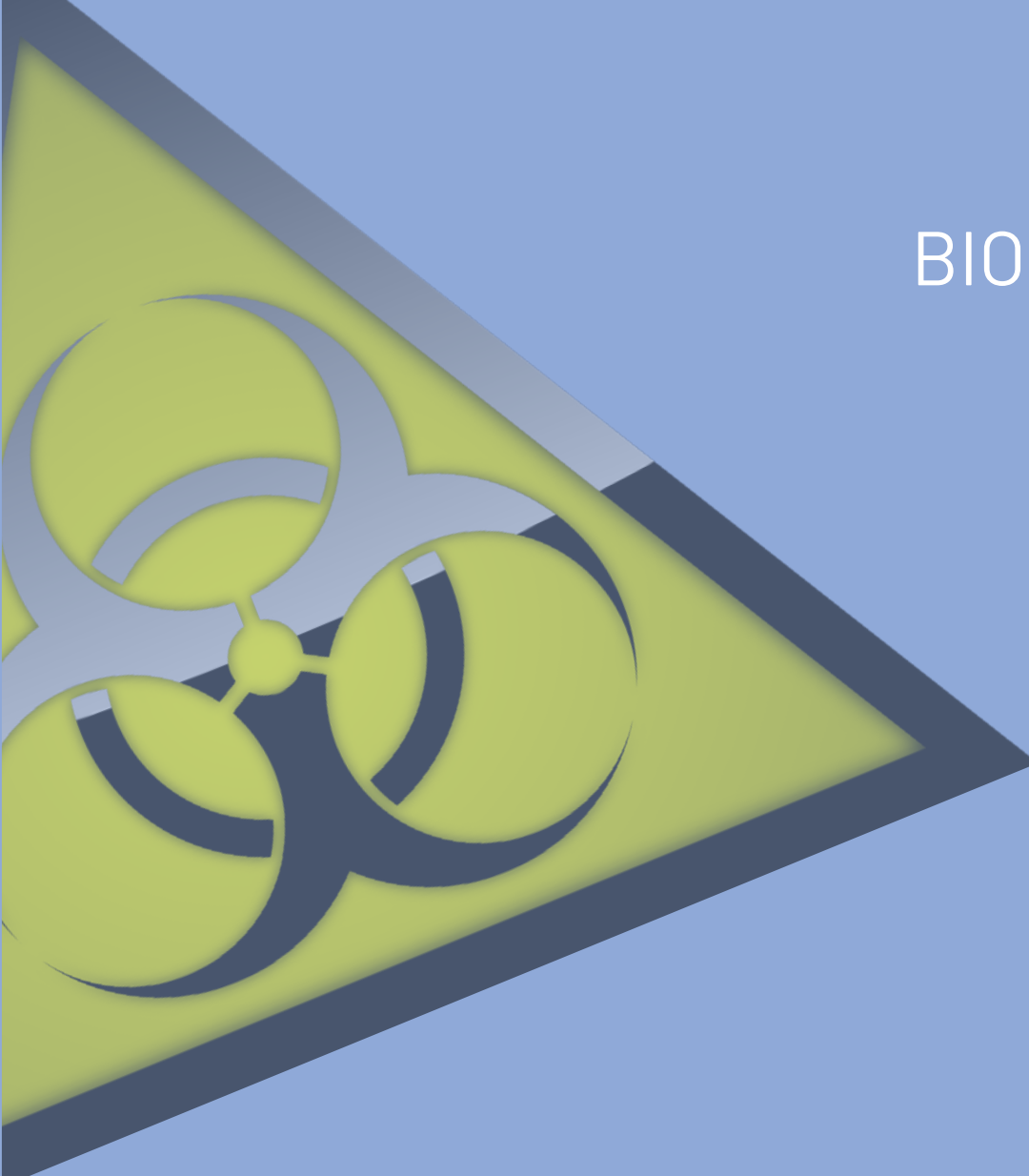


BIOSECURITY MAP 2021



National Security System

Specialized Committee on Non-Proliferation of Weapons
of Mass Destruction



GOBIERNO
DE ESPAÑA

PRESIDENCIA
DEL GOBIERNO

Catalogue of General State Administration Publications

<https://cpage.mpr.gob.es>

Published by:



© Author and publisher, 2021

NIPO (paper edition): 089-21-043-5

NIPO (on-line): 089-21-044-0

DL: M-31296-2021

Publication date: december 2021

Printed by: Cimapress

BIOSECURITY MAP 2021

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FOREWORD

“Biosecurity means putting in place robust security measures in the use and transfer of natural or modified biological agents, and in the fight against the illicit trafficking thereof. This is one of the key elements of the Biological Weapons Convention, which since 1972 has governed countries’ obligations to prevent weapons of this type from being developed or used. The impact of the Covid-19 pandemic has only served to highlight the need to pay greater attention to the proper handling and transport of such agents.

The aim of creating a ‘Biosecurity Map’ is to contribute to the National Biosecurity Plan, within the framework of the National Security Strategy. This measure seeks to improve knowledge of the existing obligations in this regard among Spanish public and private actors. These obligations are set forth in a network of treaties, codes of conduct and export regimes, which, moreover, have been developed in our country’s domestic law. The ‘Biosecurity Map’ incorporates the competences of the different ministries and other public agencies, as well as the international forums in which these measures are addressed. In short, it responds to the need for operators—and also the general public—to have detailed information about these legal regimes, so that all of their activities are conducted with full respect for the obligations undertaken by Spain, and thus contribute to global security.

This ‘Biosecurity Map’ has been created with contributions from all the ministries participating in the Specialized Committee on Non-Proliferation, under the coordination of the Ministry of Foreign Affairs, the European Union and Cooperation. The aim is for the text to be updated with new advances in the biosecurity regime, so that it may continue to serve as a reference for such a complex and sensitive matter.”



Ángeles Moreno Bau

Chair of the Specialized Committee on Non-Proliferation of Weapons of Mass Destruction
Secretary of State for Foreign and Global Affairs
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Definition

DEFINITION

Biosecurity consists of a set of structural and procedural measures, as well as the associated regulations and protocols, aimed at strengthening the physical security of all elements related to biological materials, agents and facilities, and their associated activities. Biosecurity seeks to safeguard said materials and agents, as well as their storage and transport, making it possible to combat their illicit trafficking more effectively and facilitating proper preparedness for a possible response to a malevolent, criminal or malicious biological incident. It seeks, therefore, to protect biological agents (including viruses, bacteria, fungi and protozoa), and associated biological materials, whether natural or recombinant, and the derivatives thereof (toxic products deriving therefrom), affecting human beings, animals and plants, as well as to safeguard materials or products against theft, loss or malicious or accidental diversion, which could cause a biological incident with individual and/or collective public health consequences.

