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WORLD MARITIME UNIVERSITY

Malmö, Sweden

**The importance of integrating “Biosecurity Policies”
in the Peruvian Maritime Sector**

By

CHRISTIAN VELARDE MORILLAS

Peru

A dissertation submitted to the World Maritime University in partial
fulfillment of the requirement for the award of the degree of

MASTER OF SCIENCE

in

MARITIME AFFAIRS

MARITIME SECURITY AND ENVIRONMENTAL ADMINISTRATION

2019

Declaration

I certify that all the material in this dissertation that is not my own work has been identified and that no material is included for which a degree has previously been conferred on me.

The contents of this dissertation reflect my own personal views and are not necessarily endorsed by the University.

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(Date): September 24th, 2019

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Supervisor's affiliation: MSEA

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Abstract

Title of Dissertation: The importance of integrating to integrate “Biosecurity Policies” in the Peruvian Maritime Sector.

Tool - An Investigation

Degree: Master of Science

The introduction of pathogenic agents and invasive species into a country are closely related to international ship movements, and these hazards grow proportionally with the increase of global trade.

These biological hazards travel onboard ships and can cause irreparable damage to humans, animals, plants, and the environment and biodiversity.

The comb jellyfish case in the Caspian and the Black Sea, the black death case in the sixth, seventh and fourteenth centuries, or the Cholera bacteria case in South America (1991), are clear examples of the mobility, reach, and consequences the arrival of biohazards can cause.

The intention of this research is to explore the different approaches related to biosecurity, in order to identify its main characteristics, requirements, and the measures necessary to prevent, control, mitigate, and protect the country from adverse biohazard impacts.

Subsequently, an evaluation of the current Peruvian biosecurity regime will be carried out, in order to identify the main gaps if any, competent authorities, actual legislation, and procedures.

Finally, the author of this investigation will demonstrate the importance of integrating Biosecurity Policies in the Maritime Sector, to improve national legislations, and to use the organizations, infrastructures, and the systems that are already in place.

To achieve this, an exploratory design through qualitative research will be used. The information will be collected through reliable bibliographic sources, international and national legislation, as well as case studies related to biosecurity. A SWOT matrix will be used to identify possibilities and challenges of both biosecurity approaches.

KEYWORDS: Biosecurity, FAO Biosecurity Toolkit, biohazards, Maritime Authority, International Health Regulations, biosafety, living modified organism, Biodiversity, invasive species, zoonoses, harmonized and integrated approach, quarantine, environment protection.

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APN: National Port Authority.....	12
BID: International Development Bank.....	27
BW: Ballast Water.....	19
BWMC: Ballast Water Management Convention.....	19
CAC: Codex Amimentary Commission.....	18
CBD: Convention on Biological Diversity.....	29
CBM: Coordinated Border Management.....	28
CCS: Civil Contingencies Secretariat.....	31
CONABID: National Commission of Biological Diversity.....	44
CONABIOS: National Advisory Commission of Biosecurity.....	44
CONAM: National Environment Council.....	42
CPM: Commission on Phytosanitary Measures.....	18
CSA: Competent Sector Authorities.....	42
CTN-BOVM: National Technical Committee for Biosecurity Standardization on Living Modified Organism - INDECOPI.....	44
DAFF: Department of Agriculture, Fisheries and Forestry.....	32
DEFRA: Department for Environment, Food and Rural Affairs.....	31
DFID: Department For International Development.....	31
DHSC: Department of Health and Social Care.....	31
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ESAN: Graduate School of Business.....	55
EVIRA: Finnish Food Safety Authority.....	31
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GEF: Global Environment Facility.....	29
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GMO: Genetically Modified Organism.....	50
HA: Health Authority.....	45
HNI: Health National Institute.....	38
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IHR: International Health Regulations.....	20
IMDG: International Maritime Dangerous Goods Code.....	29
IMHD: International Maritime Health Department.....	48
IMO: International Maritime Organization.....	18
INDECOPI: National Institute for the Defense of Competition and the Protection of Intellectual Property.....	44
INEI: National Institute of Statistics and Informatics.....	13
INIEA: National Institute of Agricultural Research and Extension.....	42
IOPH: International Office of Public Hygiene.....	18
ISPS: International Ship and Port Protection Convention.....	20
LMO: Living modified organism.....	22
MA: Maritime Authority.....	40
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MEB: Maritime Economic Border.....	27
MINAM: Ministry of the Environment - Peru.....	37
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MINSA: Ministry of Health.....	37

MLC: Maritime Labour Convention	27
MOD: Ministry of Defense	31
MPI: Ministry for Primary Industry	31
MSCBS: Ministry of Health, Consumption and Social Welfare	20
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SCBD: Secretariat of the Convention on Biological Diversity	22
SNP: National Society of Fisheries	37
SOLAS: Safety of Life at Sea.....	20
STCW: International Convention on Standards of Training, Certification, and Watchkeeping for Seafarers.....	29
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SWOT: Strengths, weaknesses, opportunities and threats matrix.....	16
UN: United Nations	22
UNDP: United Nations Development Program	29
VUCE: External Commerce Single Window	50
WBO: World Bank Organization	18
WCO: World Customs Organization	28
WHO: World Health Organization	13
WTO: World Trade Organization	18

Chapter 1 Introduction.

Currently, a significant portion of the Peruvian population has migrated along the coastal lines of the Pacific Ocean. These displacements from inland, in addition to the growth of the population, demand more care of the sea and responsible use of it, since it is a source of food, commerce, recreation and energy for all Peruvians.

The oceans are the main means of transport of national and international trade; approximately 90% of Peru's external trade is carried out by the sea (APN, 2016). The diverse hydro-biological resources make Peru one of the richest in this area, added to its geographically favorable location in the center of South America in the Pacific Ocean basin, where the fastest-growing economies are.

Chapter 1.1: Motivation of the investigation

A significant number of Peruvians human and commercial activities are carried out in the coastal zone, from commercial activities to sports and tourism activities (INEI, 2019). The absence of integrated policies related to biological security or biosecurity in the maritime field can affect the effectiveness of current measures to protect Peru from the unwanted arrival of pathogens a non-native species which, both, can affect the ecosystem, population, and the national economy.

Biosecurity, as discussed in this work, represents an integrated approach to face biological threats through effective resource management requiring cross-sector collaboration, harmonization of national regulatory frameworks and objectives. The aim is to prevent the arrival of an unwanted and unintentional introduction of any biological hazard.

In addition to carrying cargo, ships also transport people, animals, microorganisms, plants, and everything attached to the transport operations. The main pathways to biological hazards or biohazards (see figure 1) by ships are:

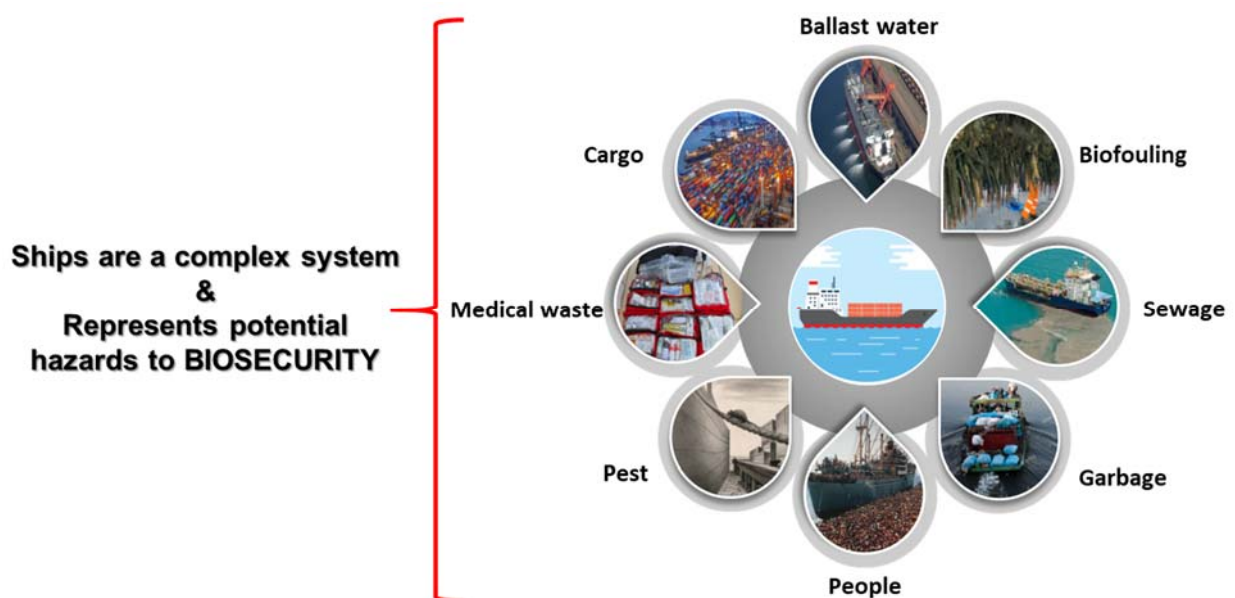


Figure 1, Self-elaboration. Source: "Biosecurity: the socio-politics of Invasive Species and Infectious Diseases."

Biological risks related to the shipping industry

The increase in international man-made transport has boosted biodiversity exchanges and risks to public health with a global reach (WHO, 2005). It is essential to see the shipping industry not only as an open window for progress but also as a pathway to several biological hazards that could affect the security and economy of countries.

To avoid biohazards affecting national interests, they must be controlled by appropriate national measures developed by various entities (FAO, 2007). To achieve it efficiently, cross-sectoral cooperation is required. The government needs to define who has the competences, responsibilities, jurisdiction, and functions. The preventive and protective measures must be guided by an appropriate harmonized, integrated, and long-term policy that generates synergies in the actions of the different sectors of the state.

Peru under a latent biohazards exposure

New investments and technological developments increase the use of marine coastal areas. Peru has 85 port facilities, which are scattered along its 3000 km of the coastal profile (APN, n/d). The main economic activities of the country are mining, fishing and agriculture and the export of these products are done through these port facilities, which makes Peru a great exporter of raw materials and intermediate products (INEI, 2019).

Peruvian importations are technological products, intermediate products, and also direct human consumption products (INEI, 2019). In this regard, maritime trade is vital to Peru's income. Therefore, the high number of port facilities and the constant increasing of international travels to the Peruvian coast (see figure 2) the risk of biohazards intrusion in any of these entry points increase. The central government has the responsibility to address this risk adequately.

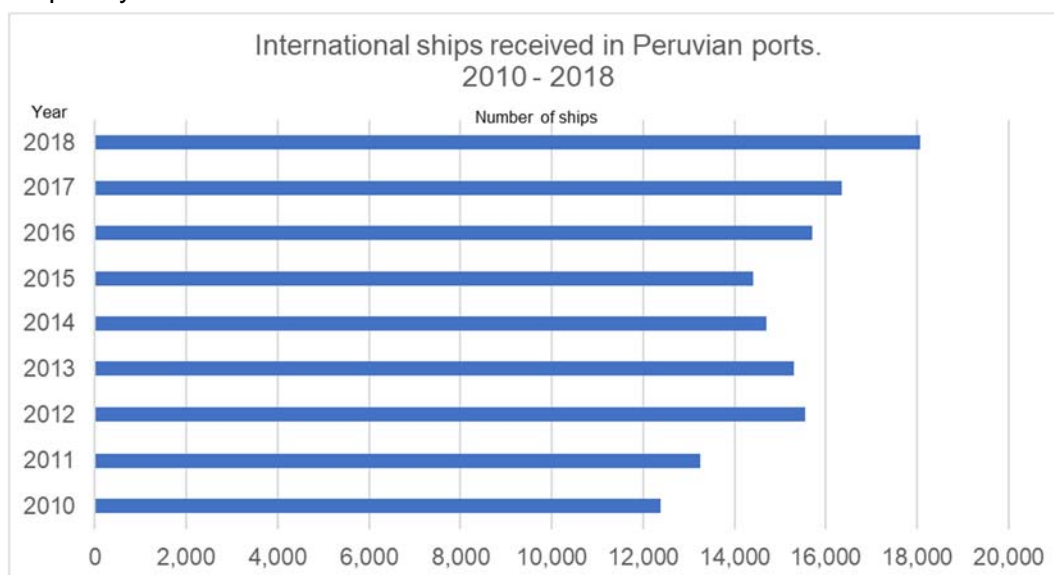


Figure 2, International ships received in Peruvian ports. Source: <https://www.apn.gob.pe>

Addressing biological hazards

By assessing the upcoming risks accurately, it could be possible to prevent the recurrence of biological incidents such as invasive species or biological pathogens (e.g., Cholera bacteria) (FAO / WHO, 2002). In order to develop a suitable risk assessment, it is necessary to develop a biosecurity framework inside, where roles and responsibilities are well

defined; technical and scientific capabilities are identified; infrastructure, communication system, and data exchange/storage are well-established.

In this sense, the purpose of this work is:

- To identify and describe the current components of the biosecurity regime in Peru.
- To assess the current regulations; and
- To identify and discuss the gaps.

This work will begin by defining the main concepts related to Biosecurity handled at the international level, continuing with a revision of the current international regulations and how they are being applied in some countries.

Next, the biosecurity approach will be compared and discussed with the Peruvian Maritime Regulations. Finally, conclusions and recommendations will be provided.

Chapter 1.2 Problem statement.

The timely identification of the biological risks derived from maritime activities is the only way to be prepared and prevented (FAO, 2007).

Because globalization and modern transport systems intensify exchanges of goods and people, there is a need to strengthen national protections against biological risks of all forms. To enhance the effectiveness of preventive measures and responses, FAO, some governmental bodies and researchers, propose to develop integrated biosecurity policy.

This approach is an answer to current disconnection among various administrations. Indeed, each sector of the State performs its functions independently without paying sufficient attention to the causes that could affect biosecurity. Most states continue facing biosecurity risks with sectoral orientation, which results in inadequate and inefficient management of resources and unsatisfactory results (FAO, 2007). This also means that each authority carries out its own risk assessment but from the perspective of its functions and responsibilities. It generates overlapping of functions, wastage of resources, redundancy of procedures, or discarding of risks associated with other authorities.

In summary, the introduction of pathogens affecting human health, animals or plants as well as invasive species are transported either: intentionally (rainbow trout case – see appendix 1) or unintentionally (Cholera bacteria case – see chapter 4). In both cases, it involves man-made transportation. In order to develop a proper biosecurity risk assessment, adequate national policies must be set.

Chapter 1.3 Objectives of the investigation.

The aim of this work is to assess the Peruvian biosecurity regime, including the legal framework, institutional framework, communication and information exchange system, competent authorities, technical and scientific capabilities, and risk assessment in the maritime field. To accomplish the main objective, it is necessary to achieve the following secondary objectives:

- To identify the main concepts related to biosecurity.
- To identify the biosecurity approaches that are actually in place around the world.
- To identify the Peruvian biosecurity regime and analyze it.
- To define the competent authorities which should be involved in the Peruvian biosecurity system.

- To assess the need for cross-sectoral cooperation.
- To elucidate which biosecurity approach is the most suitable in accordance with the Peruvian maritime legislation.

Chapter 1.4 Research questions.

- How is the biosecurity regime organized in Peru?
 - Why is it important to assess it and/or improve it if necessary?
 - Which components are necessary to develop a national biosecurity strategy?

Chapter 1.5 Methodology of the investigation.

This research will use an exploratory design through qualitative research. The information will be collected through bibliographic evaluation, international and national legislation, as well as case studies related to biosecurity. What is sought is to know, define and outline in detail the current approaches related to biosecurity policies, analyze their impact on the maritime sector, the advantages and disadvantages that their implementation may represent, and determine their applicability in Peruvian maritime legislation.

The analysis will be carried out using a SWOT matrix in order to determine the challenges and possibilities that each biosecurity policy approach provides. In this way, it will be possible to determine the most suitable approach to be applied in Peruvian maritime legislation.

Chapter 1.6 Potential limitations.

The limited availability of Peruvian authorities affected the data collection. Some agencies have not been able to share relevant information related to their internal functioning, procedures, and protocols. Therefore, the current work could be limited due to gaps in data availability and time allocated to do the work.

Chapter 1.7 Delimitation of the investigation.

Maritime-focus, the present work discusses the protective systems in place to control unintentional biological hazards coming from a ship. So, biological weapons or species purposely-introduced are not included.

During the development of this work, references to other means of transport or activities may be used, like fishing vessels or trains, in order to demonstrate how biological hazards, move with any human transportation system.

Chapter 2 Background.

Since ancient times biological hazards have been closely related to trading. Transport of biological pathogen or invasive species has been identified as a by-product of seaborne transport. For example, several plague outbreaks moved all along Europe, Africa, and Asia, following the routes of commerce (VI, VII, XIV & XIX centuries).

The initial solution to avoid the spread of the disease was to restrict the entry of goods and people coming from infected places, in other words by using preventive measures (Gensini, Yacoub & Conti, 2004).

FAO provides in its toolkit on biosecurity a broad definition of biological hazard:

- biological pathogen representing a potential risk to health and life of humans, animals, and plants; and,
- an invasive species which represent a risk to the biodiversity or the environment (FAO, 2007).

FAO identifies the main biological hazards that affect the different biosecurity sectors (health, environment, maritime, agriculture, livestock & economic), see table N° 1.

