⁶³ Regulation (EC) No 223/2009 of the European Parliament and of the Council on European Statistics.

⁶⁴ Art. 1 of Law 226/2009.

⁶⁵ Art. 5 letters (a), (b), (c), (d), (i), (k) and art. 10 pt. (2) letter (a) of Law 95/2006

⁶⁶ Art 699 pt. (2) of Law 95/2006

⁶⁷ Art. 3 letters (a), (b) and art. 4 pt. (1) of Law 134/2019 on the reorganization of the National Agency for Medicines and Medical Devices, and for the amendment of some normative acts.

⁶⁸ Art. 4 pt. (3) sub-points 2, 3, 51, 6, 8, 10, 11, 14, 16 of Law 134/2019

on the market and putting into service of individual medical devices and may withdraw from the market or prohibit or restrict the placing on the market or putting into service of medical devices.⁶⁹ In the field of health technology assessment, the ANMDMR develops and revises the methodology and criteria for health technology assessment based on the analysis of organizations, experts and researchers collaborating with academic institutions and professional bodies to inform its decisions. Furthermore, it participates in the exchange of scientific information, the development of assessment models and tools, and the production of studies and materials, in collaboration with the Member States of the European Network on Health Technology Assessment.⁷⁰

In the field of public health, ANMDMR, in collaboration with the Ministry of Health, authorizes and controls clinical trials in the field of medicinal products for human use, but may temporarily authorize the distribution of an unauthorized drug in case of a suspected or confirmed spread of chemical agents or nuclear radiation, or of drugs containing dangerous chemical substances⁷¹ that could endanger the health of the population.⁷²

The Romanian Government, through the Ministry of Health, communicates with the agencies established at EU level, the European Center for Disease Prevention and Control (ECDC)⁷³ and the European Medicines Agency (EMA)⁷⁴ on health-related issues, for the coordination of responses, assessment, monitoring of emerging health threats⁷⁵ and the scientific management and evaluation of the quality, safety and efficacy of all medicinal products in the European Union.⁷⁶

Through the legislative project of the Memorandum of Understanding between the WHO and the Romanian Ministry of Health,⁷⁷ the WHO provides technical assistance in the field of public health in the implementation of the National Recovery and Resilience Plan (NRRP)⁷⁸ funded by

⁶⁹ Art. 4 pt. (4) sub-points 1, 4, 5, 7, 9, 10, 13, 14, 16, 17 of Law 134/2019

⁷⁰ Art. 4 pt. (5) sub-points 1, 2, 3, 4, 8 of Law 134/2019.

⁷¹ The dangerous chemical substances that determine the intervention of the ANMDMR are regulated by Law no. 360/2003 on the regime of dangerous chemical substances and preparations.

⁷² Law 360/2003 and art. 7011, art. 703 pt. (2), art. 888 of Law 95/2006.

⁷³ Regulation (EC) No 851/2004 establishing a European Center for Disease Prevention and Control.

⁷⁴ Regulation (EC) No 726/2004 establishes the EMA and according to Regulation (EU) 2022/123 has a role in managing crises related to medicinal products for human and veterinary use and medical devices to ensure their safety, efficacy and quality in coordination with National Authorities to ensure their compliance with EU regulations, being regulated the functioning by Decision No 147/2023 of the Romanian Senate.

⁷⁵ Regulation (EC) No 851/2004, Regulation (EU) 2022/2370 strengthening the role of ECDC and Regulation (EU) 2022/2371 address serious cross-border threats to public health, form networks for strategic advice, collect data and assess risk factors for coordination of response in the Health Security Committee (HSC).

⁷⁶ Regulation (EU) 2017/745 on medical devices, Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 on fees payable to the European Agency for the Evaluation of Medicinal Products.