Each sovereign State is responsible for guaranteeing the physical security of biological agents and materials, as well as of the facilities in which said materials are produced, used or stored, including their transport by any means or channel used.



Researcher in a P3 laboratory at the National Microbiology Centre

Biosecurity map:
International legal framework

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BTWC) of 26 March 1975

- Scope

The Convention on the Prohibition of Biological Weapons is the principal instrument for the international non-proliferation of biological and toxin weapons. It currently has 183 States Parties, and four States that have signed it, but not ratified it. Specifically, Spain ratified this Convention in 1979. Ten States have not signed it yet.

- Objective

Its principal objective is to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons. Despite this explicit prohibition, the Convention allows the States Parties to work with biological agents and toxins for prophylactic, protective or other peaceful purposes (health, biotechnology, etc.).

- Obligations

The States Parties to the BTWC undertake:

Not to develop, produce, acquire or stockpile microbial or other biological agents or toxins, or the means of delivery thereof, that have no justification for peaceful purposes (health, research, etc.). (art. I), or otherwise acquire or retain, never in any circumstances, weapons, equipment or means of delivery designed to use such microbial or other biological agents or toxins, whether natural or artificially created or modified, as well as their components, whatever their origin or method of production, that affect human beings, animals or plants for hostile purposes or in armed conflict.

To destroy all weapons, agents, toxins, means of delivery and of release which are in their possession (art. II).

Not to transfer to other States any biological or toxin agents or technologies; or assist or encourage other States to produce or manufacture them (art. III).

To take any necessary domestic measures to comply with these objectives (art. IV).

To lodge a complaint with the Security Council of the United Nations if they find that any other State Party is acting in breach of its obligations deriving from the provisions of the Convention, and to cooperate in carrying out any investigation in this regard (art. VI).

The States Parties also commit to submitting annual reports on BTWC-related activities to the Implementation Support Unit (ISU)¹, for example: data on laboratories, information on epidemic outbreaks, information on vaccine manufacturing installations, etc.

¹ The ISU was created in 2006. Its duties include: providing administrative support and assistance, providing assistance to States for the national implementation of decisions and recommendations of the Conference, supporting the creation of confidence-building measures and measures for obtaining universality, etc.

- Dynamics

The Convention on the Prohibition of Biological Weapons has 15 articles and a series of additional agreements that are negotiated and, as the case may be, adopted by consensus every five years during the Review Conference.

The BTWC is supported by the Under-Secretary General and High Representative for Disarmament Affairs of the United Nations Office for Disarmament Affairs in New York, through the ISU, which is headquartered in Geneva and was created in 2006, during the Sixth Review Conference. This Secretariat's objectives are to provide administrative support at the meetings scheduled to review the Convention and in the comprehensive implementation and universality of the Convention, as well as to facilitate the exchange of BTWC-related control measures that must be submitted annually by all States Parties, thus building confidence between said States.

Moreover, meetings of experts are held every August, and meetings of States Parties, every December.

- Technical meetings of experts address the elements and matters that have been defined by the States Parties at their meetings as being of special interest.
- At their meetings, the States Parties discuss the technical reports from the expert meetings requested at the previous meeting, and any considerations issued by the ISU. At these States Parties meetings, financial issues regarding the implementation of measures relating to the Convention are also defined by consensus. Likewise, at these meetings the States Parties also decide which country will chair each group of experts.

In 2017, the States Parties agreed to establish the following groups of experts, whose meetings are preparatory for the meeting of States Parties:

- MX1: Cooperation and Assistance, with a Particular Focus on Strengthening Cooperation and Assistance under article X.

- MX2: Review of Developments in the Field of Science and Technology Related to the Convention.
- MX3: Strengthening National Implementation.
- MX4: Assistance, Response and Preparedness.
- MX5: Institutional Strengthening of the Convention.

Delegations at meetings of States Parties are headed by senior officials of the State Administration, who may be accompanied by experts. Likewise, Permanent Representations in Geneva participate regularly in the meetings of States Parties to the Convention.

The States Parties or Signatories who wish to attend the Meetings of Experts must send, through their Permanent Representations, a letter or note verbale to the ISU including the details of the members of the Delegation, and clearly designating a Delegation Head.

- Spain

In the absence of a legally binding Verification Protocol, Spain has found that the key to improving the national application of the BTWC to matters relating to biosafety and biosecurity lies in forums such as the BTWC itself or the Global Partnership.

Spain participates actively in the development and strengthening of the BTWC both nationally and internationally, fostering the “Confidence-Building Measures”, providing diverse educational materials, and developing technical tools and specific programmes such as the “Voluntary Visits” programme, seeking international cooperation to achieve these objectives, and promoting cooperation with other States Parties, basically Ibero-American States Parties, regarding biosafety and, in particular, biosecurity, in order to address participants’ strengths and weaknesses, learning from each other in a framework of cooperation. In this regard, up to 2019, there were 12 Ibero-American countries that had participated and collaborated in a satisfactory manner.

When programming these “Voluntary Visits”, their possible content and scope of application is agreed upon on a case-by-case basis. These visits seek to enhance the transparency and deepen the knowledge of the national reality of the countries involved, in order to design optimal forms of cooperation.

At the national level, Spain has a National Biosecurity Plan to address these problems (see p. 55 below).

United Nations Security Council Resolution 1540

- Objectives

To take effective measures to prevent the proliferation and use of weapons of mass destruction, such as biological weapons, by non-State actors, especially terrorist groups.

- Obligations

Pursuant to Resolution 1540 (2004), all States must take effective measures to prevent the use of weapons of mass destruction, such as biological weapons, by terrorist groups. Moreover, they must prevent the proliferation of said weapons and of their means of delivery. In addition, States must present reports to the Committee. Their first report must contain the steps they have taken or intend to take to implement the resolution.

In subsequent Resolutions, States that have not yet presented their first report are asked to do so without delay, and the other States are asked to provide supplementary information. These reports may include a request for technical assistance.

- Dynamics

The 1540 Committee is a subsidiary body of the Security Council, composed of the 15 Member States of the Council. Resolution 1540 (2004) sets forth the Committee's mandate, extended until 2021, and the scope of the Committee's activities, the aims of which are to provide technical assistance to States, coordinate information, enhance cooperation with international organizations

in this sphere, and conduct wide-ranging analysis of the implementation status of the Resolution. This is a significant Resolution, because one of its most important objectives is to prevent the proliferation of weapons of mass destruction by non-State actors.