PROBLEM	AFFECT	EXAMPLE	VECTOR/PATHWAY	RESPONSE
Zoonotic disease	Human health Animal welfare Economy	Swine flu Avian flu SARS	Industrial agriculture. Export of animal/animal products. International travels. Movement of pathogens from wild life to domestic.	Massive kill of infected animals. Containment for humans and animals. Vaccination of humans and animals.
Agricultural pest or disease of animals	Animal welfare. Farming subsistence. Economy	Foot & mouth disease. Bluetongue. Tuberculosis.	Usually unintentional. Contamination with animal material	Screening & interception of animals diseases on imported material. Massive kill of infected animals. Containment for humans and animals. Vaccination of humans and animals.
Forestry pest or disease of plants	Farming subsistence. Economy	Potato blight (<i>phytophthora infestans</i>)	Usually unintentional. Contamination with plant & soil material. Horticultural trade.	Embargo of cargo. Sanitation measures of exported goods. Destruction of infected plants.
Marine and aquatic pest and disease	Environment. Recreation. Economy.	Zebra mussels. Eutrophication of water bodies. Didymo.	Ballast water. Hull fouling. Intentional release of fish species. Spreading contamination of inland waters because boats & fishing activities.	Sanitary measures. Public education. Ballast water policies. Chemical sterilization of water bodies.
Environmental plant pest and disease	Environment. Environmental values. Recreation. Economy.	Sudden oak death. Ash dieback.	Usually unintentional. Contamination with plant & soil material. Horticultural trade.	Embargo of cargo. Sanitation measures of exported goods. Destruction of infected plants.
Invasives species	Environment. Environmental values. Recreation. Economy.	Possums. Rhododendron. Himalayan balsam. Jellyfish	Accidental as well as intentional human-assisted release (BW). Acclimatization practices. Biocontrol. Horticulture trade.	Risk assessment. Border control. Incursion response. Pest management.
Bioterrorism	Human health Public fear Economy	Anthrax	Intentional release.	Preparedness. Surveillance. Contingency planning. Scenario modelling.
Laboratory safety	Human health Economy	Foot & mouth disease.	Accidental release. Bioterrorism act.	Laboratory safety. Controls on research publications.

Table 1, self-elaboration "Biological hazards." Source: "Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases." (Barker, Taylor & Dobson, 2013)

These biological hazards have entry points and possible exit points. Without control, there are no limits on the distance the biological hazards can spread. The borders between countries represent administrative entry-exit points where control measures have developed for people and goods (WHO, 2016; WHO, 2005).

Any form of measure (preventive or responsive) to control biological hazards could be called biological security or biosecurity. In this respect, the development of quarantine represents the first attempt to control biological risks from ships (Mayer, 2018).

Chapter 2.1 From quarantine to biosecurity policy.

Since remote times, "quarantine" has been the first measure initiated by authorities (local or national) to protect public health and trade in ports.

Following the black death, in 1377, the term “quarantine” was used for the first time in the port of Ragusa in southern Italy, when the port authorities decreed a period of 30 days of isolation for ships arriving at port and 40 days for travelers by land (Gensini, Yacoub & Conti, 2004).

The term quarantine is derived from the Italian word “quarantina” or “Quaranta giorni,” and was used in the XIV and XV century to indicate that the vessel under that regime was in a 40-day isolation period prior to authorizing them to enter into ports (Institute for Bioethics, 2003). At that time, doctors believed that if the people or the ship's cargo came from a contaminated city, during those forty days, a sick person could die or recover. It was also used to try and assess the minimum time the “healthy people” on board took to get sick. Later, during the XV century, this practice was extended to all Europe and its colonies (Gensini, Yacoub & Conti, 2004).

However, it was not until the 11th Sanitary Conference developed in Paris in 1903, the first useful international convention, in which an integrating concept for the control of epidemic diseases was introduced (quarantine measures). This convention also had historical importance because it established the first International Health Organization, which became known as the International Office of Public Hygiene (IOPH), later the World Health Organization, in 1948 (Schepin & Yermanov, 1991).

Quarantine and isolation

Isolation refers to the separation and confinement of subjects already known to be infected by a contagious disease in order to prevent the spread of this disease.

Quarantine refers to the separation of people who have been exposed to any disease, but it is not possible to see any symptom yet (Barbera et al., 2001).

The emergence of biological control systems: biosafety

In 1865, Baron Joseph Lister instituted the practice of antiseptic techniques when working in the surgery room in order to avoid contamination of medical personnel (Madigan, Martinko & Parker, 1999). However, it was not until the mid-twentieth century that preventive standards were established in the United States in medical workplaces, facilities, and laboratories (US Department, 2009). Today renamed biosafety, include the measures containment principles, technologies, and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release (Burnette, 2013).

The emergence of biosecurity practices.

The international community adopted the term biosecurity to refer to any procedure or protocol that aims to control the consequences that arise from all types of biological agents which endanger the health of people, animals, plants and the environment (Burnette, 2013). Since then, the concept of biosecurity has taken on a broader approach which will be discussed in the following chapters.

Biosecurity related specialized agencies

There are several specialized agencies of the United Nations that have taken actions about Biosecurity, such as the World Health Organization (WHO), United Nations Organization for Food and Agriculture (FAO), World Trade Organization. (WTO), the World Bank Organization (WBO), the Codex Alimentary Commission (CAC), the Commission on Phytosanitary Measures (CPM), the World Organization for Animal Health (OIE), International

Maritime Organization (IMO), and International Civil Aviation Organization (ICAO) (FAO, 2007).

Chapter 2.2 Recent examples of biological hazards

The inadequate perception of the biological risks hinders the development of adequate policies by the responsible authorities. The need for proper distribution of resources, the establishment of appropriate practices and procedures, and proper training for personnel are derived from these policies.

The risk assessment is the tool for timely identification of the potential arrival of biohazards in order to diminish their effects (FAO, 2007). There are two cases that exhibit how biological hazards arrived.

Comb jellyfish invasion to the Black Sea and the Caspian Sea.

The scientific name of this invasive species is *Mnemiopsis leidyi*. It is a native species of the western Atlantic (Mianzan 1999). In the last 30 years, this species has expanded to almost all the seas of Europe; the Azov Sea, the Marmara Sea, the Caspian Sea, the North Sea, the Baltic Sea and the eastern and western Mediterranean Sea. However, in the early 1980s, this Jellyfish was accidentally introduced into the Black Sea through the ballast water of ships (Vinogradov et al. 1989).

In most of the invaded areas, it has been described as an invasive species with a high impact on the marine ecosystem, with dramatic effects on the zoo-planktonic and ichthio-planktonic communities; therefore, with significant ecological, social, economic and environmental consequences. (Dumont, Shiganova & Nierman, 2005). The introduction of comb jelly in the Black Sea is considered one of the most dramatic bio-invasions of recent times. In initial absence of predators, chronic overfishing, environmental and eutrophication, the *Mnemiopsis* established and invaded its new environment (Shiganova et al., 2001).

From the Black Sea, the comb jellyfish invade the Caspian Sea. Most likely the invasive species transited via ballast water of ships through the Volga-Don Canal (Bilio & Niermann, 2004). In that sea, its propagation was very fast, reaching its full extent towards the year 2000, and simultaneously observing essential effects on the zooplankton biomass, both in its density and diversity of species (Shiganova et al., 2001). In addition, similar to what happened in the Black Sea, the catch of fish decreased significantly (Kideys 2002).

In the Black Sea case, the invasion was controlled almost naturally by another spontaneous introduction (ballast water) of a new predator called "Beroe cf ovata," which is another type of jellyfish (Dumont, Shiganova & Nierman, 2005).

In this case, the unintentional release of this invasive species had high economical loses affecting fisheries and population. However, biodiversity was the most affected sector, because the comb jellyfish in the Caspian Sea almost made all zooplankton extinct and the latter is the source of the food web.

The absence of adequate biosecurity policies allowed the invasive species to move from the Atlantic Ocean to the Black and Caspian Sea. Due to the high traffic into the Caspian Sea IMO recommended to the Caspian Environment Project that they develop a new management strategy in order to reduce the risk of the new introduction of invasive species (IMO, 2006).

Ebola outbreak during 2014-2016 in West Africa.

This outbreak was the most extensive since the virus was discovered in 1976. About 28,712 people were infected with this disease (WHO, 2019). Despite that this outbreak was efficiently contained, it revealed how easily a biological pathogen can move across borders.

The first case occurred in March 2014 in Guinea. Regional movements established the disease in Liberia and Sierra Leone. Then travelers from the infected region were found in Nigeria, Senegal and United States. A contaminated healthcare professional returned from her volunteer service in Sierra Leone and brought the disease to Spain. The virus spread to almost all of the continents, reaching the United Kingdom in December 2014 (MSCBS, 2016), see figure N°3.

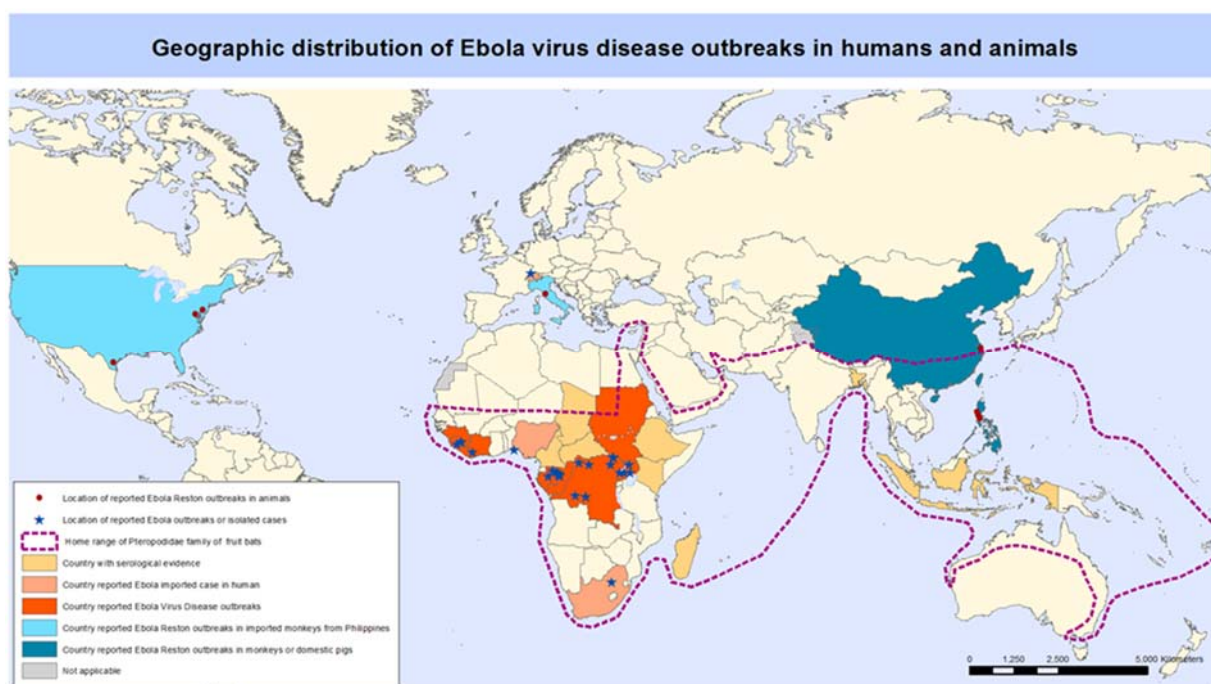


Figure 3, "Ebola outbreak distribution." Source: <http://www.imo.org>

On October 22, 2014, the 3rd meeting of the International Health Regulations (IHR) Emergency Committee declared the Ebola outbreak as a global public health emergency, under the scope of IHR article 12 (WHO, 2014).

However, the committee recommended that there should be no prohibition on trade or international travels. The IMO reinforced this recommendation, indicating to all stakeholders and states parties that they should follow the recommendations issued by the WHO in order not to worsen the economic and labor situation of the affected countries (IMO, 2014a).

IMO published the circular letter No. 3485 on September 10, 2014, for all member states, entitled "Full and effective implementation of maritime protection measures to help prevent the spread of the disease from the Ebola virus." This circular dictates the special measures to increase maritime protection contained in chapter XI-2 of the SOLAS Convention and in the ISPS Code (IMO, 2014b).

On the same day, WHO and IMO jointly sent a letter to all member states, specifically to the ministries responsible for ports and the merchant industry, port authorities, and merchant companies. This letter emphasizes the need to continue promoting free trade and

international travel with affected countries and that all measures taken are only related to the protection of the health of human beings, under the scope of the article 15 of the IHR “temporary recommendations” (WHO/IMO, 2014).

In addition, IMO developed an infographic named “What you need to know” in order to provide information concerning measures that should be taken to prevent contacting the Ebola disease in ports and terminals (see figure 4).

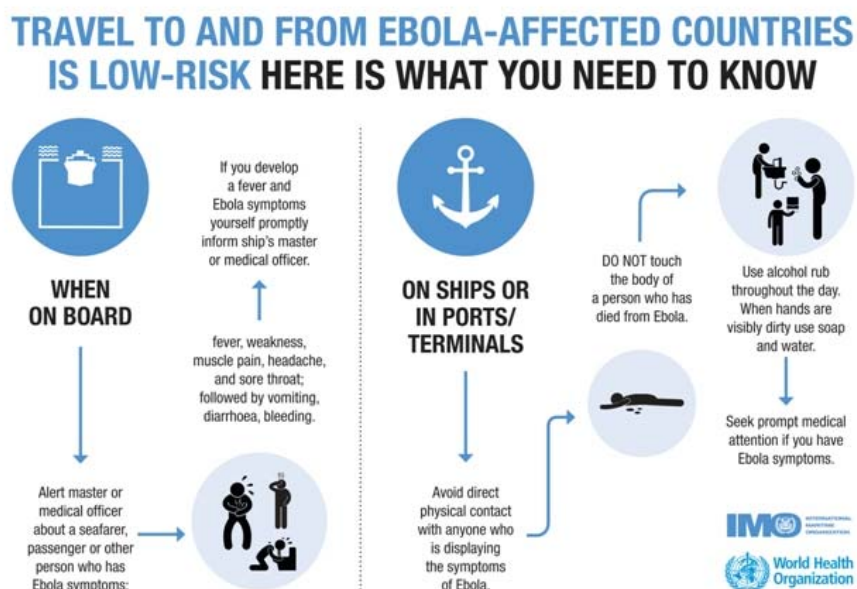


Figure 4, “What you need to know.” Source: <http://www.imo.org> Figure N° 4, “What you need to know.” Source: <http://www.imo.org>

The Ebola outbreak case elucidates the speed and mobility of the biological pathogen across borders. Despite that the virus reaches other continents, the containment of the virus was effective. Coordinated work contained the spread to rest of the world.

An appropriated risk assessment, under the scope of a strong, harmonize and integrated biosecurity policy, could help to prevent (before the hazards arrive), control (when the hazards arrive) and mitigate (after the hazards arrive) unwanted incidents.

Chapter 2.3 Literature review and clarification of Biosecurity concepts

Publications used in the development of this research were found in the library of the World Maritime University, the central library of Copenhagen - Denmark and by using academic search engines.

Although none of the publications used (books and academic articles), explicitly discuss biosecurity in the maritime field. They do however, they mention means of transport in general and physical and economic borders, which the author of this research has used as a link with the topic developed and the international instruments involved with the topic. Likewise, these publications have served as a conceptual guide and backbone during the development of this work.

Biohazards, Biorisk and Biothreat

According to Ryan Burnette (2013), biohazards is the sum of biorisks and biothreats (see figure 5). The differences between the last two are that a biorisk can be assessed because it is something that has already been identified as harmful to humans, animals, and plants health or the environment. While a biothreat is something still unknown that could be harmful too, but the consequences are still unknown; therefore, it cannot be assessed.

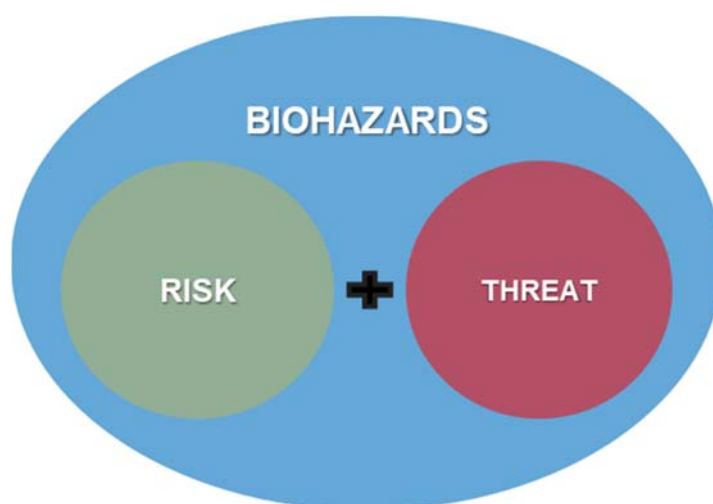


Figure 5, "Biohazards, biorisks & biothreats." Source: "Biosecurity: assessing, and Preventing the threat" (Burnette, 2013).

Biological security or biosecurity

The term biosecurity is relatively new. It arose after the attack of the twin towers in 2001 in the United States, thus reaching the agendas of international organizations (Donaldson, 2008; FAO, 2008; Falk et al., 2011).

The authors of the book "Biosecurity: The Socio-Politics of Invasive Species and Infectious Diseases" coincide with FAO, by defining biosecurity as a "strategic and integrated approach that encompasses the regulatory frameworks (including instruments and activities) for analysis and management of risks related to the life and health of people, animals and plants and the associated risks to the environment" (Barker, Taylor & Dobson, 2013; FAO, 2007).

Importance of Biosecurity in the present world

Reduction of trade barriers, globalization and effective transport at low cost, facilitate cargo and people mobility which increases the biohazards reach and density. (FAO, 2007).

In consequence, biosecurity is essential because the world needs it to build strong capacities, develop adequate measures and encourage the collaboration between the stakeholders in order to protect public health and the environment (Bakanidze, Imnadze & Perkins, 2010).

Areas where biosecurity could be applied

For the purpose of this maritime-focused research, the author considers that biosecurity could be applied in three main sectors:

- The environmental sector, in order to protect the biodiversity and human, animal and plant health because of the controlled and uncontrolled transport of biodiversity and use of biotechnology (UN, 1992; SCBD, 2000). A report shows that 10% of all preventable diseases are due to degradation of the environment (FAO, 2007).
- The health sector, in order to implement consistent policies, operating procedures and technical capacities as required by IHR (Bakanidze, Imnadze & Perkins, 2010). By implementing these requirements, every State can heed these warnings and conduct efficient prevention, control or mitigation of any biological incident.
- The maritime sector, in order to establish measures, protocols, and procedures enabling effective protection of public health, the environment, and the economy and ensuring compliance with international regulations, without undermining free trade, ensuring the safety and security of shipping and port activities (IMO, 2013).