⁷⁷ Memorandum of Understanding of June 10, 2022 between the WHO and the Ministry of Health of Romania as Principal Recipient (PR) of the National Recovery and Resilience Plan for Romania grant

⁷⁸ The Recovery and Resilience Mechanism (RRM) is established by Regulation (EU) 2021/241 of the European Parliament and of the Council for sustainable reforms and investments in the Member States of the European Union and the establishment of the institutional and financial framework was implemented according to the Emergency Ordinance of the Government of Romania No. 124/2021.

the European Commission (EC)⁷⁹ for the management and quality of health services, health care and patient safety.

5.- Chemicals management legislation under national law

The legal framework for the effective control and efficient supervision of the regime of dangerous chemical substances and preparations in order to protect public health and the environment consists of the assessment, control, marketing, trade, use, import and export of dangerous chemicals and ozone-depleting substances in accordance with international agreements on the non-proliferation of chemical and biological weapons.⁸⁰

The principles for the risk evaluation of these substances, the reporting of risk assessment data, the establishment of contraventions, the application of penalties, the authorities responsible for risk assessment, risk control and their attributions are established by Government Decision, the responsibilities for the activities being assigned to the Ministry of Agriculture, Forestry, Water and Environment, the Ministry of Health, the Ministry of Labor, Social Solidarity and Family and the Ministry of Economy and Trade.⁸¹

Under the Ministry of Agriculture, Forestry, Water and Environment there is a specialized institution, the National Agency for Environmental Protection (ANPM), which is responsible for the implementation of policies and legislation in the field of environmental protection.⁸²

ANPM has in its attributions and responsibilities the implementation, at national level, of the legislation in the field of dangerous chemical substances and chemical preparations and the control of compliance with the legal provisions, as well as the detection and sanctioning of their violation through the National Environmental Guard subordinated to ANPM.⁸³

EU Directives have applicability in the field of inspection and verification of procedures for the organization and conditions for planning, execution, recording and presentation of laboratory research, according to good laboratory practice, for all chemicals to determine the effect of these products on humans, animals and the environment.⁸⁴

⁷⁹ The implementation runs from June 10, 2022 to June 30, 2026 and besides the technical assistance, audit procedures, semi-annual technical reports and at the request of the Ministry of Health for the amount of 21,253,776 euro, with installment payments until 2024.

⁸⁰ Art. 6, art. 7, art. 9, art. 10, art. 11 of the Biological Weapons Convention (April 10, 1972) and art. 4 pts. (1), (2), (3), (4), (5) and (6) of the Chemical Weapons Convention (January 13, 1993).

⁸¹ Art. 6, art. 12 and art. 26 of Law no. 360/2003 on the regime of dangerous chemical substances and preparations and Law No. 254/2011 amending art. 26 of Law No. 360/2003.

⁸² Art. 1 of Government Decision No. 1000/2012 on the reorganization and functioning of the National Agency for Environmental Protection.

⁸³ Art. 1 pt.(1) and pt.(2) of Law no. 349/2007 on the reorganization of the institutional framework in the field of chemicals management.

⁸⁴ Art. 1, art. 2 of Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP), in conjunction with art. 1, art. 2 and art. 3 of Directive 2004/10/EC on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances transposed into national law by Decision No 266/2006 on the approval of the Principles of good laboratory practice and the inspection and verification of their applications for tests on chemical substances.

The General Assembly of the United Nations has repeatedly condemned all actions contrary to the principles and purposes of the Geneva Protocol of 17 June 1925 for the strengthening of confidence between nations, which contribute to the achievement of the purposes and principles of the Charter of the United Nations by excluding from the arsenals of States weapons based on the use of chemical and bacteriological (biological) agents.⁸⁵

Romania, if it finds that any other State Party acts contrary to its obligations, undertakes to cooperate, assist and participate in order to carry out any investigations, through which to verify, access and destroy chemical weapons, which may be undertaken by the Security Council, in accordance with the UN Charter, for the prohibition of chemical weapons and, even, to propose amendments to the Convention, for the purpose of economic or technological development of States and international cooperation in the field of bacteriological (biological) and toxin for peaceful purposes.⁸⁶