Such activities may also be channelled through the programmes of work presented by the Committee Chair to the Security Council Presidency. Given that it is a Security Council Resolution, the implementation of said programme by all United Nations Member States is obligatory.

The 1540 Committee is assisted by a group of experts, whose members and coordinators are elected by the Committee itself and appointed by the Secretary-General.



Bacillus anthracis culture

Biosecurity map:
International and national
institutional architecture

UNITED NATIONS

United Nations Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM)

- Objectives

Through the United Nations Secretary-General's Mechanism (UNSGM), qualified experts trained to conduct investigation missions investigate the alleged use of biological weapons.

- Obligations

The UNSGM carries out prompt investigations in response to allegations brought to its attention with regard to the possible use of chemical and bacteriological (biological) and toxin weapons. Said mechanism was developed in the late 1980s. Once a request from any Member State is received, the Secretary-General is authorized to launch an investigation, which includes dispatching a fact-finding team to the site(s) of the alleged incident(s), and to report the results of the

investigation to all United Nations Member States. The aim is to ascertain in an objective and scientific manner facts relating to alleged violations of the 1925 Geneva Protocol, which prohibits the use of chemical and biological weapons, or of any other relevant provisions of customary international law.

The roster of experts and laboratories provided by the Member States—including Spain—and the Guidelines and Procedures for conducting investigations constitute the key elements of the Mechanism. In 2006, the Member States encouraged the Secretary-General to update the roster of experts and laboratories, as well as the guidelines and technical procedures, that he had available for the timely and efficient investigation of alleged use of such weapons. In 2006, the Member States encouraged the Secretary-General to update the roster of experts and laboratories at his disposal, as well as the guidelines and technical procedures, for the timely and efficient investigation of alleged use of such weapons.

The Office for Disarmament Affairs has worked with the Member States to update the roster of experts and laboratories and the technical appendices of the guidelines and procedures, so that they may be fully aligned with the rapid and significant developments that have taken place in the biological sphere since the 1980s.

- Dynamics

The aim of the UNSGM's 2020-2021 Action Plan is to acquire effective capacity to:

- Launch, deploy and maintain investigation of alleged use (IAU) missions to address the outbreak of an infectious zoonotic disease when there are indications that it could be a deliberate act.
- Put in place scientific and logistical support for an UNSGM IAU.

- Have a team of at least 12 to 20 qualified experts that is geographically representative and can provide proper support for investigations.
- Conduct an IAU in a cooperative and comfortable environment, including the absence of extreme climate conditions.
- Produce results that are scientifically and technically robust, with a view to ensuring the political acceptability of the mission’s final report.
- Establish a network of laboratories to participate in the relevant External Quality Assurance Exercises, comprising laboratories capable of receiving and analysing samples to support a UNSGM IAU.

The initial approach of this Action Plan is to build the capacity to respond to a deliberate event that could involve zoonotic biological agents. However, the aim is to expand this Action Plan to respond to alleged attacks with biological weapons against animals (livestock) and plants (basic or commercial crops).

Global Health Security Agenda (GHSA)

- Objective

To promote coordinated international action for five years, to tackle security threats related to biological agents, whether they originate naturally, accidentally or deliberately, as well as to mitigate any deficiencies that the countries in question may have in this regard.

To this end, the GHSA strengthens the capacities of the States Parties to prevent, detect and respond to biological threats that could affect human beings, animals and plants.

- Obligations

The States Parties undertake to strengthen their health systems and comply with international standards and obligations, such as the International Health Regulations (2005). Moreover, the States Parties must implement a sustainable legal programme of comprehensive national oversight of biosecurity. Said programme must encompass the safe use, storage, containment and elimination of infectious substances at laboratories, as well as the safe transport of such substances.

Each State Party is required to have a minimum amount of working capacities related to research, diagnosis and biotechnology. It must also have groups of experts in biological risk management that can train other scientists in their respective institutions in matters regarding such risk.

- Dynamics

The GHSA functions as an international cooperation forum between States Parties (49), relevant international organizations, civil society, and the private sector. The most effective procedures to combat biological risk are discussed at this forum, leading to the GHSA Programme, which, with a multilateral and multisectoral approach, is aimed especially at promoting and strengthening biosafety and biosecurity.

The GHSA holds an annual Ministerial Meeting which, together with the Steering Group and the Permanent Advisors, furthers the implementation of the 11 Action Packages.

Other international
instruments

Global Partnership Against the Spread of Weapons and Materials of Mass Destruction

- Objectives

To seek and promote the adoption, universalization, full implementation and strengthening of multilateral treaties and other international instruments related to controlling the proliferation of weapons of mass destruction, noteworthy among which is the fight against biological threats. Its principal objectives are:

1. To strengthen nuclear and radiological security.
2. To reduce and contain biological threats.
3. To destroy and guarantee the security of chemical weapons.
4. To contribute to the implementation of Resolution 1540 (see above).

These objectives are especially aimed at preventing terrorist groups from obtaining weapons of mass destruction, relating to Resolution 1540.

The current members of the Partnership are: Australia, Belgium, Canada, Chile, Czech Republic, Denmark, the European Union, Finland, France, Georgia, Germany, Hungary, Ireland, Italy, Japan, Jordan, Kazakhstan, the Republic of Korea, Mexico, the Netherlands, New Zealand, Norway, the Philippines, Poland, Portugal, Spain, Sweden, Switzerland, Ukraine, the United Kingdom and the United States. In addition, the Partnership works together with the Australia Group (AG), the Biological and Toxin Weapons Convention (BTWC) and the Implementation Support Unit (ISU), the Food Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the 1540 Committee, and many other relevant international organizations.

- Obligations

The States Parties undertake to implement specific measures and projects to combat bioterrorism and the proliferation of biological weapons. It is of the utmost importance to strengthen biosecurity, strengthening national and international capacities to identify and respond rapidly to biological attacks.

- Dynamics

The Global Partnership was created by the G7 in 2002, and has a working group on biosafety and biosecurity , whose aim is to prevent the deliberate use of biological agents and propose the adoption of common strategies on biosecurity. The Chairmanship of the group rotates annually, together with the G7 Presidency.