Operationalizing biosecurity concepts

By developing a National biosecurity strategy with the proper policy framework, legal framework, institutional framework, communication and information exchange system, risk analysis and designating the competent authorities, provide technical and scientific capability and infrastructures (FAO, 2007). To improve the national biosecurity capability, it is necessary to enhance cross-sectoral convergence towards biosecurity objectives (FAO, 2007).

Limitations related to biosecurity

The main limitations to the implementation of biosecurity framework are the absence of political will, often related to a conflict of interest or prioritization of other state problems. Another limitation is the sectorial approach and silo thinking (FAO, 2007). Each sector of the state develops its own regulations, objectives, and procedures without taking into consideration those developed by related sectors.

The question is, what can we do as a State to face biohazards? Examples of states that have developed and implemented biosecurity policies in their domestic regulations can be applied (New Zealand, Finland, Australia).

Globalization and biosecurity stakeholders.

The shipping industry is the ideal representation of the globalization of the economies. Therefore, the most interested parties in this sector are all those who have some relationship with economic development (private, public or civil society) (Meyerson & Reaser, 2002). The public players could be the Ministry of Foreign Affairs, finance, production, agriculture, livestock, fisheries, transport, and tourism, among others.

On the other hand, there are all the authorities responsible for ensuring compliance with the laws and security of the States, their inhabitants, and the environment. These could be the Maritime Authority, Port Authority, Police, Customs, Migration, Ministry of Environment, Ministry of Health, among others.

For the proper function of the state body, there must be a close link between all the different authorities, the level of coordination and mutual support must be adequate, focusing on the same objective: the protection of the Nation.

Chapter 2.4 International instruments related to biosecurity

Instrument	Organization	Publication Year	Objective	Description
International Convention for the Prevention of Pollution from Ships (MARPOL)	International Maritime Organization	1973/1978	Aims to minimize pollution of the seas, including dumping, oil and exhaust pollution. Its stated object is "to preserve the marine environment through the complete elimination of pollution by oil and other harmful substances and the minimization of accidental discharge of such substances."	Annex IV: Prevention of pollution by sewage from ships. contains a set of regulations regarding the discharge of sewage into the sea from ships, including regulations regarding the ships' equipment and systems for the control of sewage discharge, the provision of port reception facilities for sewage, and requirements for survey and certification. Annex V: Prevention of pollution by garbage from Ships. to eliminate and reduce the amount of garbage being dumped into the sea from ships. Its terms include all kinds of food, domestic and operational waste that are likely to be disposed of during the normal operation of the ship.
Convention on Biological Diversity (CBD)	United Nations	1992	International legally-binding treaty with three main goals: -conservation of biodiversity -sustainable use of biodiversity -fair and equitable sharing of the benefits arising from the use of genetic resources.	The Convention on Biological Diversity covers biodiversity at all levels: ecosystems, species and genetic resources. It also covers biotechnology, including through the Cartagena Protocol on Biosafety.
Cartagena Protocol on Biosafety	United Nations (Secretariat of CBD)	2000	International agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.	Pharmaceutical products. Procedure for modified living organisms intended for direct use as human or animal food or for processing. Risk assessment. Risk management.
Handbook of the CBD	Secretariat of CBD	2005	Is intended as a reference guide to decisions adopted by the Conference of the Parties (COP) to the Convention on Biological Diversity and the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP).	Include the full CBD and protocol. Rules and procedures for the meetings. Financial rules. Guide to the decisions of the COPs. Status of member participation. Declarations. Nairobi final act. Decisions of the COPs.
International Health Regulations	World Health Organization	2005	International legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO. Their aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.	Definitions. Public health response. Points of entry. Public health measures. Health documentation.
FAO Biosecurity Toolkit	Food and Agriculture Organization	2007	To provide practical guidance and support to develop and implement national biosecurity frameworks at the country level by providing a framework to identify cross cutting biosecurity capacity needs.	Biosecurity principles and components. Guide to assess biosecurity capacity. An overview and framework manual for biosecurity risk analysis.
Nagoya Protocol on Access and Benefit Sharing	Secretariat of CBD	2011	Its aim is the implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.	Response measures. Deadlines and financial limits. Financial guarantees. State responsibilities for international illicit acts. Civil liability.

Instrument	Organization	Publication Year	Objective	Description
Handbook for inspection of ships and issuance of ship sanitation certificates	World Health Organization	2011	Intended to be used as reference material for port health officers, regulators, ship operators and other competent authorities in charge of implementing the IHR (2005) at ports and on ships.	Part A of this document is a reference for pre-inspection planning and administrative arrangements for issuing the Ship Sanitation Control Exemption Certificate or the Ship Sanitation Control Certificate. Part A describes activities that are the responsibility of port health officers, and national or local public health authorities. These activities maintain adequate standards for ship inspection and issue of SSCs. Part B of this document is a template for the inspection and issue of SSCs. It describes the areas to be inspected; the relevant standards that apply; the possible evidence that may be found or sample results that could constitute a public health risk; the documentation that must be reviewed before, during and after the inspection process; and control measures or corrective actions that must be taken. The format of this template follows the IHR model SSC in Annex 3 of the IHR (2005). Part B may also be used as reference material for regulators, ship operators and ship builders, and serve as a checklist for understanding and assessing the potential health impacts of projects involving the design of ships.
Guidelines for the control and management of ships' biofouling to minimize the transfer of invasive aquatic species.	International Maritime Organization	2011	Are intended to provide a globally consistent approach to the management of biofouling, which is the accumulation of various aquatic organisms on ships' hulls.	Invasive aquatic species. Biofouling as a vector for the transfer of invasive aquatic species by ships. Related international regulatory framework. The Biofouling Guidelines. Ship fouling and its management. Additional benefits from managing biofouling.
Vector surveillance and control at ports, airports, and ground crossings	World Health Organization	2016	Provide guidance to Member States on the practical aspects of maintaining sanitary standards at international borders at ports, airports, and ground crossings (points of entry) as set out in the International Health Regulations (2005).	Overview of the IHR legal framework. Purpose and scope, roles and responsibilities. Important vector-borne diseases and target vector species. Surveillance and vector control at points of entry. Emergency measures, monitoring and evaluation.
Handbook for management of public health events on board ships	World Health Organization	2016	This document aims to provide technical advice to competent authorities at the port level for management of public health events on board ships; it complements other WHO publications addressing risk assessment at the national level, contingency planning at ports, and establishment of capacities and application of emergency plans at the port level.	Communications. Event detection. Preliminary standard response at the port. Event risk assessment at the port level. Response measures. Options for health measures.
International Convention for the Control and Management of Ships' Ballast Water and Sediments (BWM)	International Maritime Organization	2017	aims to prevent the spread of harmful aquatic organisms from one region to another, by establishing standards and procedures for the management and control of ships' ballast water and sediments.	Reception facilities. Research and monitoring. Survey, certification and inspection. Technical assistance.
List of ports authorized to issue Ship Sanitation Certificates	World Health Organization	2019 (updated every year)	All States Parties to the IHR 2005 are required to send to the WHO a list of all ports authorized by the State Party to issue Ship Sanitation Certificates.	List of ports with the capacity to receive foreign ships.

Table 2, self-elaboration "International Instruments description." Source: <http://www.un.org>

These regulations will guide the implementation process, dictate guidelines, and establish protocols, in order to encourage the governments to take some measures to protect their country. Biosecurity has a broad spectrum of influence, different international organizations, and different sectors of the state have to deal with it. International regulations must be assimilated and adequate to domestic regulations by each member state, according to their own characteristics in geopolitics, environment, geography, health management, economy, biodiversity, and society.

Chapter 3 Biohazards in the maritime domain

Over the years, international organizations have been fulfilling their normative function in order to establish global standards, consequently order and justice, in safeguard of the interests of the states, their populations, private companies and the environment (U.N., n.d.).

The specialization of each organization set a level playing-field where any external stakeholder can avoid or take short cuts compromising security, safety, and environmental performance (IMO, n.d.). However, there are some issues that exceed the scope of a single international body, so in order to face these issues properly, it is necessary to develop interagency work.

Since biohazards affect different sectors of a State, the development of biosecurity policies lie within these sectors too.

Chapter 3.1 Biosecurity relationship with physical and economic borders

In previous chapters, entry points were referred to as the points of access for biohazards. The borders represent entry and exit gates for almost everything. The borders are usually the best opportunity to discover the best and worst of each country, especially talking about development and security (IDB, 2010). The “legal resources” (authorized import/export) need to travel across borders, but also the “illegal resources” (drugs, smuggling products) that contribute to insecurity. In this sense, the starting point for adequately addressing biohazards is related to the proper management of borders.

By referring to borders not necessarily means physical borders, but rather about economic borders such as airports, railroads, and ports (entry/exit of cargo and people). In the case of this work, we will only refer to ports as maritime economic borders (MEB).

Global interconnection of economies demands stronger control of MEB by the responsible agencies, that means more pressure and stress on the MEB. This control must be efficient so as not to detriment or discourage legal commerce and consequently encourage competitiveness (IDB, 2014).

Competent authorities in the borders

In normal conditions, referring to trade, this responsibility falls on Customs, and referring to the movement of people, this responsibility falls on migration. However, there are hazards related to these activities, whose responsibility goes beyond customs or migration agents. For example, with drug identification, the responsibility lies with the police or coast guard; Identification of infectious pathogens, the responsibility lies with the health authority; invasive species, the responsibility lies on the environmental authority and maritime authority. These examples show that coordination between authorities, joint work, and adequate training is needed.

The objectives of establishing adequate control in the MEB, according to the preceding paragraphs are three (WCO, 2015):

- To ensure the security of the State and its population.
- To improve economic competitiveness and encourage legal trade
- To ensure and strengthen international relations.

The focus of the present research work will be on the first objective, which, in the author's understanding, contributes to the achievement of the other two.

In the case of customs work in the MEB there are several strategies and tools sponsored by the World Customs Organization (WCO), such as the Regulatory Framework for Agile and Secure Trade (SAFE Framework) which entered into force in the year 2005 and the Trade Facilitation Agreement, regulation carried out in coordination with the WTO in 2014. These regulations have their pillars in international collaboration and coordination (customs - customs) and collaboration between governments and companies (customs - private sector) (IDB, 2014). WCO promotes the concept of Coordinated Border Management (CBM), which basically refers to a coordinated approach among all customs agencies worldwide (WCO, 2015).

However, customs agents often lack competencies, jurisdiction, and training to prevent, identify or address the different threats to biosecurity.

Actions on MEB is usually the role of the Health Authority, who implement in entry points (WHO, 2005). Generally, IHR may be complemented by specific international instrument which address hazards that comes from vector and vector-borne, such as malaria, dengue, chikungunya, Zika virus, yellow fever (WHO, 2016).

In conclusion, MEBs are highly vulnerable to biohazards arrival, due to their large extent, high capacity of movement of cargo and their location along the coastlines. Therefore, it is necessary to have means of monitoring and control, as well as a system of appropriate penalties, whether criminal or economic.

Chapter 3.2 Authorities participating in biological control

Each Government possesses numerous entities empowered to implement their requirements. Each administrative organization has responsibilities, scope of actions, functions, jurisdictions, specific regulatory frameworks, competencies and capacities, resources and assigned budgets.

But how such organizations can be connected to enhance the effectiveness of the response to biohazards? What happens if one detects any infraction or hazards that compete or affect other entities? How should it act?

In the following table 3, it is possible to identify which entity may be involved.

Biohazard	Sector involved	Authorities involved	International instruments related	International Organization
Cargo	Ministry of Defense/Transport	Maritime/port authority	SOLAS/IMDG code	IMO
	Ministry of finance	Customs	SAFE Framework Trade Facilitation Agreement IMDG code	WCO/IMO
	Ministry of Internal Affairs	Police	Drug regulations	N/A
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Medical waste	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Pest/vectors	Ministry of Health	International Sanitary Authority	Vector surveillance and control at ports, airports, and ground crossings.	WHO
Crew/passengers	Ministry of Defense/Transport	Maritime/port authority	MLC/STCW	IMO/ILO
	Ministry of Finance	Customs	SAFE Framework. Trade Facilitation Agreement.	WCO
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates. Handbook for management of public health events on board ships.	WHO
	Ministry of Internal Affairs	Migrations	Migratory regulations	N/A
Garbage	Ministry of Defense/Transport	Maritime/port authority	MARPOL annex V	IMO
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates. Vector surveillance and control at ports, airports, and ground crossings.	WHO
	Ministry of Environment	Environmental Authority	CBD & protocol Garbage disposition regulations	SCBD
Sewage	Ministry of Defense/Transport	Maritime/port authority	MARPOL annex IV	IMO
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
	Ministry of Environment	Environmental Authority	CBD & protocol	SCBD
Ballast water	Ministry of Defense/Transport	Maritime/port authority	BWMC	IMO/GESAMP
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
	Ministry of Environment	Environmental Authority	CBD & protocol	
Biofouling	Ministry of Defense/Transport	Maritime/port authority	Biofouling Guidelines -resolution MEPC.207/62	GEF/UNDP/IMO
	Ministry of Health	International Sanitary Authority	IHR. Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
	Ministry of Environment	Environmental Authority	CBD & protocol	SCBD

Table 3, self-elaboration "Ships biohazards sources."

Ballast water and biofouling challenges

Of the several existing ways to transport invasive species in the marine environment, the shipping industry has been identified as the most harmful (Hewitt, Campbell, Thresher & Martin 1999; Gollasch, 2002). Due to the small size of aquatic microorganisms and their high density in ballast water bodies (Carlton, 1985; Olenin, Gollasch, Jonusas & Rimkute 2000; Taylor et al. 2007) or biofouling attached in the hull of ships (Lewis, Hewitt, Riddle & McMinn 2003; Coutts & Taylor, 2004), their transport and introduction into other ecosystems are effortless, while their control is a bit more complicated. Therefore, the accidental risk of the release of Harmful Aquatic Organisms and Pathogens multiplies exponentially, especially in ports (Carlton 1996; Floerl & Inglis I. 2005).

Both ballast water and biofouling represent significant challenges for the maritime community. Because regulations and instruments are recent. Technology, protocols, and procedures require further validation on a long-term basis. For example, the determination of representative sampling and the detail of sample analysis remains challenging in the context of Ballast Water Management Convention (BWMC).

Biofouling is complex to address because it represents technical, scientific, environmental and economic challenges (UNDP, 2019). The Glofouling initiative with the collaboration of the Global Environment Facility (GEF), the United Nations Development Program (UNDP), and the IMO, work together to identify solutions.

The project consists of carrying out awareness campaigns aimed at all economic sectors linked to the sea, including recreational navigation, through a “global alliance of industries” (UNDP, 2019). However, on the side of technological development, nothing has been found yet that exceeds former results provided by antifouling paint systems (Chiavarini, Ubaldi & Cannarsa, 2014).

To summarize, different authorities are involved in the biosecurity regime of any country which requires appropriate levels of coordination.

Chapter 3.3 The relevance of Biosecurity approach promoted by FAO

The maritime sector is moving from a purely reactive (e.g., Titanic and SOLAS) to a more proactive and preventive sector. Although there is still a long way to go, some examples such as Polar Code or the Goal-based ship construction standard open possibilities.

The development of preventive measures is required in order to develop a suitable risk analysis. The risk analysis consists of three distinct but closely related components: risk assessment, risk management and risk communication (FAO, 2007).

The risk assessment for biosecurity means conducting a scientific process through which you can estimate the risks to life and health, biodiversity, and the environment (FAO, 2007). But how can risks be assessed if each authority has a different perception of them? With a harmonized and integrated policy.

The risk management is the decision-making process in an environment of uncertainty. For this, the information collected during the risk assessment is used as well as socially determined measures (FAO, 2007).

The risk communication is the exchange in real-time, of the information obtained and processed in the two previous components, between the people responsible for taking measures before the possible biohazard that they are going to or could possibly face (FAO, 2007).

FAO biosecurity approaches

FAO indicates in its toolkit (2007) that there are two types of biosecurity approaches, traditional and integrated:

The traditional approach gives priority to sectorial biosecurity management which means that each sector of the state (health, environment, defense, fisheries, agriculture, livestock, homeland security, among others) develop their own regulations, protocols, and procedures separately, focusing on achieving their own goals (FAO, 2007). Such an approach may disconnect each sector if no exchange mechanisms are put in place.

The integrated approach promotes a harmonized and integrated multidisciplinary way to work, where under a single national legislation, each sector of the state is assigned functions, responsibilities, and jurisdiction, in order to achieve all the objectives that are common to all the sectors (FAO, 2007).

Due to the constant growth of biohazards, FAO encourages the development of integrative and harmonized policies.

Although FAO invites states to develop a harmonized approach to address biohazards, it will be up to the State to choose which approach is more suitable to their national context (e.g., economic, geopolitics, society, legislation, technological and scientific capacity). Some national organizations can be seen in table 4 and appendices 2 to 5.

Country	Approach	Competent Authority/Authorities	Year of establishment	Responsibilities
Australia	integrated	Department of Agriculture, Fisheries & Forestry (DAFF)	2013	<ul style="list-style-type: none"> To develop and implement policies and programs to ensure Australia's agricultural, fisheries, food and forestry industries remain competitive, profitable and sustainable, and supports the sustainable and productive management and use of rivers and water resources.
Finland	integrated	Finish Food Authority (EVIRA)	2019	<ul style="list-style-type: none"> To predict, preventing and managing risks related to food. To predict, preventing and managing the risks related to plant health and agricultural production. To promote animal health and welfare.
New Zealand	integrated	Ministry for Primary Industry (MPI)	2004	<ul style="list-style-type: none"> Biosecurity New Zealand's focus is on stopping pests and diseases at the border, before they get to New Zealand, and eradicating or managing the impact of those already here. With the help of New Zealanders, they ensure their unique environments and the value of their primary industries are maintained.
United Kingdom	traditional	Department for Environment Food & Rural Affairs (DEFRA). Civil Contingencies Secretariat (CCS). Department of Health and Social Care (DHSC). Department for International Development (DFID). Ministry of Defense (MOD)...et al.	2018	<ul style="list-style-type: none"> Understand the biological risks that we face today and could face in the future. Prevent biological risks from emerging (where possible) or from threatening the UK and UK interests. Detect, characterize and report biological risks when they do emerge as early and reliably as possible. Respond to biological risks that have reached the UK or UK interests to lessen their impact and allow the rapid return to business as usual.