6.- International responses to chemical terrorism threats

The UN Security Council met to combat the continuing threat⁸⁷ of ISIL/Da'esh.⁸⁸ Indonesia was assisted to prepare for chemical terrorism attacks through realistic simulation exercises to find a coordinated response to the complex and tangible threat of chemical terrorism.⁸⁹

The exercise deployed in Semarang where a chemical attack on a train was simulated in which passengers simulated symptoms of exposure while emergency teams, dressed in protective suits, responded by searching for bombs and providing medical assistance.⁹⁰

The exercise is part of a series of drills organized by the UN Office on Drugs and Crime (UNODC) and the Indonesian National Counter Terrorism Agency (BNPT), with the support of the National Police Mobile Brigade.⁹¹

Chemical terrorism has occurred at least 8 times in Indonesia since 2011,⁹² as terrorist groups

⁸⁵ Extract from the Preamble to the Biological Weapons Convention (April 10, 1972) on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.

⁸⁶ Art. 6, art. 7, art. 9, art. 10, art. 11 of the Biological Weapons Convention (April 10, 1972) and art. 4, pts. (1), (2), (3), (4), (5) and (6) of the Chemical Weapons Convention (January 13, 1993).

⁸⁷ The Security Council Committee adopted amendments to Resolutions 1267 (1999), 1989 (2011) and 2253 (2015) establishing sanctions against ISIL (Da'esh) and Al-Qaida such as the asset freeze, travel ban and arms embargo provided for in paragraph 1 of Security Council Resolution 2610 (2021).

⁸⁸ United Nations Security Council Resolution 2249 (2015) on threats to international peace and security caused by terrorist acts by ISIL (Da'esh) and associated groups.

⁸⁹ United Nations Office on Drugs and Crime (UNODC), *"Global Programme on Addressing and Countering the Terrorist Use of Chemical Weapons,"* 2020.

⁹⁰ UNODC and Indonesian National Counter Terrorism Agency (BNPT), <https://www.unodc.org/roseap/en/indonesia/2023/08/chemical-weapons-terrorism-training/story.html>.

⁹¹ UNODC component of the project, *"Building a Safer South-East Asia by Preventing and Responding to the Use of Chemical Weapons by Terrorists and other non-state Actors in Indonesia"*.

⁹² *Managing Team of The Updated 2015 Indonesia's Risk Assessment on Terrorist Financing Crime. (2015). The updated 2015 Indonesia's risk assessment on terrorist financing crime* (P. Irawan, SE., M.Ak., CFE, Coordinator).

have previously used chemical weapons in Iraq and Syria.⁹³

Industrial chemicals are dual-use in nature, thus chlorine can be used in legitimate industries such as water treatment which adds complexity to the threat landscape, requiring strong cooperation between the public and private sectors.⁹⁴

The exercise also consisted of setting up decontamination stations to assess contamination levels and establish perimeters and various scenarios with incidents in hotel rooms and airplanes, in which participants encounter simulated dangerous materials, hostages, and explosions.⁹⁵

UNODC is prioritizing future training on scene management to ensure the proper collection and recording of evidence, essential for prosecution, to identify and address operational gaps in a controlled environment, enabling better preparation and response to real incidents.⁹⁶

UNODC has launched a repository of national legislation for the deterrence and prosecution of nuclear and radiological terrorism to implement the criminalization provisions of the International Convention for the Suppression of Acts of Nuclear Terrorism (ICSANT), the Convention on the Physical Protection of Nuclear Material (CPPNM) and its amendment (A/CPNM).⁹⁷

UNODC also contributed to the exercise "Glowing Tulip 2.0: from crime scene to courtroom"⁹⁸ in which participants explored the investigation and prosecution of such nuclear-related crimes, the admissibility of forensic evidence in court, and the importance of coordination between law enforcement and scientific organizations.⁹⁹

7.- Conclusion

Respect for human rights, a problem of domestic as well as international law, has gone through lengthy processes of legislative maturity, mainly at the international level, since the Geneva

Financial Transaction Reports and Analysis Center (INTRAC). ISBN: 978-602-9285-34-5, 2019. Also see the *Country Reports on Terrorism 2022: Indonesia*, <https://www.state.gov/reports/country-reports-on-terrorism-2022/indonesia>.