The programmes, initiatives and priorities of the working group are discussed at a biannual meeting. These meetings include specialized thematic sub-groups that the group considers priority (radiological security, nuclear security, chemical security, biological security, and Resolution 1540).

This group has developed a comprehensive strategy to help Member States. Said States must undertake to implement specific projects to combat bioterrorism and proliferation.

In the area of biosafety and biosecurity, there are five spheres for coordinating and strengthening collective actions in order to combat bioterrorism and the proliferation of biological weapons, as well as other related threats. These spheres of biosecurity do not constitute a closed, legally binding or exhaustive list, but, rather, a series of goals that Member States must pursue, taking into account the international legal framework, especially the BTWC, the Geneva Protocols and Resolution 1540. Moreover, these goals must be sought in cooperation with international organizations and other external collaborators such as the Implementation Support Unit (ISU), the United Nations Food and Agriculture Organization (FAO), INTERPOL, the World Health Organization (WHO), and the World Organization for Animal Health (OIE).

The Member States undertake to review these spheres periodically to adapt and update them every five years, considering the voluntary contributions made by Member States or international organizations in this regard.

The members of the Partnership defined the following spheres as priorities, with lines of work for each of them:

1. Secure and account for materials that represent biological proliferation risks:
 - Facilities (enhance their security, conduct inspections and evaluations, etc.)
 - Train personnel (strengthen training programmes, implement good practices, etc.)
 - Reduce storage and guarantee security in the transport of dangerous biological materials.

2. Develop and maintain appropriate and effective measures to prevent, prepare for, detect and disrupt the deliberate misuse of biological agents:
 - Tools (support for the development and implementation of guides, legislation and good practices, support and strengthening of epidemic detection systems, etc.)
 - Mechanisms (improvements in laboratories' detection and response capacity, improvements in intersectoral cooperation, etc.)
 - Capacity building (assistance for the implementation of biological risk management systems, support for training programmes in biosecurity and biological containment, etc.)
3. Strengthen national and international capabilities to rapidly identify, confirm/assess and respond to biological attacks:
 - Identification and reporting
 - Laboratory capacities (containment capacity, improvements in infrastructure, etc.)
 - Response (improvements in intersectoral response capacities, training of specialized staff and provision of equipment, etc.)
4. Reinforce and strengthen the BTWC and other biological disarmament and non-proliferation instruments, principles and practices.
 - Strengthen the BTWC (support for the ISU, strengthening of voluntary initiatives on transparency)
 - Universalization and implementation (support for States to draft and enact effective domestic legislation to comply with the Convention,

development of confidence-building measures, support for and collaboration with the States of the Australia Group, etc.)

- Mechanisms (strengthening of mechanisms and capacities to respond to the deliberate use of biological agents, launch of effective and accurate investigations into allegations regarding the use of biological weapons, etc.)
5. Reduce biological proliferation risks through the promotion of safe and responsible conduct.
- Materials and tools (development and renovation of training and education materials, dissemination of such materials, development of codes of conduct, etc.)
 - Training (management of associated risks, dual use materials, etc.)
 - Mechanisms (strengthening and encouragement of national and regional associations and forums on biosecurity).

G7 Expert Groups

Expert Group on Open Science:

This group, which was created during the Italian G7 Presidency in 2017, has the aims of sharing open science policies, exploring supportive incentive structures, and identifying good practices for promoting increasing access to the results of publicly funded research. It also promotes international coordination and collaboration to develop appropriate infrastructure to support open access to scientific data.

This group could be useful for developing research and sharing information and good practices between States.

Expert Group on Neglected Tropical Diseases and Poverty Related Diseases:

Also established during Italy's G7 Presidency, its main aim is to seek ways to improve and coordinate R&D activities, share information, foster interoperability, and set forth possibilities of joint action in the future so as to address the problems generated by these diseases. To this end, the proposal is to create a different "network of networks" structure for each disease, so that the G7 countries may share information, good practices, etc.

The existence of this network could be useful for sharing information and good practices on biosecurity, and for conducting studies in this regard. Moreover, conducting studies on these types of diseases may increase a country's capacity to respond to possible emergencies or to improper use of the biological agents that cause such diseases, as well as providing information about biosecurity that could be useful.

Australia Group for the control of exports of dangerous chemical and biological materials

- Scope

The Australia Group is an informal forum comprising 42 countries, including Spain, as well as all of the members of the Organization for Economic Cooperation and Development (OECD), the European Commission (which participates as an observer), all of the members of the European Union, Ukraine, and Argentina.

Given that it is a forum, it is not a legally binding instrument, but, rather, an initiative that seeks to coordinate and support these countries' efforts.

- Objective

To ensure that exports do not contribute to the proliferation of biological and chemical weapons, by harmonizing participating countries' national biological agent export licensing policies.

- Obligations

The participating States must comply with all of their obligations under the Biological and Toxin Weapons Convention (BTWC) and the 1925 Geneva Protocol. Moreover, they must seek to adopt measures to ensure that their exports do not contribute to the development of biological or chemical weapons. These rules must be effective, easy to apply, and not hinder exports for legitimate purposes.

- Dynamics

As regards biosecurity, the Australia Group first focused on the exhaustive control of exports of pathogens and related biological and technological equipment.

In 1994, the members of the Group created a list of licensing criteria for the export of said materials. To this end, they made lists of products which, for biosecurity purposes, include: biological equipment and technology, genetically modified microorganisms (originating from human and animal pathogens) and pathogens. Thus, the members need to previously obtain an export licence and guarantee that the exported product will be used exclusively for peaceful purposes. In addition, the amount of product to be exported and its possible dual use shall also be taken into account.

Moreover, the States participating in the Group also exchange information and suspicions regarding potential biological risks in countries that are not participants. The Group meets annually and also distributes among the industrial sector—in collaboration with national authorities—an unofficial alert list of dual-use products and technologies.

European Union

European Union Strategy against the Proliferation of Weapons of Mass Destruction

- Objective

Council Decision 2013/668/CFSP of 18 November 2013 in support of World Health Organization activities in the area of biosafety and biosecurity in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction has as its main objective the strengthening of the EU's Non-Proliferation Strategy by supporting the WHO activities regarding biosafety and biosecurity. Moreover, it seeks to assist the EU Member States in drafting national legislation focused on biosecurity. Thus, the EU intends to strengthen its Member States so that they may comply, as effectively as possible, with all the biosecurity measures set forth in the Sixth (2006) and Seventh (2011) Review Conferences of the States Parties to the BTWC.