Table 4, self-elaboration. Source: "Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases." (Barker, Taylor & Dobson, 2013)

To be a feasible process, some requirements must be set, regardless of the approach chosen:

- To establish clear national policies with appropriate objectives which facilitate the opportune assessment of the risks that affect biosecurity.
- Effective legal framework, which provides support to the authorities responsible for ensuring the security of the nation and compliance with the corresponding regulations, always respecting the rule of law.
- A clear institutional framework is needed to identify competent authorities and their respective responsibilities.
- Communications and the exchange of information between the parties involved, including the private sector.
- Infrastructure, technical and scientific capacity support risk assessment (FAO, 2007).

Chapter 3.4 Biosecurity framework of actions

Current biosecurity practices require the implementation of preventive measures as in the past (e.g., Ragusa port restrictions) (Gensini, Yacoub & Conti, 2004).

According to Barker, Taylor, and Dobson (2013), a way of understanding where and on who the responsibilities about biosecurity lie, is by defining the place where the strategies, protocols, and procedures should be applied.

Any biosecurity strategy requires the implementation of measures at pre-entry or pre-border (prevention), point of entry or border (control and inspection), and post-entry or post-border (mitigation, monitoring, and protection) (Barker, Taylor & Dobson, 2013).

Following the literature and practice of certain countries (e.g., Australia), the author of this research work deems this three-stage approach to be suitable for maritime needs. MEB represent the entry/border to develop and implement pre-arrival, at arrival and post-arrival measures. In the case of Peruvian inspections process will be easier to assign responsibilities, functions, and jurisdictions to the competent authorities because there is already some technological tools in place, such as single windows, which will allow handling of all information needed and communication exchange between authorities.

Chapter 3.4.1 Pre-arrival.

This stage starts from the previous port where the ship loaded its goods or/and embarked passengers. It represents the first challenge for all biosecurity systems as accurate data must be provided by the ship in order for the authorities to be able to identify the risks prior to ship arrival and implement preventive measures. At this stage, biohazard begins its journey.

Some type of goods that may affect the biosecurity of the visited country must be previously declared, such as fruits, unwashed clothes, or shoes. There is also some kind of discomfort or illness that must be monitored, among other things (WHO, 2005).

However, local authorities must be cautious not to interfere with commercial activities unnecessarily. Any implementation in biosecurity systems should not be restrictive to international trade (Barker, Taylor & Dobson, 2013). At this point WTO plays an important role, being the trade regulatory body and resolving conflicts that may exist within the framework of its competences, without affecting the sovereignty of the states and their national security rules.

Chapter 3.4.2 At-arrival.

In this stage, the necessary inspections are carried out on people, luggage, cargo, and the ship, including all its systems and subsystems, in order to identify any biological hazards that can be introduced intentionally or unintentionally (Barker, Taylor & Dobson, 2013).

It is a critical stage and requires a lot of training and professionalism from the responsible authorities in addition to do a proper risk assessment (Barker, Taylor & Dobson, 2013). At this stage, potential biohazards should be identified if there are any.

If any type of biohazards is detected during this stage, all biosecurity services established for this purpose should be deployed immediately (WHO, 2005).

Chapter 3.4.3 Post-arrival.

This stage consists of following up on the potential biological hazards once the MEB is crossed. Indeed, many hazards may not have been seen or identified previously, such as the case of invasive species (WHO, 2005).

Monitoring and alert systems have to be developed and implemented with the support of authorities but also universities, research centers, and ordinary citizens (Barker, Taylor & Dobson, 2013). At this stage, authorities should deal with potential biohazards.

The involvement of citizens will facilitate early detection and continuous monitoring at a reasonable cost. Education and dissemination of the information play a vital role in the country's biosecurity strategy. For example, in the United Kingdom, fishermen perform the function of collecting seawater samples, becoming a powerful tool for massive data collection (Kinver, 2015).

Using the definitions of each of the three stages previously described, the author of this research elaborated figure 6.

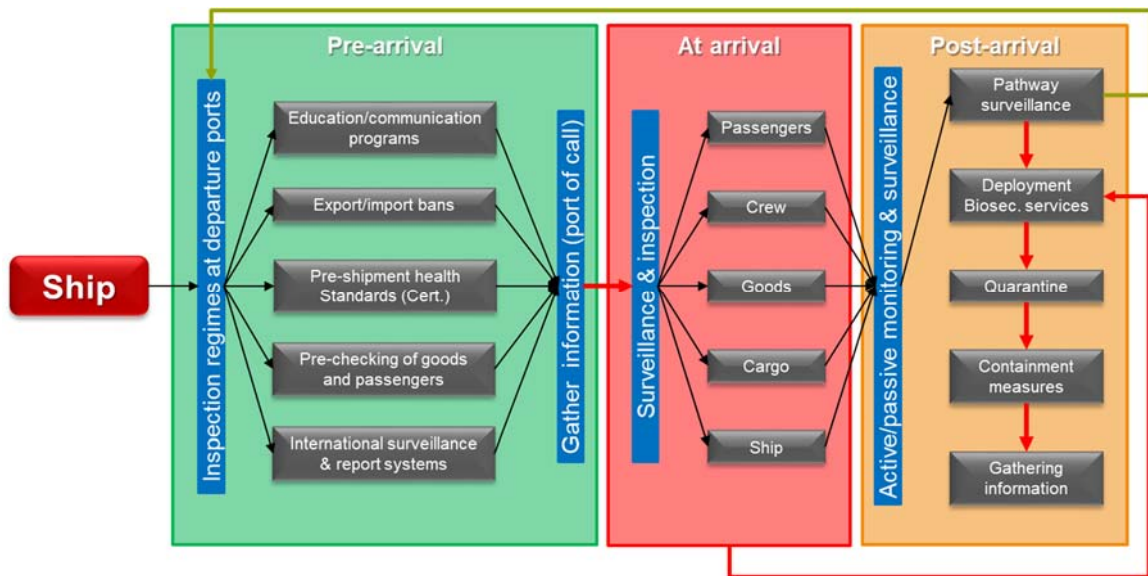


Figure 6, Self-elaboration "Biosecurity framework of actions." Source: the book "Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases."

This framework of actions for biosecurity must be reinforced through trust between different states. The use of the same international standards generates confidence between States. This trust will be reflected through bilateral or multilateral agreements. However, this does not mean that you should take down your guard against potential biological hazards but instead turn it into a global strategy through these agreements.

Chapter 3.5 Biosecurity approaches SWOT analysis.

<p style="text-align: center;"><u>TRADITIONAL APPROACH</u> <u>(sectoral)</u></p>	<p style="text-align: center;">STRENGTHS</p>	<p style="text-align: center;">WEAKNESSES</p>
		<ul style="list-style-type: none"> • Strong organizational structure. • Highly trained & specialized workers. • Easy monitoring of their own functions. • Good internal communication. • Clear internal hierarchy levels. • Well established institutional framework. • Infrastructure already in place.
<p style="text-align: center;">OPPORTUNITIES</p>	<p style="text-align: center;">POSSIBILITIES SO</p>	<p style="text-align: center;">POSSIBILITIES WO</p>
<ul style="list-style-type: none"> • Willingness of some authorities and particulars to collaborate. • Improve the organizational structures, planning & execution process. • The commitment of the political body. • To educate inhabitants in order to contribute to national protection. • To involve the whole nation in the mitigation of the biological hazards. • To cover some expenses generated due to biosecurity operations, by using a sanctions & penalties system (who made the damage pay). 	<ul style="list-style-type: none"> • To develop national educative programs, in order to involve all inhabitants, organizations & companies in the process. • To improve the monitoring system by involving other organizations. • To develop a joint training program. • To promote periodical report meetings with all stakeholders (governmental & private sector). • To develop a proper policy framework. 	<ul style="list-style-type: none"> • To develop strong and complementary regulations. • To establish a sanction & penalty system. • To create a multisectoral teamwork in order to assess the risks, share knowledge & elaborate joint plans. • To create a national fund to support biosecurity operations. • To delimitate jurisdiction, responsibilities & functions between organizations. • To establish accurate communication channels & data exchange systems.
<p style="text-align: center;">THREATS</p>	<p style="text-align: center;">CHALLENGES ST</p>	<p style="text-align: center;">CHALLENGES WT</p>
<ul style="list-style-type: none"> • Continued growth of shipping industry & biological hazards. • The plan usually is done in the most likely scenario. • No on-time communication of the biological hazards to other authorities. • Insufficient logistic support. • Insufficient authorities budget to face the problem. • Conventional workers are not involved with the objectives. • Risks assessment is only focus in their area (blindness of other sectors). • Professional zeal conduct to hide information. • Corruption. 	<ul style="list-style-type: none"> • To assign budget in accordance of the achievements. • To integrate all the national resources in one national contingency plan. • To develop a proper institutional framework. • To develop joint protocols & procedures. 	<ul style="list-style-type: none"> • To commit the workers with the objectives. • To develop a culture of collaboration between authorities. • To develop a proper legal framework. • Automation of some processes to reduce bureaucracy & eliminate corruption.

Table 5, self-elaboration, "Traditional Approach SWOT analysis." Source: "Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases." (Barker, Taylor & Dobson, 2013)

<u>INTEGRATED APPROACH</u> <u>(cross-sectoral / integrated)</u>	STRENGTHS	WEAKNESSES
	<ul style="list-style-type: none"> • Clear policy, legal & institutional framework. • All organizations work to reach common objectives. • Well-defined jurisdiction, responsibilities & functions. • Well-defined competent authorities. • Clear channels of communications and coordination between different organizations and easy access. • Participation of all state sector, including private & NGOs. • Same national contingency plan for all organizations. • Highly trained, committed & specialized workers. • All organization participate in risk assessment process. • Common data collection & exchange of information system. • Broad geographical coverage (National, regional & local). • Focus on both process (quality) & results (quantity). 	<ul style="list-style-type: none"> • Insufficient financial and technical resources. • Poor collaboration culture between competent authorities. • Local & national priorities could be different. • To many authorities, NGOs & private companies dealing with the same hazard.
OPPORTUNITIES	POSSIBILITIES SO	POSSIBILITIES WO
<ul style="list-style-type: none"> • Interdisciplinary nature of biosecurity promotes synergies & complementarities in organizations daily work. • Higher levels of public participation in the biosecurity system. • Avoid budget redundancy, better use of economic resources. • Involvement of the workers in all the process. • Simplification of national regulations. • Rationalization of controls & technical capabilities. • Privatization of some biosecurity services. • To reduce bureaucratic barriers. 	<ul style="list-style-type: none"> • To enhance international trade. • To improve the protection of the public health, agriculture, livestock & environment. • To protect the national economy. • To improve sanitary measures. • To increase the scope of biosecurity systems. • To develop a proper risk assessment with periodical updates. • To develop trust between industries & the government. • To enhance the ability to achieve national biosecurity objectives. • To develop a national integrated response to biosecurity problems. 	<ul style="list-style-type: none"> • To assign a sufficient budget in order to increase technical capabilities. • To provide cost-efficient government services. • To develop a culture of collaboration between authorities. • To promote national wide access to biosecurity information. • To develop a strong monitoring & surveillance system. • To develop a harmonized certification system.
THREATS	CHALLENGES ST	CHALLENGES WT
<ul style="list-style-type: none"> • Continued growth of shipping industry & biological hazards. • Absence of professionals in the sector. • Professional zeal conduct to hide information. • Corruption. • High initial investment & operational budget. • Lack of national fund to sustain biosecurity operations. 	<ul style="list-style-type: none"> • To cope all economical borders. • To develop new international strategic alliances (bilateral or multilateral agreements). • To increase the identification capacity of biological hazards. • To improve public awareness related to biological hazards. • To map all biological hazard pathways. 	<ul style="list-style-type: none"> • To share knowledge between authorities. • To develop new organizational controls. • To delegate some biosecurity functions to privates. • To promote capacity building according to international perspective.

Table 6, self-elaboration, "Integrated Approach SWOT analysis." Source: "Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases." (Barker, Taylor & Dobson, 2013)

The development of these matrices were carried out for the author after the analysis of the concepts, theories, and affirmations extracted from the books and publications used during this research, which are included in the literature review.

Chapter 4 Biosecurity in Peru.

The first question that must be answered in this chapter is why is it essential to consider National policies related to biosecurity in the Peruvian maritime sector? As already mentioned in Chapter 2, it is crucial to have these policies due to the negative impact on human and animal health, biodiversity and the national economy (Barker, Taylor & Dobson, 2013).

Peru has had several dramatic episodes to face such as the 1991 Cholera outbreak and several reported invasions.

Among the effects, invasive species produce on natural ecosystems are the introduction of diseases, changes in the composition of biological communities, and the displacement of local species by competition and predation (Davis, 2009).

The case of the microalgae *Dydimosphenia geminata* impacts freshwater aquatic ecosystems such as rivers and lakes where it has been introduced (southern Peru). This species has a high reproduction rate that allows it to form extensive blooms, which makes it not only an invasive species but also harmful to the ecosystem (Spaulding & Elwell, 2007). The case of rainbow trout is also emblematic of uncontrolled invasion in water systems.

Being an exporting and importing country, Peru is highly exposed to the introduction of harmful aquatic organisms and pathogens. In addition, the country is vulnerable mainly because of its dependence on the fishing sector - 7% of Peruvian exports (SNP, 2019), and each citizen consumes approximately 14.5 kilograms of fish per year (PRODUCE, 2018), and tourism, one of the most visited countries in South America (MINCETUR, 2019).

In that sense, a biosecurity gap could lead to losses of life, irreparable damage to biodiversity, and a significant economic crisis.

Finally, the 1991 "Cholera outbreak" is by its own a clear justification for enhanced maritime biosecurity considerations.

Chapter 4.1 1991 cholera outbreak response

In a report, the WHO indicates that around 100 outbreaks of diseases in the world are associated with trade through ships between 1970 and 2003 (Rooney et al., 2004).

The cholera epidemic of 1991 in Peru was the result of the extension of the seventh pandemic initiated in the Celebes (Sulawesi) in 1961, which reached North to Korea, West to Africa and South Europe (Maguiña, Seas, Galán & Santana, 2010). The first recorded case occurred in the fishing port of Chancay located 60 km north of Lima (Petrera, 1993). The source of the pathogen originates from a country around the Indian Ocean (Maguiña, Seas, Galán & Santana, 2010). The bacteria may have traveled with ballast water, biofouling, or sewage.

The primary carrier of cholera bacteria is the human being; however, it also can be found in phytoplankton and zooplankton in saline and fresh waters (Borroto, 1997).

Almost at the same time as cholera appeared in Chancay, there was a significant increase in the number of adults treated for diarrhea in Chimbote (Ancash), another important port in Peru. The disease followed the route from south to north (Maguiña, Seas, Galán & Santana, 2010), and then spread throughout Peru and America (see figure 7).

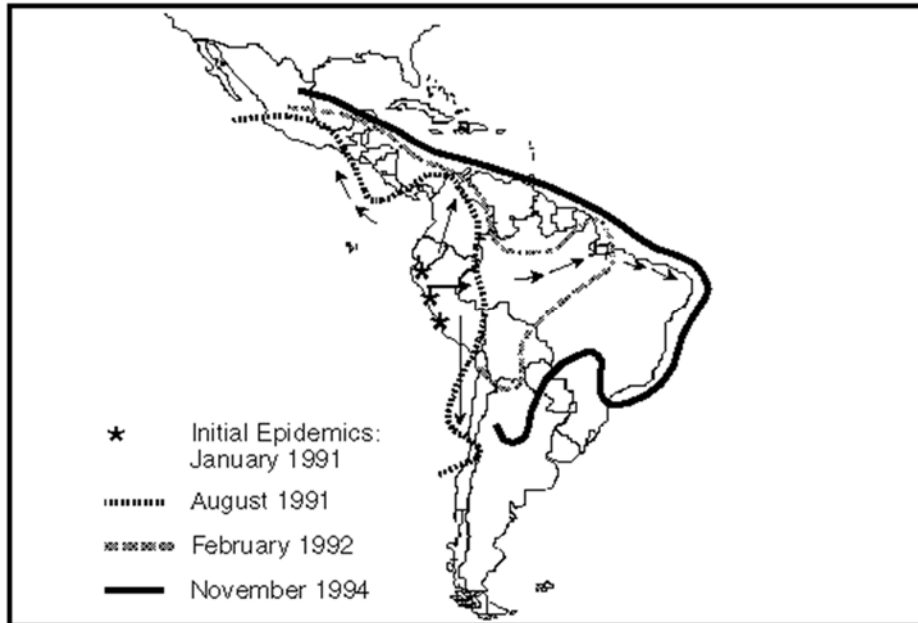


Figure 7, Spread of Cholera bacteria in America. Source: <https://www.cdc.gov>

At the V Pan American Congress of Infectology, held in Lima, the Health National Institute (HNI) reported about the isolation of cholera bacteria in fish, shellfish and phytoplankton and zooplankton, in areas near the water collectors along the coast (Carrillo, 1991).

Biosecurity procedures in 1991.

In 1991, when a ship came from a foreign port, it had to submit all the relevant documentation to the local Harbor Master. This documentation was presented between 3 to 1 days before arrival, depending on the type of cargo of the ship, having the corresponding authorities to review it, analyze it and prepare for the reception of the ship (Congress, 1996). These are the basics of a pre-arrival risk assessment. It can be assumed that the documentation analysis did not show any sign of diseases on board.