⁹³ Organisation for the Prohibition of Chemical Weapons (OPCW), Syria – Report by the organization for the prohibition of chemical weapons on the use of chemical weapons in Marea (24 February 2024); See <https://www.diplomatie.gouv.fr/en/country-files/syria/news/article/syria-report-by-the-organization-for-the-prohibition-of-chemical-weapons-on-the> and https://www.eeas.europa.eu/eeas/syria-statement-high-representative-latest-report-use-chemical-weapons-syria_en.

⁹⁴ European Commission, "Communication on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union," COM/2017/0610 final; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52017DC0610>

⁹⁵ UNODC, <https://www.unodc.org/unodc/en/terrorism/expertise/countering-chemical-biological-radiological-and-nuclear-terrorism.html>.

⁹⁶ UNODC, Chemical terrorism: Indonesia tests its response to the threat; <https://www.unodc.org/roseap/en/indonesia/2024/03/chemical-terrorism/story.html>.

⁹⁷ The repository is integrated into UNODC's SHERLOC platform to facilitate international cooperation in managing security threats; <https://sherloc.unodc.org/cld/v3/sherloc/legdb/>.

⁹⁸ Hosted in The Hague, the Netherlands, 23-26 April 2024 and organized by the governments of the Netherlands, Romania and the United States, in collaboration with UNODC and UNOCT to strengthen capacity building in nuclear forensics and crimes involving nuclear or radioactive materials.

⁹⁹ The judicial process under ICSANT in the prevention and prosecution of nuclear security incidents was simulated; the promotion and application of ICSANT was co-funded by the EU.

International Conference of 1864 which marked the birth of humanitarian law, since the prohibition of poisons and poisoned weapons by the Fourth Hague Convention of 1907, the establishment of nuclear-weapon-free-zone statutes by international treaties to prohibit the production, acquisition, possession, use, possession, deployment or testing of nuclear weapons, and to prohibit the development, production, acquisition, stockpiling, use or retention of biological weapons or weapons of mass destruction, chemical or incendiary weapons. In case of serious human rights violations, coercive measures may be used against a State only if its acts constitute a threat to international peace and security and on the basis of an authorization by the UN Security Council.

Romania, in consideration of its territorial and strategic importance, becomes a vulnerable zone, which due to its low economic capacities, policies that operate in electoral cycles and lack of public opinion information turns the country into a protectorate zone of more powerful state actors.

Romania obliges that it will never, under any circumstances, refine, produce, stockpile, acquire or otherwise acquire or possess microbial agents, biological agents or toxins or weapons, ancillary equipment and means of delivery of these chemicals for hostile purposes or armed conflict. Romania shall, destroy or convert for peaceful purposes all agents, toxins, all weapons, weapons, equipment, facilities and means of transportation to the target, in its possession or under its jurisdiction or control and shall not transfer to anyone, directly or indirectly, or in any way assist, encourage or incite, aid, induce, in any way any other State group of States or international organizations to produce or acquire any agents, toxins, weapons, equipment or means of delivery to the Target, taking all necessary measures in accordance with the constitutional provisions and appropriate international procedures of the United Nations and in conformity with the Charter of the United Nations¹⁰⁰.

The protection of public health against laboratories with destructive impact on security and human rights is sustained by the regulations of international and domestic law, responsible public authorities, agreements and communications with international organizations that have been the subject of the article's analysis whereby Romania commits itself to manage research and laboratory activities according to good practices for the promotion of international peace and to prohibit the development, production and stockpiling of chemical weapons, bacteriological (biological) and toxin weapons by any means.

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¹⁰⁰ Art. 1, art. 2, art. 3, art. 4, art. 5 of the Biological Weapons Convention (April 10, 1972) and art. 1 pt. (1) lit.(a), (b), (c), (d), pt.(2), pt.(3), pt.(4), pt.(5) of the Chemical Weapons Convention (January 13, 1993).



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