- Obligations

The EU Member States must define biosecurity and biosafety measures in their national regulatory frameworks in order to guarantee the proper security and safety of pathogens and their toxins in laboratories and other facilities, including, as the case may be, during their transportation, to prevent unauthorized access to such agents and toxins and their unauthorized removal.

It is the obligation of EU Member States to promote biological risk reduction practices and their importance, especially as regards biosecurity, biosafety, bioethics and the intentional misuse of pathogens and their toxins. Moreover, they must foster international cooperation in this area.

- Dynamics

The High Representative of the Union for Foreign Affairs and Security Policy is responsible for certifying that the Member States implement all of the aspects of Council Decision 2013/668/CFSP. The High Representative shall enter into agreements with the WHO so that it provides the Member States with technical support on biosecurity and biosafety so that they may comply with their obligations under said Decision.

Moreover, the WHO must prepare periodic reports for the High Representative on the implementation of the measures set forth in the Decision. Correspondingly, the High Representative undertakes to inform the Council about the WHO reports. The Commission, for its part, is in charge of the financial aspects.

European Union Instrument contributing to Stability and Peace

- Objectives

Regulation (EU) No 230/2014 of the European Parliament and of the Council of 11 March 2014 contributing to stability and peace constitutes an instrument providing support for the European Union by seeking to increase the efficiency and coherence of the Union's common foreign policy in the areas of crisis response, threat management, conflict prevention, etc. Said Regulation is focused on three specific cooperation development and security measures as principal objectives:

- To provide a rapid and effective response to situations of crisis or emerging crisis, thus contributing to stability.
- To strengthen response capacity in pre-crisis and post-crisis situations and assist in peace-building, in addition to contributing to conflict prevention.
- To address threats to peace, international security and stability.

- Obligations

The European Union undertakes to guarantee technical and financial assistance to Member States and to cooperate with third States in the areas of peace, security and stability. As regards biosecurity, the Union advocates strengthening safety and security precautions regarding pathogens, establishing measures for an effective response against the intentional or accidental misuse of said agents.

Measures to strengthen biosecurity are particularly focused on promoting the capacities of the competent authorities, be they law enforcement, judicial, or administrative bodies, in combating bioterrorism and trafficking in biological agents and toxins. Moreover, Regulation 230/2014 seeks to implement effective measures of control over trade in these pathogens and other dual-use materials.

Said Regulation also seeks to ensure and strengthen safety and security practices at facilities where pathogens are stored and handled for research purposes, through the provision of technical assistance to such centres.

Furthermore, these measures are especially focused on the application of international standards regarding biosecurity, on the control of biological materials and of the equipment necessary for their production and use, on transregional cooperation in this field and on risk awareness, vulnerability analysis, emergency preparedness, alerts, and crisis management.

- Dynamics

The technical and financial assistance provided to Member States, and to related third States, through exceptional assistance measures and interim response programmes, thematic strategy documents and multiannual indicative programmes, annual action programmes, isolated measures, special measures and support measures.

Exceptional assistance measures are rapid response measures to a crisis or emerging crisis situation. They have a limited period of application (maximum of 18 months) which may be extended twice for an additional 6 months up to a maximum total of 30 months. In the event of a prolonged crisis, the Commission may adopt a second exceptional assistance measure with a duration of up to 18 months. The Commission must inform the European Parliament and the Council when it adopts an exceptional assistance measure. The Commission is also required to keep the Council informed regarding the value and objectives of, as well as any changes to, the exceptional assistance measures that it adopts.

Interim responses are based on exceptional assistance measures and relate to the examination procedure referred to in article 16.3 of Regulation (EU)

N° 236/2014. They are aimed at establishing or re-establishing conditions that are essential for the application of EU external cooperation policies. The Commission must inform the European Parliament of the planning, implementation, changes to or substantial increases in said interim responses.

Thematic strategy documents and multiannual indicative programmes constitute the implementation basis for the assistance provided by the Union pursuant to articles 4 and 5 of Regulation (EU) No 236/2014. Said documents offer a framework for cooperation, based on aid effectiveness principles, between the European Union and third countries or regions. Similarly, thematic strategy documents shall be based on dialogues between EU Member States and third country authorities, seeking at all times to ensure that these countries involve the competent authorities, as well as civil society, to guarantee their participation in the programming process. Thematic strategy documents must be coherent with the programming documents adopted in the framework of other external assistance instruments in order to avoid duplications. Multiannual indicative programmes must stipulate the financial allocations for the programmes they deal with.

Action Plan to enhance preparedness against chemical, biological, radiological and nuclear security risks (CBRN)

- Objective

This Action Plan seeks to strengthen European cooperation regarding chemical, biological, radiological and nuclear (CBRN) threats. As regards biosecurity, said plan is primarily focused on reducing access to hazardous biological materials, ensuring greater control over them. The principal objective is to establish biosecurity measures to ensure protection from pathogens and toxins.

In addition, the Action Plan sets out to increase EU Member States' capacity to identify the location of facilities at which pathogens are being handled as promptly as possible, restricting and overseeing access to such materials as much as possible. The safety and security of laboratories and other facilities storing high-risk biological materials also receives particular attention in said Action Plan.

Moreover, this Action Plan aims to address and analyse the vulnerabilities of EU Member States to bioterrorist attack. It also seeks to establish prevention, preparedness and response measures against terrorist attacks with biological materials through closer cooperation between Member States and more intense sharing of knowledge and information.

- Obligations

The Action Plan to enhance preparedness against chemical, biological, radiological and nuclear security risks contains a number of commitments, including, in particular:

- To reduce access to high-risk biological materials,
- To ensure a satisfactory response to biological incidents,
- To step up European cooperation in the sphere of biosecurity and to work in collaboration with relevant international organizations, such as NATO and Interpol.
- To improve knowledge about the risks of biological attack.

These commitments consist in systematically and technically increasing the sharing of information regarding the use, whether for research or any other purposes, of pathogens and their toxins through the European Bomb Data System.

The Action Plan also seeks to increase intersectoral awareness within the EU regarding the risks that biological incidents, whether intentional or accidental, may entail. It provides for training programmes especially tailored for competent national authorities in the sphere of biological risk: law enforcement and civil protection officers, in addition to the emergency healthcare services offered by the European Centre for Disease Prevention and Control, in collaboration with Europol.

Furthermore, the Union seeks to adopt measures to support the sharing of good practices in the field of biosecurity, as well as to offer training regarding the risks of biological material being intercepted by criminal and terrorist groups. Supporting the EU Member States in combating bioterrorism is an essential part of said Action Plan, and to this end the EU prepared a handbook on bioterrorist threats in European territory in 2018.