The ship's reception committee was chaired by the MA and included the HA, customs, and migrations (Congress, 1996). If this was a fishing vessel and did not enter the port, it was not received. However, to carry out its fishing operations in Peruvian waters, the ship must hold a navigation permit granted by the MA, prior inspection at its port of origin (safety of navigation, International Oil Pollution Prevention Certificate and sewage) (President, 2005) and permission of fishing, granted by the Ministry of Production, prior payment of fees and presentation of documentation (PRODUCE, 2018).

In 1991 the BWM convention was not yet into force, nor the Biofouling guidelines existed, and Peru only had ratified the MARPOL annexes I, II and V. In the health sector IHR of 1969 was not precise in the procedures, and FAO Biosecurity toolkit did not exist.

Therefore, insufficient development of national maritime regulations and procedures, added to the socio-political situation in Peru around those years diverted the attention of the state apparatus towards what they considered as a priority for the government at that time (internal conflicts), leaving the maritime field vulnerable.

As the biological threat and its origin could not be established in a timely manner, its precise source was not identified. However, it is inevitable that the bacteria arrived by sea (McCarthy & Khambathy, 1994). Between 1991 and 1992, several studies of the non-potable

waters (ballast, sewage, and bilge) of ships that arrived on the Gulf of Mexico in the United States were conducted. The Cholera bacteria with the same biochemical characteristics were found on ships coming from ports around the Indian Ocean (McCarthy & Khambathy, 1994).

The measures were taken once the bacteria was in Peru which aimed to protect the population. To achieve these objectives, a large-scale campaign of oral rehydration was carried out. A dissemination and education campaign about preventive measures was also carried out (Maguiña, Seas, Galán & Santana, 2010). These activities only involved the Ministry of Health, with the support of the Ministry of Education, local governments and all media (see figure 8).



Figure 8, Infographic “Kill cholera before the Cholera kill you.” Source: www.minsa.gob.pe

It can be affirmed that the measures taken “post-arrival” were protective but reactive. It entailed mainly of containment and succeeded to control the spread. Even so, this disease generated 321,334 cases in 1991 only (See table 7) and economic losses of around US \$ 489,424 million for the Peruvian state (Petra & Montoya, 1993).

Country	Total population	Total cases	Incidence (*100,000)	Mortality rate (*100,000)	Global lethality rate	Last report date
Peru	22,002,856	321,334	1,460.42	13.21	0.9	28-Dec-91
Ecuador	9,622,700	44,126	458.56	6.98	1.52	14-Dec-91
Colombia	31,997,520	11,218	35.06	0.63	1.8	14-Dec-91
USA	251,400,000	24	0.01	0	0	13-Dec-91
Brasil	141,500,000	937	0.66	0.01	2.13	21-Dec-91
Chile	12,400,000	41	0.33	0.02	4.88	5-Jan-92
Mexico	81,900,000	2,605	3.18	0.04	1.31	14-Dec-91
Guatemala	8,400,000	3,530	42.02	0.56	1.33	21-Dec-91
El Salvador	5,300,000	921	17.38	0.64	3.69	21-Dec-91
Bolivia	8,000,000	175	2.19	0.15	6.86	23-Dec-91
Panama	2,300,000	1,177	51.17	1.26	2.46	28-Dec-91
Honduras	4,700,000	11	0.23	0	0	25-Dec-91
Venezuela	18,800,000	13	0.07	0.01	15.38	27-Dec-91
Nicaragua	3,500,000	11	0.31	0	0	28-Dec-91
TOTAL	601,823,076	386,123	64.14	0.65	1.01	

Table 7, Epidemiological information of cholera in America, 1991. Source: www.who.org

In summary, the main routes of transmission had been contaminated water, the inadequate preparation of food, including the intake of shellfish and raw fish (Brandling, Libel & Migliónico, n.d.).

At the pre-arrival stage, no adequate information was collected, enabling risk assessment, and thus developing preventive measures.

In the arrival stage during the reception and dispatch of the ship, no irregularity was identified because the ship received the corresponding free practice and departure authorization. There is no record in the MA files that indicates any negative incident onboard (archives of the Captancy of Puerto del Callao in Peru).

In the post-arrival stage, what was done was to decrease the mortality rate and prevent the spread of the bacteria (see figure 9).

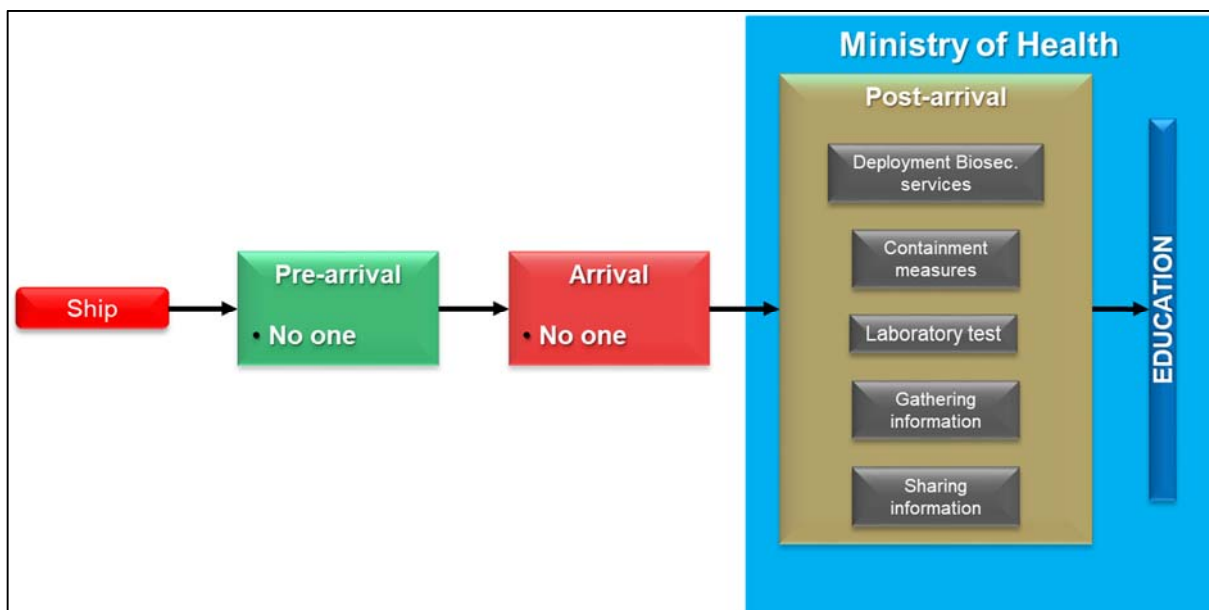


Figure 9, Self-elaboration "Strategy used during the Cholera outbreak." Source: Cholera History (Maguiña, Seas, Galán & Santana, 2010).

Chapter 4.2 Distribution of regulations and competent authorities

During this research, it was possible to identify three sectors (See figure 10) linked with the Peruvian biosecurity regime:

- The environmental sector, which mainly focuses on protecting, human, animal, and plant health, and environment but more related to food safety and invasive species.
- Health sector, which focuses on protecting the health of the inhabitants.
- Maritime sector, which also seeks to protect the health of the inhabitants and the environment.

The health sector supports the other two sectors but not vice versa (no documented evidence was found). However, every sector has developed its own regulations that, in many cases overlap responsibilities, create redundancy of efforts or even generate biosecurity gaps.

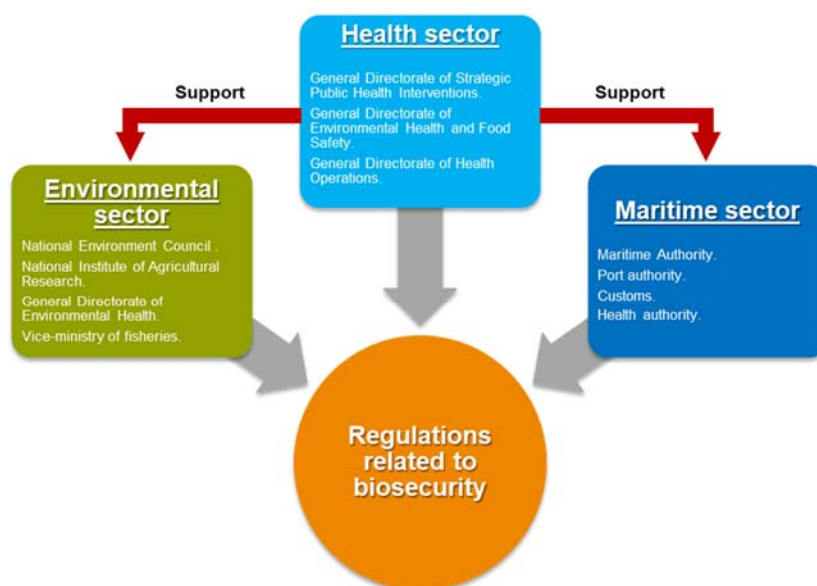


Figure 10, self-elaboration. "Sectors with regulations related to biosecurity." Sources: Peruvian domestic regulations. (Law N° 28611; Law N° 26842; D.L. N° 1147).

Chapter 4.2.1 Distribution of regulations and competent authorities in the environmental sector.

The Political Constitution of Peru (1993), in its title III "Economic Regime," and chapter II, "Environment and natural resources," articles 67 and 68, establishes the legal framework for environmental and natural resources issues:

Article 67 The State determines the national environmental policy. Promotes sustainable use of natural resources.

Article 68 The State is obliged to promote the conservation of biological diversity and protected natural areas.

In May 2008, the Ministry of Environment (Legislative Decree D.L. N° 1013) was created and in compliance with article 67 of the Political Constitution of Peru, on May 22, 2009, Supreme Decree DS-012-2009-MINAM the National Environmental Policy (see appendix 6) was approved.

With these National Scope regulations, the government set the starting point for the development of further environmental regulations. However, these regulations still remain too broad in scope. The National Environmental Policy, state that all competent authorities shall take actions regarding the protection of the environment and biodiversity, but who are the competent authorities?

This means that any authority that feels it has competences in accordance with this national policy can develop its own institutional regulations, which creates disorder and confusion of the objectives and responsibilities.

National Environment Council (CONAM)

The National Environmental Council (CONAM), is the National Environmental Authority of Peru and governing body of the National Environmental Management System, and the focal point between SCBD and the national bodies, it is also responsible for promoting, adequate and implement international instruments into domestic legislation (Laws No. 28245 and No. 28611 - see appendix 7). Its institutional mission is to promote sustainable development, promoting the balance between economic growth, social welfare, and environmental protection. It constitutes a decentralized public body attached to the scope of the Presidency of the Council of Ministers.

To meet its objectives, CONAM coordinates the design and application of the National Environmental Policy with all State institutions, including those of the national, regional and local levels of government, encouraging the participation of the private sector and civil society.

In order to adequately fulfill the international commitments assumed (CBD and Its protocol), CONAM has developed an environmental policy and management instruments, which must promote the system of environmental control, monitoring, and surveillance, economic and financial instruments.

Law on Prevention of Risks Derived from the use of Biotechnology – N° 27104.

This law has the following objectives: to protect human health, the environment and biological diversity; promote safety in research and development of biotechnology; regulate, manage and control the risks arising from the confined use and release of LMOs; and, regulate the exchange and commercialization of LMOs, both within the country and with the rest of the world.

Subsequently, on October 28, 2002, through the Supreme Decree D.S. N°108-2002-PCM, its Statute was approved. This document establishes as competent Sector Authorities (CSA): The National Agricultural Research Institute (INIA) for the agriculture sector, today INIEA; Vice Ministry of Fisheries of PRODUCE for fishing sector and the General Directorate of Environmental Health (DIGESA) for the health sector.

This regulation indicates that it is the function of CSAs to comply with and enforce the provisions related to biosecurity and biotechnology established in the Convention on Biological Diversity, Law N° 27104, its statute and other national or international complementary provisions related to the subject. The CONAM is the instance of transectoral coordination and the focal point for the Cartagena Protocol on biosecurity and for the Information Exchange Center (Biosafety Clearing House).

National Institute of Agricultural Research and Extension (INIEA). Competent Sector Authority related to Agriculture.

This authority established the Internal regulations for the development of activities on LMOs or their derived products of agricultural origin. The Regulation has as a general objective to regulate activities to guarantee the safety of biotechnology in relation to agricultural LMOs and their derived products.

INIEA should be the authority responsible for ensuring food safety of the exported product, generating trust in the importer country. The certification granted by INEA is the start point to avoid biohazards shipment to another country.

**General Directorate of Environmental Health (DIGESA).
Competent Sector Authority related to Health.**

This authority, which belongs to the Ministry of Health, developed the internal biosecurity regulation for the development of activities with products derived from LMOs for human consumption. The regulation has as a general objective to regulate the activities to guarantee the safety of biotechnology in products derived from LMOs for human consumption, according to the existing legal framework for this.

The directorate also indicates that the risk analysis will be carried out on a case-by-case basis for each product derived from LMOs. The transport and packaging of products derived from LMOs destined for human consumption of national production or import matter will also be carried out in accordance with the provisions that emanate from the risk analysis.

DIGESA has as an additional function through the Directorate of Metaxhenic Diseases and Zoonoses (one of its STGs). It is responsible for identifying and coordinating the strategic interventions for prevention, control, and reduction of risks and damages caused by vector-borne diseases (Metaxhenic) and contagious diseases from animals to humans (zoonoses).

**Ministry of Production, Vice Ministry of Fisheries.
Competent Sector Authority related to fisheries.**

This authority developed the internal biosecurity regulation for the development of activities on LMOs of hydro-biological origin. The general objective of the regulation is to establish biosecurity procedures to regulate the development of generation, research, pilot-level use, production, marketing education, confined use, storage, transportation, import, transit, disposal, and any other use or handling of LMOs, guaranteeing the safe use of Modern Biotechnology.

The Institute of the Sea of Peru (IMARPE) is a Specialized Technical Organization of the Ministry of Production and is part of the Sector Technical Group (STG) of the Vice-Ministry of Fisheries.

IMARPE oriented its scientific research to study the Peruvian sea and its resources, to advise the State in making decisions regarding the rational use of fishery resources and conservation of the marine environment, actively contributing to the development of the country. Under this approach, IMARPE investigates the relationship between fishery resources, the environment, and fishing activity. The aim is to provide advice related to management of resources and the marine environment, in respect to sustainable development, marine biodiversity preservation, environmental protection, and responsible fishing.

In addition, CONAM has four support bodies, whose functions are to advise on the development of instruments and their implementation. These bodies are National Commission of Biological Diversity (CONADIB), National Advisory Commission of Biosecurity (CONABIOS), National Biosecurity Structural Framework Support Projects, and Technical Committee for Biosecurity Standardization in Living Modified Organisms (CTN-BOVM-INDECOPI). See figure 11.

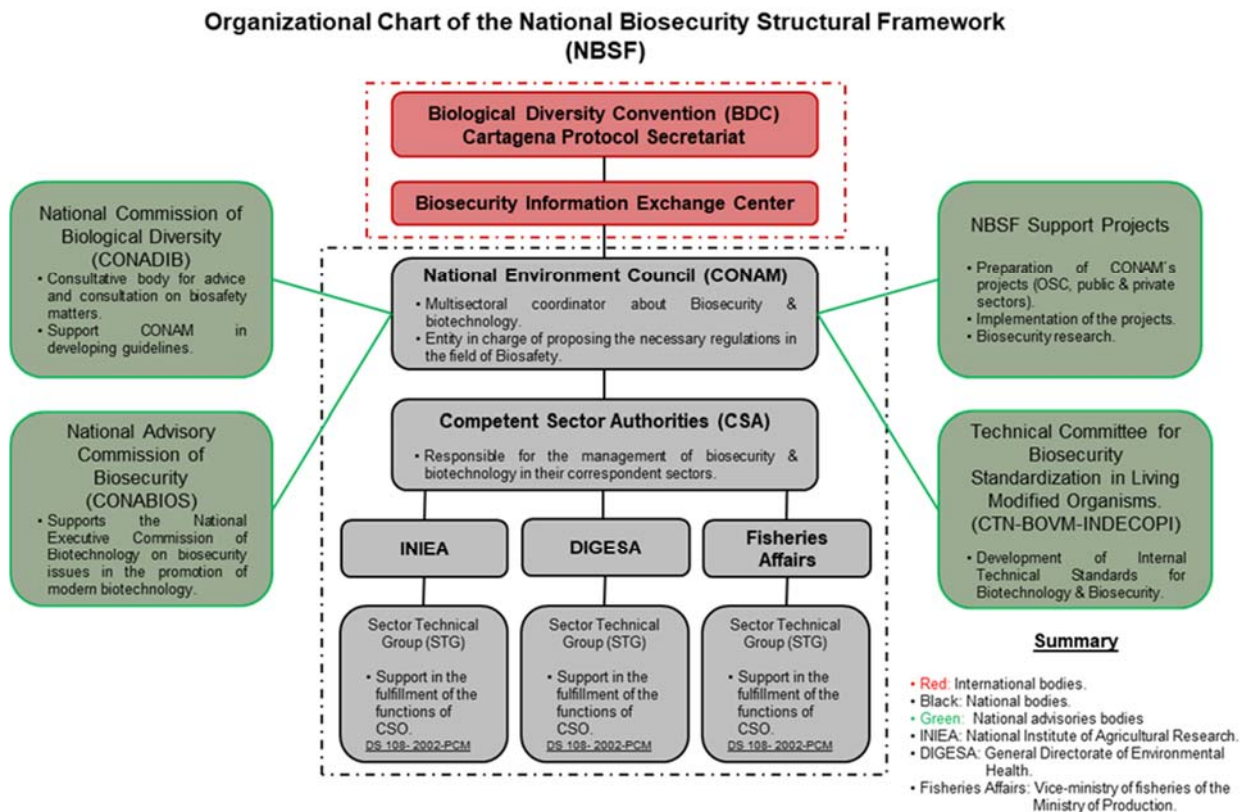


Figure 11, Organizational Chart of the National Biosecurity Structural Framework. Source: National Environment Council

Chapter 4.2.2 Distribution of regulations and competent authorities in the Health sector.