The European platform for sharing information regarding threats—the Early Warning and Response System (EWRS)—shall be used, on the basis of procedures for sharing information with other rapid alert systems at Union level, to favour the management of incidents in the event of cross-border bioterrorist

threats deriving from any type of risk. In this way, European information and alert systems shall be linked to ensure the proper functioning of the system and prevent the duplication of activities or actions. The Action Plan establishes rapid identification and characterization and rapid sample sharing mechanisms to ensure efficient biosecurity measures.

- Dynamics

This Action Plan has a horizontal approach, seeking to meet the cross-cutting needs of the different actors engaged in the biological sphere, such as law enforcement, emergency management, the private sector and public health, among others. With a view to strengthening the biological risk management and biosecurity capacities of these national actors, the Commission developed the Action Plan with relevant initiatives in the biological sphere so that Member States can participate in them voluntarily.

The Commission organizes and prepares a number of training activities and exercises for relevant national authorities and actors in the biological sphere. These activities and exercises are related to biosecurity and biosafety, in addition to prevention and response in the event of biological attack.

The funding of the initiatives proposed in the Action Plan is guaranteed through the mobilization of funds in the framework of several Commission instruments, such as the Instrument contributing to Stability and Peace, the Internal Security Fund, the Development Cooperation Instrument and the European Neighbourhood Instrument.

CBRN Centres of Excellence

- Objective

The principal objective of this initiative is to strengthen the long-term capacity of the national and regional authorities, as well as that of the bodies responsible for tackling CBRN threats. It also seeks to promote lasting cooperation between national authorities.

The Commission provides partner countries with tools and a methodology to assist them in assessing their own needs and in preparing national action plans to mitigate CBRN risks.

However, it does not provide sufficient guidelines on how risks must be identified and prioritized. Despite this drawback, the Needs Assessment Questionnaire and the national action plans continue to be fundamental elements underpinning the Initiative.

- Dynamics

Although a significant proportion of the international community has signed treaties and conventions regulating the use of CBRN materials and weapons, the acquisition and malicious use of CBRN substances (or accidents involving them) are considered by the European Commission to represent a situation which, while improbable, could have a very high impact.

To respond to this threat, the EU Chemical, Biological, Radiological and Nuclear (CBRN) Risk Mitigation Centres of Excellence (CoE) Initiative was launched in 2010. This is one of the main instruments for mitigating CBRN threats and risks

from outside the EU. It is the EU's largest civilian external security programme and is funded through the Instrument contributing to Stability and Peace (Regulation (EU) No 230/2014 of the European Parliament and of the Council of 11 March 2014 establishing an instrument contributing to stability and peace).

The initiative primarily funds capacity-building projects, but also seeks to create and consolidate networks for cooperation between partner countries and within them.

The Initiative is managed by the Directorate-General for International Cooperation and Development (DG DEVCO), and is organized around regional secretariats. There are eight regional secretariats (South East Asia, African Atlantic Façade, North Africa Sahel, South East and Eastern Europe, Central Asia, Middle East, Eastern and Central Africa, and Gulf Cooperation Council Countries), which are platforms for sharing knowledge and experience, as well as for promoting and facilitating cooperation at the regional and international levels.

The regional secretariats collaborate with the national coordination centres of their region and provide them with support (facilitating the sharing of information, supervising regional activities—up to a certain extent—and promoting the Initiative).

The governments of partner countries designate a national coordination centre. This centre shall be their principal representative regarding the Initiative, and shall be responsible for relations with interested parties at the national (project beneficiaries, etc.) and international levels.

Council Advisory Group: Working Party on Non-Proliferation (CONOP)

- Objective

In the Working Party on Non-Proliferation (CONOP), the Member States cooperate to promote the non-proliferation of weapons of mass destruction and to attempt to ensure that such weapons do not fall into the hands of terrorist groups.

- Dynamics

CONOP is a preparatory working group of the European Council which coordinates action and dialogue on non-proliferation issues with countries that are not members of the EU, as well as with relevant international organizations, such as the IAEA. It also contributes to the implementation of international non-proliferation agreements, primarily the Non-Proliferation Treaty (NPT).

CONOP examines the legislative proposals of the European Commission that are sent to the Committee of Permanent Representatives (COREPER), contributing a political and technical analysis. After this examination, the proposals are sent to the Foreign Affairs Council of the European Union.

CONOP is formed by a group of experts from each Member State and has a rotating six-month presidency. The group is presided over by the delegate of the country that holds the presidency at that moment

Health Security Committee

Decision N° 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, currently under review, provided for the creation of the Health Security Committee, in close cooperation, where applicable, with other structures established at EU level and pursuant to the Euratom Treaty. This Committee is formed by representatives from the Member States and its objective is to coordinate, in cooperation with the Commission, the Member States' preparedness and response planning activities, as well as communication in risk and health crisis situations, including those potentially involving intentional use , without interfering in other legislations.

European Centre for Disease Prevention and Control

The European Centre for Disease Prevention and Control is responsible for providing scientific advice to the European Commission and to Member States regarding possible cross-border threats and for guaranteeing the improvement of countries' capacities to address biological risk threats. Its mission includes:

1. Providing scientific advice and up-to-date information that enables effective decision-making by Member States and by the European Commission.
2. Supporting efficient decision-making by providing evidence and scientific-technical assistance, including training.
3. Supporting the strengthening of public health infrastructure and processes.
4. Supporting the strengthening of public health capacities and workforce.
5. Ensuring the early detection of serious cross-border threats to health.
6. Coordinating and supporting the rapid assessment of biological risks and the identification of response options.
7. Supporting the national and international response in the field.
8. Ensuring preparedness for the future, evaluating and analysing the potential impact and the benefits generated by technical and scientific advances.

At the national level

National actors: activities and responsibilities

- **Ministry of Health**

The Coordination Centre for Health Alerts and Emergencies (CCAES) of the Ministry of Health was created in 2004 by Order SCO/564/2004 of 27 February and is under the aegis of the Directorate-General for Public Health (DGSP) of the Ministry of Health.

Its principal function is to coordinate information management and support the response to national or international health alerts or emergencies that may constitute a threat to public health. It also formalizes collaboration agreements with the central nodes of the different surveillance and alert systems and networks that operate in Spain's General State Administration. The CCAES is, moreover, the unit responsible for preparing and developing preparedness and response plans against public health threats.

Its biosecurity-related activities include:

- Conducting ongoing monitoring of potential risks for human health and assessing their possible impact on national public health.
- Acting as the National Liaison Office with the WHO (Order SCO/3870/2006), and the Focal Point of the European Commission's Early Warning Response System (EWRS).
- In coordination with other public institutions concerned, drafting preparedness and response plans against current or emerging public health threats.
- Coordinating actions and information exchanges corresponding to epidemiological surveillance, both nationally and at the level of the European Union, the World Health Organization (WHO) and other international organizations.
- Coordinating and maintaining the National Early Warning and Rapid Response System (SIAPR). The SIAPR comprises a network of regional liaison centres enabling permanent and rapid reporting of risk situations, in order to improve the timeliness and coordination of the national or international response.

- **Ministry of Science and Innovation**

The Ministry of Science and Innovation has, in its different centres, highly qualified specialists, and offers versatile and interdisciplinary research in order to acquire knowledge and develop new technologies in such areas as human and animal health, agriculture, microbiology and the environment, among others.

Noteworthy among these centres is the National Centre for Biotechnology (CNB), which is part of the Spanish National Research Council (CSIC), an agency under the aegis of the Ministry of Science and Innovation. As regards biosecurity, the CNB contributes with publications and research in this regard, and also offers training courses for specialists in different areas in collaboration with many associations.

Likewise, noteworthy as a centre of reference in animal health research is the Centre for Animal Health Research-National Institute for Agricultural and Food Research and Technology (CISA-INIA) in Valdeolmos (Madrid), whose Biosafety Level 3 facilities are a nationwide reference, in addition to being one of only two centres authorized to handle the foot-and-mouth disease virus.

The **Carlos III Health Institute (ISCIII)** is a public research body under the aegis of the Ministry of Science and Innovation, whose principal objective is to improve the health of the entire population and to combat diseases, by fostering research and innovation in the field of health sciences and biomedicine, and by providing scientific and technical services of reference. Moreover, through the ISCIII, the Ministry of Science and Innovation coordinates the network of Biological Alert Laboratories (RE-LAB) (see below).

- **Ministry of Agriculture, Fisheries and Food (MAPA)**

The Animal Health Laboratories of Reference, under the aegis of the MAPA's Directorate-General for Health in Agricultural Production, play an important role in the field of biosafety and biosecurity of pathogens that affect animals and of zoonotic agents; in this latter case, they work in coordination with the Carlos III Health Institute and the CCAES.

Specifically, the Central Veterinary Laboratory in Algete (Madrid) is the other laboratory authorized at the national level to handle the foot-and-mouth disease virus, and is part of RE-LAB (see below).

- **Ministry of the Interior**

The principal objective of the Directorate-General for Civil Protection and Emergencies of the Ministry of the Interior is to protect persons and goods, offering an appropriate response to different types of emergencies and disasters, whether they are the result of natural causes, or caused by accidental or intentional human action. This is linked to Act 17/2015 of 10 July, which comprises all the parties that may contribute to civil protection.

Even though biosecurity is not specifically mentioned, the duties of this Directorate-General cover possible technological accidents caused by the transport of dangerous goods; therefore, it plays a role in biosecurity.

- **Ministry of Transport, Mobility and the Urban Agenda**

The Ministry of Transport, Mobility and the Urban Agenda is responsible for transport and, specifically, for regulating the transport of dangerous goods. This Ministry also carries out the interministerial coordination of the transport of dangerous goods.

- **Ministry of Defence**

The Armed Forces, by virtue of their mission, participate in the biosecurity of biological agents after reconnaissance or sample collecting missions by specialized teams, as well as during their transport.

In addition, the “La Marañosa” Biological Laboratory, which is part of the “Esteban Terradas” National Institute for Aerospace Technology (INTA), and the Military Emergency Unit (UME) with its Rapid Identification Laboratory (LABIR), are also part of RE-LAB.

- **Department of National Security**

The Department of National Security (DSN) of the Office of the Presidency of the Government is the President of the Government's advisory body on National Security. In relation to the DSN, the following bodies and structures are noteworthy as being of interest to biosecurity:

- **Specialized Committee on Non-Proliferation of Weapons of Mass Destruction**, responsible for implementing the National Biosecurity Plan.

The Specialized Committee on Non-Proliferation of Weapons of Mass Destruction is a support body for the National Security Council (art. 20 of Act 36/2015 of 28 September on National Security) and falls within the framework of the National Security System.

The Committee supports the National Security Council in its duties related to the non-proliferation of weapons of mass destruction, contributing a comprehensive view of the nuclear, radiological, chemical and biological spheres. Furthermore, it strengthens relations with the public administrations, as well as collaboration between the public and the private sectors.

Noteworthy among the duties assigned to the Committee regarding the non-proliferation of weapons of mass destruction are:

- Proposing to the National Security Council guidelines on planning and coordination of the National Security policy.
- Contributing to strengthening the proper functioning of the National Security System, the oversight and coordination of which is the responsibility of the National Security Council.
- Supporting the National Security Council in its duties of verifying the degree of compliance with the National Security Strategy and proposing, when appropriate, its review.

- Supporting the National Security Council’s decision-making processes on issues pertaining to the non-proliferation of weapons of mass destruction, through the analysis, study and proposal of national and international initiatives.
- Strengthening relations with the public administrations concerned, as well as coordination, collaboration and cooperation between the public and private sectors.

The Specialized Committee on Non-Proliferation is chaired by the Secretary of State for Foreign Affairs, who is assisted by the Director of the Department of National Security as Vice-Chair. The Department of National Security, in its capacity as Technical Secretariat and working body, acts as the Technical Secretary of the Committee.

The other members of the Committee are representatives—with a minimum rank of Deputy Director-General or General Officer—of the Ministries considered affected: Ministry of Foreign Affairs, the European Union and Cooperation; Ministry of Justice; Ministry of Defence; Ministry of Finance and the Civil Service; Ministry of the Interior; Ministry of Transport, Mobility and the Urban Agenda; Ministry of Industry, Trade and Tourism; Ministry of the Presidency of the Government, Relations with Parliament and Democratic Memory; Ministry of Territorial Policy; Ministry of Economic Affairs and Digital Transformation; Ministry of Agriculture, Fisheries and Food; Ministry of Ecological Transition and the Demographic Challenge; Ministry of Health; Ministry of Science and Innovation; and the National Intelligence Centre.

The Committee holds meetings every two months, but it may meet whenever the urgency of the matter makes it advisable. These meetings may be held face-to-face or online.