Social protection of health is a non-delegable responsibility of the State, and it is its duty to determine the national health policy (Congreso, 1993). For this, the HA must exercise vigorous leadership in the government and the strategic management of health in the maritime sector. In this sense, HA must have control of risks and associated diseases and execute the corresponding sanitary and epidemiological surveillance.

General law of health – Law N° 26842.

According to this law, the Ministry of Health is the National Health Authority, and the Regional Governments acts as Regional Health Authority - RHA (Congreso, 1997).

In Title III, Chapter IV, Article 82 to 86, this law indicates that the HA will exercise National and International control of communicable diseases in accordance with national regulations and international regulations ratified by the State, such as IHR and all related instruments. The implementation and control of IHR mandates lie over the General Directorate of Health Operations and its Regional Health Directorates along with the Peruvian territory.

To accomplish these aims, it will have to establish an adequate control and sanitary surveillance of the borders, monitoring endemic diseases, restrict the entry of products, people, even the realization of activities that represent a risk to the health of the country.

In Title III, Chapter VI, Article 96 and 97, this law indicates that the HA has jurisdiction over import and export products when any of these may affect human and animal health or the environment.

In Title III, Chapter VIII, Article 103 and 104, indicate that in order to protect the environment, any natural or legal person is impeded from discharging waste or polluting substances into the sea.

National Health Plan – Ministry Resolution M.R.589-2007/MINSA

This plan lists and describes health policies, details of the objectives, goals, and strategies for the implementation of each of the policies in relation to health problems, and the health system. The Plan is based on the international State commitments regarding health and the national health law. It has established 8 objectives of which objective number 7 is related to the subject under investigation: “Ensure environmental sustainability, incorporating the principles of sustainable development into national policies and programs and reverse the loss of environmental resources.”

National Health Authority or Ministry of Health – Law N° 27657

HA is responsible for the direction and management of the National Health Policy (NHP) and acts as the highest regulatory authority on health. This authority is also responsible for has the following organization in relation to biosecurity, see figure 12.

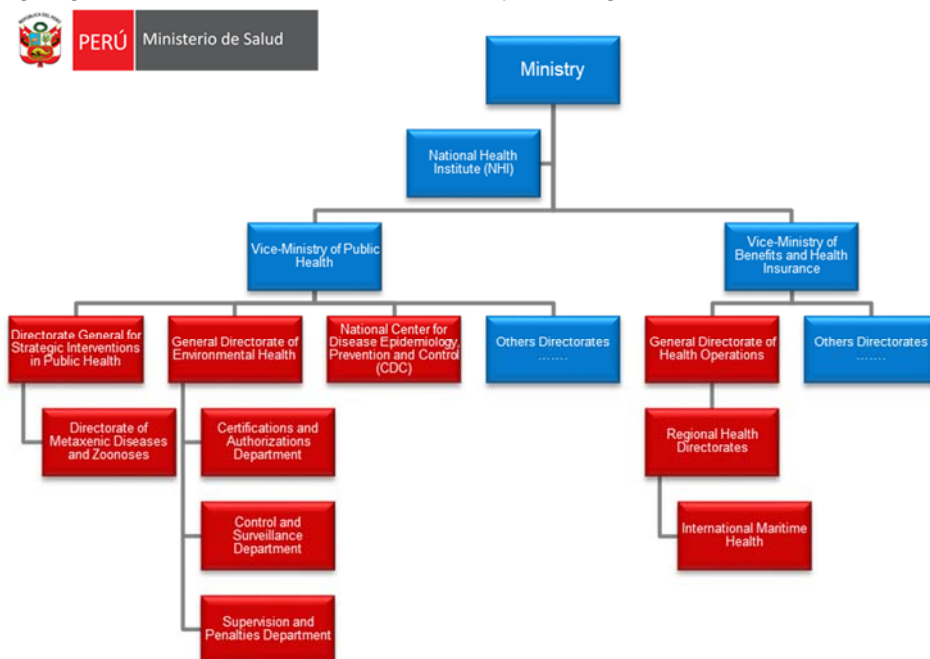


Figure 12, Organizational structure of the Ministry of Health. Source: <https://www.minsa.gob.pe>

Regional Health Authority or Regional Government – Law N° 27657

RHA is responsible for the implementation of the NHP and can develop supplementary regulations in order to achieve national objectives. This authority has the following organization in relation to biosecurity, see figure 13.

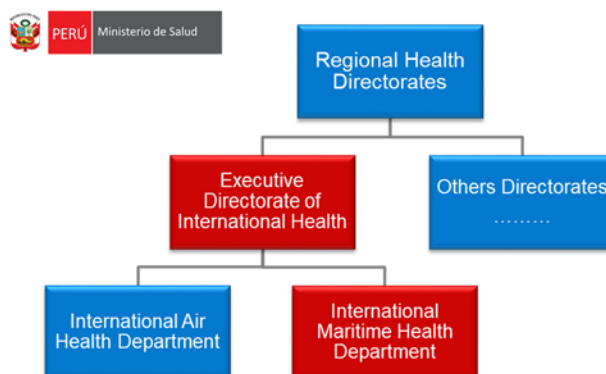


Figure 13, Organizational structure of the Regional Health Directorates. Source: <https://www.minsa.gob.pe>

Chapter 4.2.3 Distribution of regulations and competent authorities in the Maritime sector.

The MEB in Peru occupies a great extension, and is able to maintain an active control and surveillance of them, a combination of different resources (human, material and organizational) is needed. In that sense, the Peruvian state has organized itself in the following way to be able to face the biohazards from the MEB:

Maritime Authority – Peruvian Navy - Ministry of Defense – Legislative Decree D.L. N°1147

The General Directorate of Captaincies and Coastguard is the National Maritime Authority, and it has the organizational structure, as shown in figure 14. Its functions related to biosecurity are:

- To ensure the safety and security of human life at sea.
- To prevent and combat pollution, as well as protect the aquatic environment according to international instruments ratified by the state and environmental National standards.

In accordance with this Legislative Decree, the MA wields Port State Control (PSC). The PSC officer supervises foreign-flagged ships in national ports with the purpose of verifying the statutory certification of the ships evidencing compliance with the minimum security and safety standards and the prevention of contamination in accordance with international instruments.

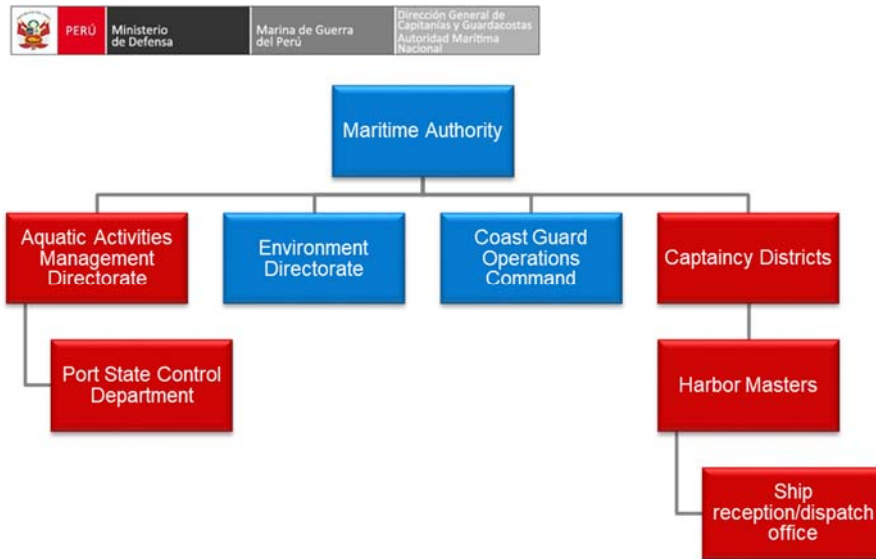


Figure 14, Organizational structure of the Maritime Authority. Source: <https://www.dicapi.mil.pe>

MA is involved in the reception and dispatch of ships. With this function, the country ensures that the ship which arrived at any national port may not represent a hazard to the national security, safety, and environment.

Port Authority - Ministry of Transport – Law N° 27943

The National Port Authority (PA) is a decentralized public in charge of the National Port System (APN, 2016). The PA is responsible for the development of the National Port System, the promotion of private investment in ports and the coordination of the different public or private actors involved in port activities and services.

Its objective is to establish and consolidate a strong maritime community port that links all agents of maritime-port development, state and private, with a common goal: strengthening the competitiveness of national ports to face the phenomenon of globalization and the challenges posed by the need to develop their export sector fully.

The link between PA and the biosecurity system is the port reception facility described in the Directorial Resolution R.D. N°087-2013-MTC-16 and the control and monitoring of dangerous goods inside the port facility described in Directory Resolution Assembly RAD N°020-2006-APNDIR.

National Superintendence of Customs and Tax Administration (SUNAT) – Ministry of Economy and Finance – Law N° 24829

The main objective of SUNAT is the management, inspection, and control of customs policy in the national territory, ensuring the correct application of international treaties and conventions and other rules that govern the matter. The link between SUNAT and the biosecurity regime is the cargo inspected by them. In this regard, their specific objectives related to biosecurity are:

- To control and verify the traffic of goods, no matter what their origin and nature at the national level.
- To inspect the international traffic of people and means of transport.
- To participate in the control of borders.

International Maritime Health Department (IMHD) – Directorial Resolution R.D. N°051-2000-SA-DS-CALLAO/ DG

It is the line department of the Executive Directorate of International Health (EDIH) in Callao - Lima. Its main aims are:

- To Plan, organize, direct, and supervise the Maritime Health actions of Callao Port.
- Ensure effective compliance with epidemiological surveillance measures in the area of Maritime Health jurisdiction.
- Supervise sanitary and epidemiological controls in case of diseases that are subject to regulation.
- Ensure compliance with national and international standards and regulations.
- Maintain proper coordination with the International Health Organizations and equivalent Authorities of other countries.
- Coordinate the health actions of the Maritime Health, with the other competent sectors.
- Keep the Regional Health Directorate of Callao permanently informed about the notification of diseases, vectors, food, and the accounting movement of the Maritime Health Service.
- Supervise the medical and technical staff of environmental sanitation at the reception and dispatch office.
- Represent the Regional Health Director of Callao in the necessary coordination with the competent authorities of the sector.

The EDIH only exists in the Region of Callao (see figure 13), in the other regions along the Peruvian coast, the local government designate a doctor of the nearest hospital to the port in order to comply with these functions of the HA.

The IMHD provides four different services (see figure 15) to the shipping industry in accordance with its “Administrative procedures Manual” (GRC, 2018):

- Ship Sanitation Control Certificate (provided by private companies).
- Ship Sanitation Control Exemption Certificate (provided by private companies).
- Free practice.
- Maritime healthy patent.

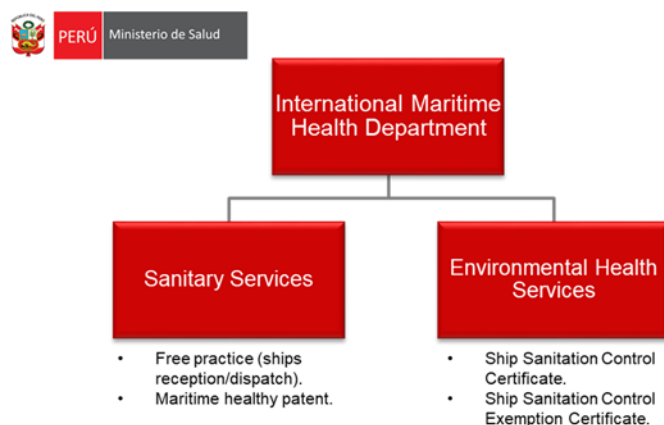


Figure 15, Organizational structure of the International Maritime Health Department. Source: <http://www.diresacallao.gob.pe>

Chapter 4.2.4 Compiled of competent authorities according to biohazards in the Peruvian biosecurity regime.

Biohazard	Ministry involved	Authorities involved	International instruments related	International Organization
Cargo	Ministry of Defense/Transport	Maritime / Port authority	SOLAS / IMDG code	IMO
	Ministry of finance	SUNAT	SAFE Framework; Trade Facilitation Agreement IMDG code	WCO/IMO
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Medical waste	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Pest/vectors	Ministry of Health	International Sanitary Authority	Vector surveillance and control at ports, airports, and ground crossings.	WHO
Crew/passengers	Ministry of Defense/Transport	Maritime / Port authority	MLC-2006 / STCW	IMO/ILO
	Ministry of Finance	SUNAT	SAFE Framework; Trade Facilitation Agreement.	WCO
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates; Handbook for management of public health events on board ships.	WHO
	Ministry of Internal Affairs	Migrations	Migratory regulations	N/A
Garbage	Ministry of Defense/Transport	Maritime / Port authority	MARPOL annex V	IMO
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates; Vector surveillance and control at ports, airports, and ground crossings.	WHO
Sewage	Ministry of Defense/Transport	Maritime/port authority	MARPOL annex IV	IMO
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Ballast water	Ministry of Defense/Transport	Maritime/port authority	BWMC	IMO/GESAMP
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO
Biofouling	Ministry of Defense/Transport	Maritime/port authority	Biofouling Guidelines -resolution MEPC.207(62)	GEF/UNDP/IMO
	Ministry of Health	International Sanitary Authority	IHR; Handbook for inspection of ships and issuance of ship sanitation certificates.	WHO

Table 8, self-elaboration, "Peruvian Competent Authorities by biohazard."

To summarize:

The environmental sector, through CONAM (focal contact point with the SCBD), performs functions focused on environmental protection related to food security, agriculture, and livestock. Its aim is to control and supervise LMOs that may affect the health of people, animals, and plants, as well as the environment. However, the approach of the legislation related to this sector is intended to ensure the market subsistence of the products obtained from agricultural and livestock activities.

For example, of the three CSAs in the environmental sector, INIEA is responsible for certifying the products to be exported in accordance with international standards, and ensuring that they are safe for human consumption. The other two sectors are DIGESA and the Vice-Ministry of Fisheries through IMARPE. The former provides scientific evidence about livestock conditions, and the latter, the health, and stock of fish and biochemical conditions of the sea.

Until this point, it was not possible to find any connection between the environmental sector and the maritime one. Even though this sector was responsible for the development of the National Biosecurity Policy (NBP) (See appendix 8), they did not include in their regulations and procedures any activity in order to assess the biohazards (invasive species) that come from ballast water, biofouling or sewage. In addition, the environmental authority does not participate in the maritime sector inspections regime (see table 8).

The Health sector plays an essential role in the national biosecurity regime because it provides support to the other two sectors. As already mentioned, DIGESA is the specialized health entity that helps CONAM to accomplish with CBD and its protocol mandates. EDIH in the Maritime sector is the specialized health which helps the HA to accomplish with IHR and

its related instruments. However, the lack of coordination between the competent authorities in all sectors remains.

The Maritime sector needs the support not only of the Health sector but also of the Environmental sector, in order to assess the risks represented by a ship arriving at national ports. The arrival inspections conducted by the Harbor Master or the PSC supervisors should have a broader spectrum, but there are many gaps related to the lack of knowledge in other fields that could be covered by joint inspections or training.

Chapter 4.3 Facing a Cholera outbreak with current Biosecurity regime, a practical example.

If the cholera bacteria arrived today at the port of Chimbote, the most important fishing port in Peru, would the current biosecurity regime detect it in a timely manner?

- Pre-Arrival:
 - The competent authorities verify the status of the ship's documentation on its way to the port, through the VUCE.
 - If the Ship's Master does not give information concerning a sick person on board, there is no possibility of knowing about the bacteria.
 - It is impossible for the Ship's Master to know that the ship is carrying the bacteria into the ballast water, biofouling or sewage.
 - The first barrier to avoid the introduction of the cholera bacteria should be IMARPE during its seawater and fish monitoring. However, IMARPE does not work a 24/7 regime, along the whole Peruvian coast.
 - If IMARPE detects bacteria, they should inform in accordance with its hierarchical line CONAM, then DIGESA. The latter should inform the HA, which will activate the national health protocols.
 - If IMARPE cannot detect it, then the responsibilities move to the next stage.
 - No possibility to take preventive measures.
- Arrival:
 - To identify the source, a physical inspection should be carried out by the inspector conducting the reception of the ship (Harbor Master), after the free practice granted via VUCE by HA.
 - Then, if PSCO chooses the same ship, he will conduct another inspection on board.
 - For both MA representatives, it will be impossible to identify the arrival of the bacteria, because of the lack of knowledge in the medical field, and the lack of procedures related to ballast water, biofouling and sewage.
 - The MA inspector will then dispatch the ship without any incident.
 - No possibility to take control measures
- Post-Arrival:
 - The ship departs, leaving the cholera bacteria in the Chimbote coast and in the City.
 - The spread of the disease starts through the food web (seafood) and contact with infected people.
 - The solution, as in the 1991 cholera outbreak, should be surveillance and protection in order to avoid the spread of the disease.

The difference with the 1991 outbreak is that the disease is now well-known. Therefore, the HA and the population will be able to deal effectively and efficiently with it. But what would happen if a new or unknown disease arrived in Peru? It would be the beginning of a new epidemic.

Chapter 5 Analysis of the Peruvian biosecurity regime.

The identification of the State entities related to the biosafety regime in Peru (See chapter 4.2), revealed a separation of objectives, functions, and responsibilities. Significant overlaps of roles and responsibilities have not been identified, but it has been possible to identify vulnerabilities and redundancy.

Competent Authorities Objectives Vs. Vulnerabilities

Each authority involved in biosecurity has a different objective. It may create gaps and the possibility of leaving a door open to biohazards. Two unfavorable conditions have been identified:

- The lack of coordination and collaboration between the competent authorities in relation to biosecurity between environmental, health, and maritime sectors. Each administrative body has its own objectives and expect specific results. It seems that there is no willingness to create synergy with others. This deficiency is also noticeable even within sectors. For example, in the Maritime sector there are four competent authorities who hold some responsibilities related to biosecurity: MA, PA, HA, and SUNAT. Each of these authorities fulfills its functions on board and in port, but there is no exchange of information, particularly in areas beyond its own functions (blindness to other sectors).
- The lack of physical inspections. It seems that the Trade Facilitation Agreement ratified by Peru (WTO, 2017) affects the amount of control which may disturb or slow down cargo flows. This agreement obliges states to use the Single Window, to reduce time, encourage trade and investment, to reduce bureaucratic barriers, especially at the borders. The result is that today, the only authority that goes onboard is the PSCO and private Sanitary companies because even the dispatches and receptions of ships are done virtually by using External Commerce Single Window called VUCE in Peru.