National Biosecurity Plan

The principal objective is to enable the effective protection of relevant biological agents, controlling access to them, guaranteeing their containment and the physical protection of the facilities where these agents are handled, as well as their secure transport. This is included in Spain's National Security Strategy of 31 May 2013.

The National Biosecurity Plan is the national instrument that responds to the National Security Strategy of 2013, as well as to the obligations contained in United Nations Security Council Resolutions 1540 and 2325, whose purpose is to prevent non-State entities or terrorist groups from having access to weapons of mass destruction, including biological weapons.

The National Biosecurity Plan seeks to develop all the necessary measures to enable:

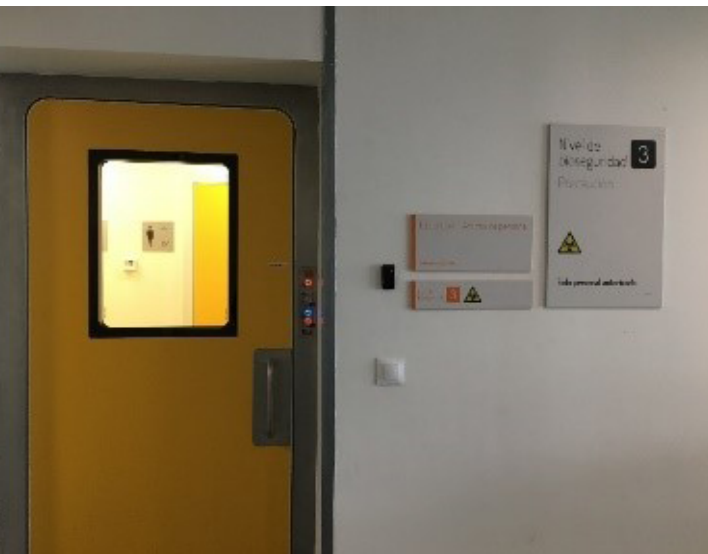
- The drafting of a nationwide inventory of relevant biological agents.
- The effective security of biological agents, controlling physical access to them and the physical protection of the facilities where such agents are handled.
- Control of the transport and transfer of biological agents within national territory.

The National Biosecurity Plan was drafted by the Ministry of Foreign Affairs, the European Union and Cooperation, in coordination with all the public administrations with powers in this matter.

This Plan is led by the Specialized Committee on Non-Proliferation, which is one of the support bodies for the National Security Council set forth in article 20.3 of Act 36/2015 of 28 September on National Security. It is responsible for exercising the duties assigned by the National Security Council in the sphere of non-proliferation of weapons of mass destruction and in the framework of the National Security System.

This Specialized Committee, moreover, coordinates the activities of GRUPABI, which is the working group for the prohibition of biological weapons.

The Committee brings together and coordinates the activities of GRUPABI, as well as those of other coordination groups at the national level in the sphere of disarmament. GRUPABI, coordinated by the Ministry of Foreign Affairs, the European Union and Cooperation, is the working group for the non-proliferation of biological weapons. The National Biosecurity Plan was designed and drafted in this working group, in compliance with the functions entrusted to the group. This Plan was approved by the National Security Committee on 21 January 2019.



Entrance to a P3 laboratory of the National Microbiology Centre

Network of Biological Alert Laboratories (RE-LAB)

As regards responding to possible aggressions with biological weapons, the Network of Biological Alert Laboratories (RE-LAB) was created 2003 at the initiative of the National Committee on Civil Emergency Plans (CNPCE), to design a response tool after the events deriving from the terrorist attacks of 11 September 2001 in the United States and from the biological alert situations in Spain after the appearance of envelopes suspected of containing spores of the bacteria that causes anthrax.

The RE-LAB, the direction of which is the responsibility of the Ministry of Science and Innovation, through the Carlos III Health Institute, was formalized in an Order of the Presidency of the Government in February 2009. Its primary objective is to interconnect Spain's major biological research laboratories, and to exchange information and data to support crisis management.

Moreover, the RE-LAB provides operational support to the National Security System against risks and threats due to biological agents. It is an alert network comprising microbiology laboratories specializing in the detection and identification of biological agents in five areas: human, animal, plant and environmental health, and food safety. The Network is currently coordinated by the Carlos III Health Institute, which, in turn, coordinates with the Networks of Laboratories of other countries, especially in the framework of the EU.

In the event of a biological terrorist threat, or of the accidental release of biological agents, the RE-LAB can receive information and be activated by its focal points. The focal points receive information in different manners, normally through the State Security Forces.

The RE-LAB Management Unit is responsible, after receiving this information, for analysing the alert and coordinating a response.

National Biosecurity Commission

Order PCI/168/2019 of 22 February, which published the National Biosecurity Plan, approved by the National Security Council, sets forth, in section IV, the creation of the National Biosecurity Commission.

The National Biosecurity Commission is an interministerial body whose principal objective is to facilitate compliance with the National Biosecurity Plan, and to collaborate with other entities that have, or may have, powers in this regard (art. 1), as well as to strengthen the public health system (art. 2).

To this end, the duties of the National Biosecurity Commission include (art. 4):

- Creating a catalogue of facilities where biological agents are handled, worked on or managed, taking into account the biosecurity levels established according to the type and class of biological agent.
- Contributing, in coordination with the competent authorities, to creating and maintaining a response system for biological emergencies and damage mitigation.
- Receiving and analysing the periodic information obtained from the Network of Biological Alert Laboratories (RE-LAB) in the framework of the National Security System.
- Ensuring coordination with equivalent regional bodies, if such exist.
- Producing the national inventory of relevant biological agents.

The same article 4 sets forth that, in the international sphere, the Commission shall contribute, in coordination with the Ministry of Foreign Affairs, the European Union and Cooperation, to everything regarding the implementation of the BTWC and United Nations Security Council Resolutions 1540 and 2325, and the EU's New Lines of Action. The Commission may also be consulted on matters related to defence projects in NATO and the EU, if appropriate.

Article 5 recognizes the possibility that all the ministries with powers in the sphere of biological agents and their security be represented in the Commission. The ministries considered to have such powers are listed in Appendix I of the same document, and include: Ministry of Foreign Affairs, the European Union and Cooperation; Ministry of Defence; Ministry of the Interior; Ministry of Industry, Trade and Tourism; Ministry of Health; Ministry of Agriculture, Fisheries and Food; Ministry of Science and Innovation; Ministry of Transport, Mobility and the Urban Agenda.

BIOSECURITY MAP