Findings in the Environmental sector

The most relevant findings regarding the biosecurity regime in this sector are two:

- The environmental sector focus on LMOs and GMOs impacts on food security, the health of humans, animals, and plants, and the environment. Only in the article No. 102 of the General Environmental Law (Law No. 28611) mention that some measures must be taken against the introduction of invasive species. It is possible to notice that its objectives and functions are related more to biosafety. Even though, CONAM, as a focal point with SCBD, promote the enforcement of the CBD and Cartagena protocol into the national administration.
- The use of concepts developed by international organizations may be inappropriate. Existing Peruvian environmental legislation misinterprets the concepts of "biosecurity" and "biosafety" (probably translation issue). A clear

example is the National Biosecurity Policy, which are actually procedures related to biosafety as defined by Cartagena Protocol.

Regarding the second finding, FAO is obvious in mentioning problems related to the translation from English into Spanish and French: The English words "biosecurity" and "biosafety" generate a problem for translation into Spanish and French, because both have been translated as "biosecurity"; so, FAO said in its "Biosecurity Toolkit" that it is understood that the term biosecurity corresponds to "bioseguridad" and the term "biosafety" is translated as "bioinocuidad" in Spanish (FAO, 2007).

Findings in the Health sector

In relation to the biosecurity regime focused on the maritime field, the Health sector acts as a support entity for the maritime sector. However, as already mentioned in previous paragraphs there are no clear channels of coordination or harmonizing and integrating regulations to perform good teamwork between sectors and authorities.

EDIH is the specialized health entity supporting the HA to accomplish IHR and its related instruments.

On the other hand, when referring only to the health sector, its internal regulations are focused on the biosecurity and biosafety of medical facilities and their staff.

Findings in the Maritime sector

The first one is redundancy of procedures, mostly related to the protection of the environment, cargo, and garbage. Several authorities inspect the same way, but with different approaches. For example, in the protection of the environment, the HA verifies the final disposal of the garbage, as well as the existence of vectors that can affect the health of people, animals, and plants. While the MA verifies that the garbage management plan complies with international instruments mandates.

The same happens with the cargo, SUNAT verifies the type of cargo, quantity, and destination to calculate the taxes that must be paid and to verify controlled products by law in the Peruvian state while the HA verifies the composition of the load in order to check if it is harmful to public health. The MA verifies that the corresponding segregation of dangerous goods complies with international instruments not affecting the security and safety of the ship or the crew.

The second one is the absence of authorities onboard. The single window system - VUCE replaced physical inspection and visits onboard by virtual allowances. The supervisions made by PSCOs are random and do not affect 100% of ships.

During the research, it was not possible to find a maritime Contingency Plan for Outbreaks emergencies. However, a Contingency Plan for disease outbreaks through Air economic borders already exists, perhaps it is easier to develop since there is only one international airport vs. 85 port facilities (see figure 16).

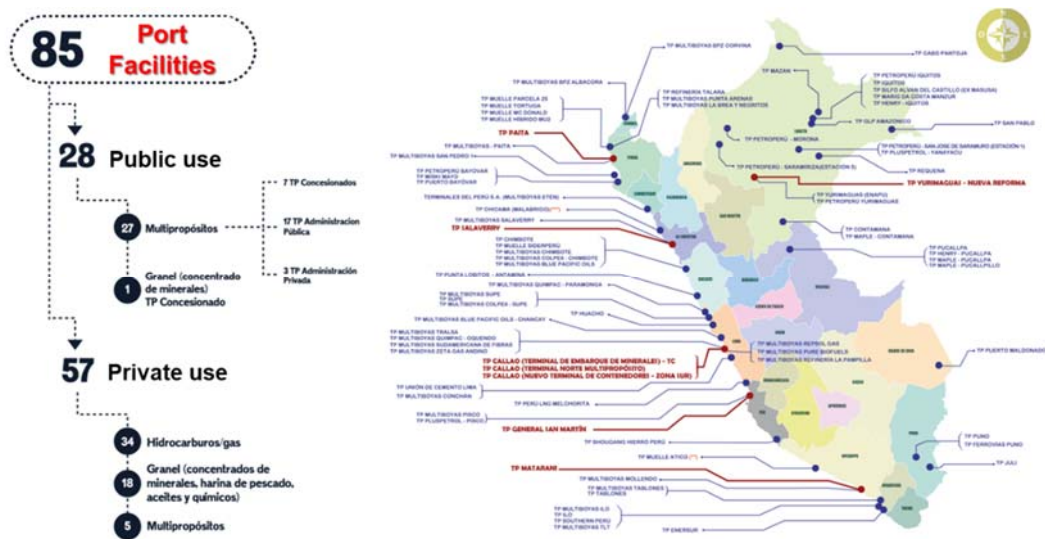


Figure 16, Distribution of port facilities in Peruvian territory. Source: <https://www.apn.gob.pe>

Peru has 20 logistics corridors and 2 structural axes that connect the 85 port facilities and the international airport with all other countries around America. These are roads with difficult surveillance and protection (post-arrival) of national territory, raise operating costs, and facilitate the spread of biohazards.



Figure 17, Logistics corridor in Peruvian territory. Source: <https://www.apn.gob.pe>

VUCE as a potential tool for biosecurity system

The VUCE was created through Legislative Decree No. 165-2006, and its control was granted to the Ministry of Foreign Trade and Tourism (MINCETUR) through the Foreign Trade Facilitation Law (Law No. 28977).

The VUCE is the unified system through which foreign trade operators will be able to manage, by using electronic means: certifications, permits, licenses and other authorizations

required by the competent authorities, for carrying out import and export operations of goods (see figure 18).

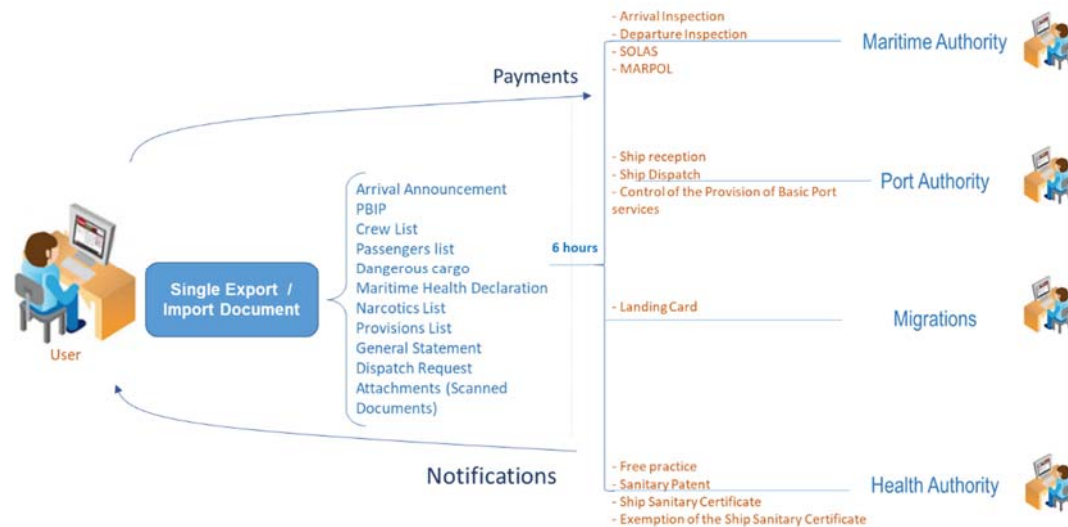


Figure 18, Self-elaboration. VUCE exchange of information. Source: <https://www.apn.gob.pe>

VUCE main functions:

- To facilitate foreign trade.
- To integrate and improve processes.
- To provide legal certainty.
- To promote the exchange of information between entities.
- Administrative simplification.

To fulfill their functions, all competent Authorities must have access to the system, in order to verify the information that by law corresponds to them. The software used by VUCE divides the authorities into components (see figure 19).

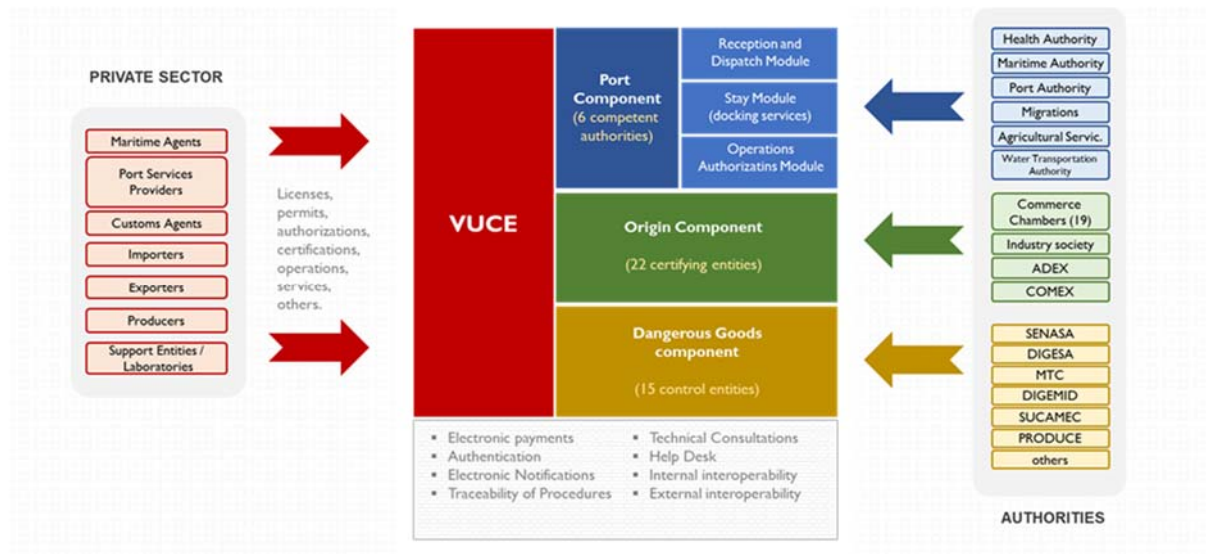


Figure 19, Self-elaboration. VUCE Components. Source: <https://www.apn.gob.pe>

VUCE has all the necessary characteristics to be used as part of the biosecurity regime (see figure 20) because it involves all the competent authorities and serves as a platform for the exchange and storage of information. Although some changes are necessary to adapt to the procedures that must be followed during the pre-arrival, arrival, and post-arrival of the Ships.

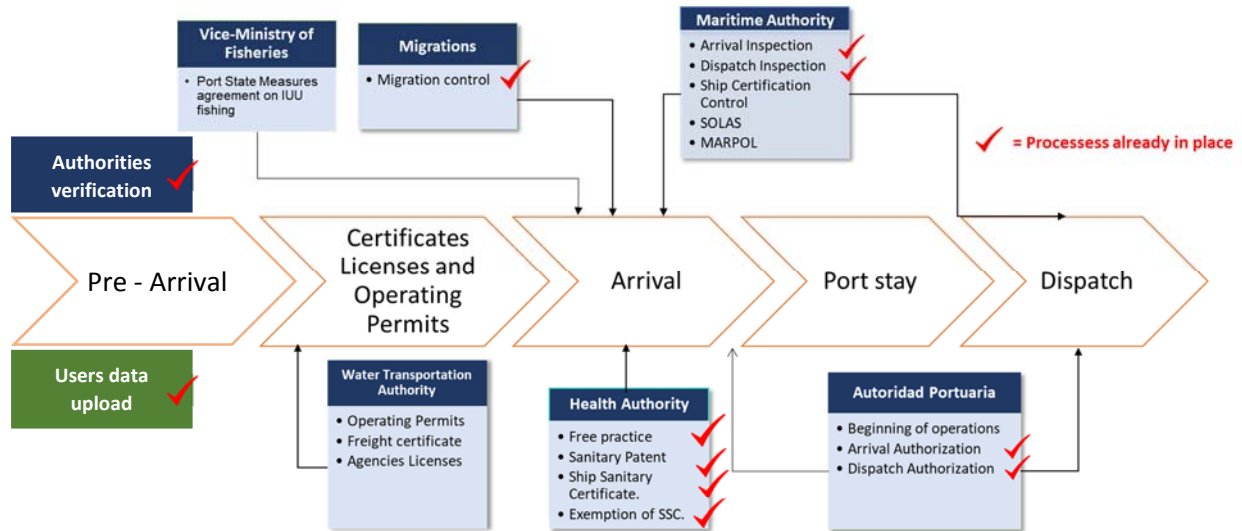


Figure 20, Self-elaboration. VUCE processes on port. Source: <https://www.apn.gob.pe>

Chapter 6 Conclusions and recommendations

Biosecurity is a broad topic which requires the involvement of several state sectors in order to face biohazards properly. The appropriate way to successfully address this topic is by implementing a suitable “Biosecurity Policy” in accordance with every country’s needs. FAO promote a harmonized and integrated approach instead of a traditional approach, but each country has its own administrative, sociopolitical, geopolitical, economic, and environmental characteristics.

Despite the biosecurity approach used to develop a National Biosecurity Policy, it should observe special features, such well-defined objectives, competent authorities, jurisdiction, functions, and responsibilities, providing them with scientific infrastructure and a sufficient budget to perform their work. The entire country must be involved in the biosecurity regime. To achieve it, the coordination and collaboration between all sectors are needed (private and public) see figure 21.

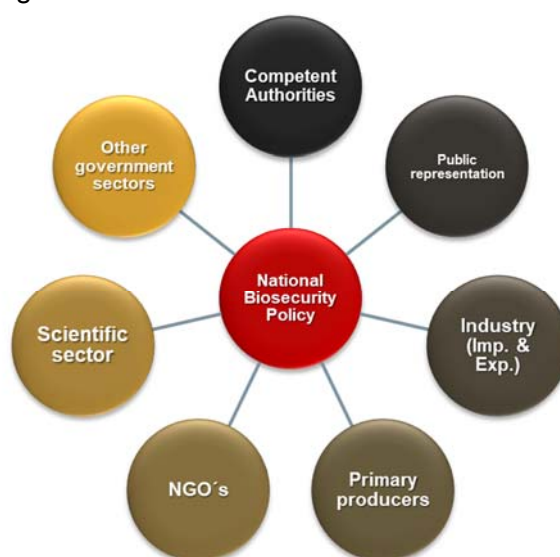


Figure 21, Sectors involved in a National Biosecurity regime. Source: FAO Biosecurity Toolkit

The next step in the development of a Biosecurity Policy is to define the potential biohazards and their entry points. Economic borders (land, air and maritime) are by nature the doors for biohazards, and in the case of MEB, ports are potentially more vulnerable to them.

In order to protect ports areas, a three-stage system must be implemented: during the “pre-arrival” of the ship (preventive measures), during the “arrival” (control measures), and during the “post-arrival” of the ship (surveillance and protection measures).

The Shipping industry represents not only globalization of economies but also massive transportation for biohazards across the world.

Peru is considered a mega-diverse country (WBO, 2013), with rich biodiversity that is the result of its wide-ranging geography which includes Andes mountain, the Amazon rainforest, and cold ocean. To protect this biodiversity, the population, and its economy, effective biosecurity policies must be developed.

Currently, Peru faces a political, economic, and social scenario that favors and makes the application of changes viable (ESAN, 2019).

These aspects are:

- The sustained growth of the economy related to international trade.
- The strengthening of the democratic and institutional process.
- The decentralization process
- The growing expectation of citizens to exercise and realize their rights.
- The growing culture for responsible health care.
- The will and political support of the Government to make decisions within the framework of a public policy of social inclusion.

This set of aspects should allow necessary changes to enhance policies related to biosecurity and effectively protect national interests through improved public service.

The importance of the relationship between competent authorities in the biosecurity system is achievable as those entities share common goals related to the protection of people, animals, plants health, and the environment.

Another problem identified during the investigation is related to the interpretation and translation of international instruments in order for it to be adequate for Peruvian legislation. For example, The NBP is, in reality, a National “Biosafety” Policy and this Policy does not include the Maritime sector in the risk assessment process. Consequently, the Environmental Authority remains out of the Maritime Biosecurity regime.

In Peruvian legislation there are two good examples of regulations related to biosecurity, even though in the text of this document is never mentioned like that. One of them is the “Contingency Plan for airborne outbreaks,” which set the strategy to face a biological pathogen arriving by plane to the only international airport in Peru. The second one is the “Ebola Protocol” this regulation establishes timely and effective internal communication mechanisms in the case of suspected cases of Ebola Virus Disease in the country.

To change the current Peruvian approach to a harmonized and integrated policy will require time and effort. Political will and allocation of resources would facilitate such necessary evolution. Completely integrated agency may not be possible, but a well-thought out coordination mechanism could enhance the current framework.

Meanwhile, a national committee (figure 20), could consider a NBP without changing the traditional approach and by using the organizations, systems, and facilities that are already in place (see figure 22).

The NBP should include:

- National scope:
 - Objectives
 - Legal framework.
 - Competent Authorities.
 - Jurisdiction.
 - Responsibilities.
 - Support agencies.
 - Allocation of resources.
 - Data exchange and collection.

- Sectorial scope:
 - Functions.
 - Procedures and protocols (Pre-arrival, Arrival & Post-arrival).
 - Penalties and sanctions.
 - Infrastructure.
 - Coordination channels.
 - Collaboration mechanism.
 - Contingency plans.

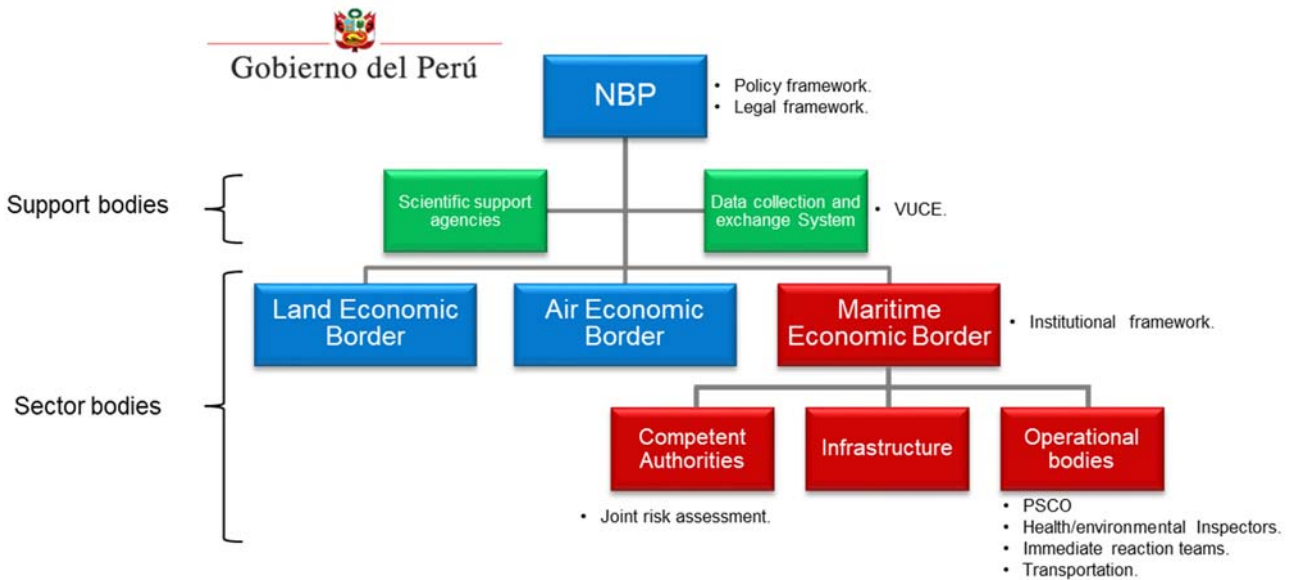


Figure 22, Self-elaboration, "National Biosecurity Policy template."

The VUCE is a tool that could be used in Biosecurity Systems. It is already in place and integrates all competent authorities. Although, some changes are needed in VUCE platform, such as the inclusion of a biosecurity module inside the Port component with a risk assessment component, and including the Environmental Authority in the inspection process (see figure 23) then dividing the authority actions into stages (see figure 24).

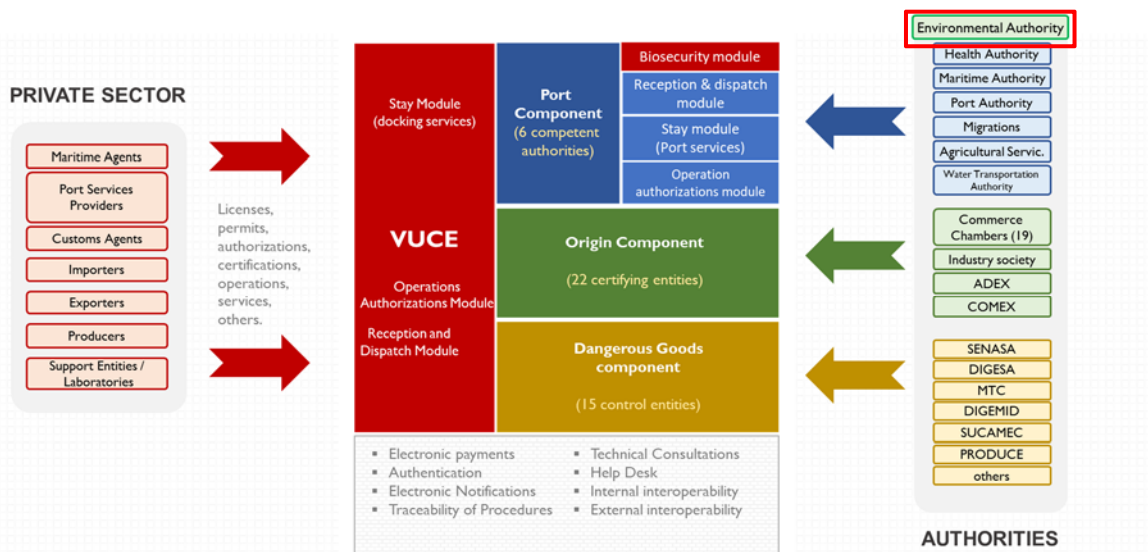


Figure 23, Self-elaboration, "New VUCE organization."

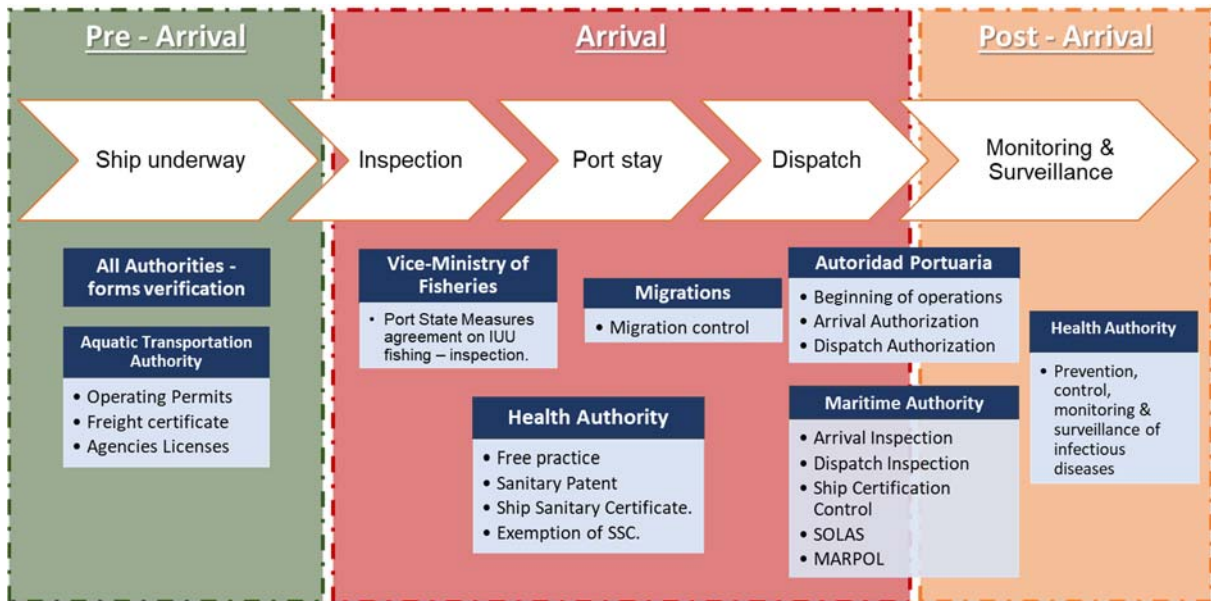


Figure 24, Self-elaboration, "Authority actions by stages."

References

- Autoridad Portuaria Nacional del Perú [Peruvian Port Authority] (2016). Plan Nacional de Desarrollo Portuario [National Plan of Port Development]. Retrieved from <https://www.apn.gob.pe>
- Autoridad Portuaria Nacional del Perú [Peruvian Port Authority] (n/d). Sistema Portuario Nacional. [National Port System]. Retrieved from <https://www.apn.gob.pe>
- Barker, K.; Taylor, S. & Dobson, A. (2013). Biosecurity The Socio-Politics of Invasive Species and Infectious Diseases. New York, United States: Taylor & Francis group.
- Bakanidze, L.; Imnadze, P. & Perkins, D. (2010). Biosafety and biosecurity as essential pillars of international health security and cross-cutting elements of biological nonproliferation. Retrieved from: <https://bmcpublichealth.biomedcentral.com>
- Barbera J., Macintyre A., Gostin L., Inglesby T., O'Toole T., DeAtley C., Tonat K., Layton M. (2001). Large-scale quarantine following biological terrorism in the United States: scientific examination, logistic and legal limits, and possible consequences. Retrieved from <https://www.ncbi.nlm.nih.gov>
- Brandling, D.; Libel, M. & Migliónico, A. (1994). El cólera en las Américas en 1991 [Cholera in the Americas in 1991]. Retrieved from: <https://econpapers.repec.org>
- Bilio, M. & Niermann, U. (2004). Is the comb jelly really to blame for it all? Mnemiopsis leidyi and the ecological concerns about the Caspian Sea. Retrieved from: <https://www.researchgate.net>
- Borroto, R. (1997). Ecology of Vibrio cholerae serogroup 01 in aquatic environments. Retrieved from: <https://www.ncbi.nlm.nih.gov>
- Burnette, R. (2013). Biosecurity: Understanding, Assessing, and Preventing the Threat. New Jersey, United States: John Wiley & Sons.
- Carlton, T. (1996). Pattern, process, and prediction in marine invasion ecology. Retrieved from: <https://academic.oup.com>
- Carlton, J. (1985). Transoceanic and interoceanic dispersal of coastal marine organisms: the biology of ballast water. Retrieved from: <https://academic.oup.com>
- Coutts, A. & Taylor, M. (2004). A preliminary investigation of biosecurity risks associated with biofouling of merchant vessels in New Zealand. Retrieved from: <https://www.researchgate.net>

- Chiavarini, S.; Ubaldi, C. & Cannarsa, S. (2014). Biocides in antifouling paints: environmental concentration levels and distribution. Retrieved from: <https://www.researchgate.net>
- Carrillo, C. (1991). La epidemia actual de cólera [The current Cholera epidemic]. Retrieved from: <http://www.scielo.org.pe>
- Congreso de la República del Perú [Peruvian Parliament] (1996). Ley de control y vigilancia de las actividades marítimas, fluviales y lacustres [Law on control and surveillance of maritime, river and lake activities]. Retrieved from: www.congreso.gob.pe
- Congreso de la República del Perú [Peruvian Parliament] (1993). Constitución Política del Perú [Political Constitution of Peru]. Retrieved from: www.congreso.gob.pe
- Congreso de la República del Perú [Peruvian Parliament] (2008). Decreto Legislativo N° 1013 Ley de Creación, Organización y Funciones del Ministerio del Ambiente. [Legislative Decree N° 1013, Law of Creation, Organization and Functions of the Ministry of Environment.]. Retrieved from: www.congreso.gob.pe
- Congreso de la República del Perú [Peruvian Parliament] (2004). Ley N° 28245 Ley marco del Sistema Nacional de Gestión Ambiental [Law N° 28245, Framework Law of the National Environmental Management System]. Retrieved from: www.congreso.gob.pe
- Congreso de la República del Perú [Peruvian Parliament] (2005). Ley N° 28611 Ley General del Ambiente [Law N° 28611, General Environment Law]. Retrieved from: www.congreso.gob.pe
- Congreso de la República del Perú [Peruvian Parliament] (1997). Ley N° 26842 Ley General de Salud [Law N° 26842, General Health Law]. Retrieved from: www.congreso.gob.pe
- Davis, M. (2009). Invasion Biology. Retrieved from: <https://www.researchgate.net>
- Donaldson, A. (2008). Biosecurity after the Event: Risk Politics and Animal Disease. Retrieved from: <https://journals.sagepub.com>
- Dumont, H.; Shiganova, T. & Nierman, U. (2005). Aquatic Invasions in the Black, Caspian and Mediterranean seas. Retrieved from: <https://www.researchgate.net>
- ESAN University (2019). Balance económico 2019: perspectivas del crecimiento económico en el Perú [Economic balance 2019: prospects for economic growth in Peru]. Retrieved from: <https://www.esan.edu.pe>

- Falk, I.; Wallace, R. & Ndoen, M. (2011). Managing biosecurity across borders. Retrieved from: <https://www.researchgate.net>
- Food and Agriculture Organization of the United Nations (2008). Capacity building for standards compliance and certification. Retrieved from: <http://www.fao.org>
- Food and Agriculture Organization of the United Nations (2007). FAO biosecurity toolkit. Retrieved from <http://www.fao.org>
- Floerl, O. & Inglis, G. (2005). Starting the invasion pathway: the interaction between source populations and human transport vectors. Retrieved from: <https://www.researchgate.net>
- Gensini G., Yacoub M. & Conti A. (2004). The concept of quarantine in history: from plague to SARS. Retrieved from www.elsevierhealth.com
- Gobierno Regional del Callao [Regional Government of Callao] (2018). Texto único de procedimientos administrativos del gobierno regional [Manual of administrative procedures]. Retrieved from: <http://www.diresacallao.gob.pe>
- Gollasch, S. (2002). The Importance of Ship Hull Fouling as a Vector of Species Introductions into the North Sea. Retrieved from: <https://academic.oup.com>
- Hewitt, C., Campbell, M., Thresher, R., & Martin, R. (1999). Marine biological invasions of Port Philip Bay, Victoria. Retrieved from: <https://academic.oup.com>
- International Maritime Organization (2006). Assessment of Shipping Traffic and Ballast Water Movements to and from Caspian Sea, and preliminary appraisal of possible Ballast Water Management Options. Retrieved from: <http://www.imo.org>
- International Maritime Organization (2013). A concept of a sustainable maritime Transportation system. Retrieved from: <http://www.imo.org>
- Institute for Bioethics, Health Policy and Law University of Louisville School of Medicine (2003). Quarantine and isolation: lessons learned from SARS. Retrieved from <https://biotech.law.lsu.edu>
- International Maritime Organization (2014a). Ebola virus disease. Retrieved from: <http://www.imo.org>
- International Maritime Organization (2014b). Full and effective implementation of maritime security measures to assist in preventing the spread of the Ebola virus disease (Circular Letter No.3485). Retrieved from: <http://www.imo.org>

- International Maritime Organization & World Health Organization (2014). Letter to Ministers responsible for ports and shipping, port authorities and shipping companies. Retrieved from: <http://www.imo.org>
- Instituto Nacional de Estadística e informática del Perú [Peruvian Institute of statistic and computing] (2019). Evolución de las exportaciones e importaciones en el Perú [Evolutions of exports and imports in Peru]. Retrieved from <https://www.inei.gob.pe>
- Inter-American Development Bank (IDB) (2010). Best practices in security and border control. Retrieved from: <https://www.iadb.org>
- Inter-American Development Bank (IDB) (2014). Integration and trade. Retrieved from: <https://www.iadb.org>
- International Maritime Organization (n.d.). Introduction to IMO. Retrieved from: <http://www.imo.org>
- Kinver, M. (2015). Fishing boats become citizen science data platforms. Retrieved from: <http://www.bbc.com>
- Kideys, A. (2002). Fall and rise of the Black Sea ecosystem. Retrieved from: <https://www.researchgate.net>
- Lewis, P., Hewitt, C., Riddle, M., & McMinn, A. (2003). Marine introductions in the Southern Ocean: an unrecognized hazard to biodiversity. Retrieved from: <https://www.researchgate.net>
- Madigan, M.; Martinko, J.; & Parker, J. (1999). Brock: Biology of Microorganisms. Retrieved from <https://www.researchgate.net>
- Mayer, J. (2018). The Origin of the word “Quarantine”. Retrieved from: <https://www.sciencefriday.com>
- Mianzan, H. (1999) Ctenophora. Retrieved from: <https://academic.oup.com>
- Meyerson, L. & Reaser, J. (2002). Biosecurity: Moving toward a Comprehensive Approach: A comprehensive approach to biosecurity is necessary to minimize the risk of harm caused by non-native organisms to agriculture, the economy, the environment, and human health. Retrieved from: <https://academic.oup.com>
- McCarthy A. & Khambaty M. (1994). International Dissemination of Epidemic *Vibrio cholerae* by Cargo Ship Ballast and Other non-potable waters. Retrieved from <https://www.researchgate.net>

- Ministerio de la Producción - PRODUCE [Ministry of Production] (2018). Consumo per cápita de pescado en los hogares peruanos creció de 12,9 a 14,5 kilos [Per capita consumption of fish in Peruvian households grew from 12.9 to 14.5 kilos]. Retrieved from: <https://www.produce.gob.pe>
- Ministerio del Ambiente [Environmental Ministry] (1999). Ley N° 27104 Ley de prevención de riesgos derivados del uso de la biotecnología [Law N° 27104 Law for the prevention of risks derived from the use of biotechnology]. Retrieved from <https://www.gob.pe/minam>
- Ministerio de Salud [Health Ministry] (n/d). Centro Nacional de Epidemiología, prevención y control de enfermedades [National Center for Epidemiology, Prevention, and Control of Diseases]. Retrieved from <http://www.dge.gob.pe>
- Ministerio de Sanidad, Consumo y Bienestar Social [Ministry of Health, Consumption and Social Welfare] (2016). Epidemia de Enfermedad por Virus del Ébola en África [Ebola Virus Disease Epidemic in Africa]. Retrieved from: <http://www.msccbs.gob.es>
- Maguiña, C.; Seas, C.; Galán, E. & Santana, J. (2010). History of cholera in Peru in 1991. Retrieved from: <http://www.scielo.org.pe>
- Ministerio de Salud – MINSa [Ministry of Health] (1993). Epidemia del Cólera en el Perú [Cholera epidemic in Peru]. Retrieved from: <https://www.minsa.gob.pe>
- Ministerio de la Producción - PRODUCE [Ministry of Production] (2018). Texto único de procedimientos administrativos [Manual of administrative procedures]. Retrieved from: <https://www.produce.gob.pe>
- McCarthy, S. & Khambathy, F. (1994). International Dissemination of Epidemic *Vibrio cholerae* by Cargo Ship Ballast and Other Nonpotable Water. Retrieved from: <https://www.researchgate.net>
- Ministerio de Comercio Exterior y Turismo - MINCETUR [Ministry of Foreign Trade and Tourism] (2019). Reportes estadísticos de turismo [Tourism statistical reports]. Retrieved from: <https://www.mincetur.gob.pe>
- Olenin, S., Gollasch, S., Jonusas, S., & Rimkute, I. (2000). En-route investigation of plankton in ballast water in ship's voyage from the Baltic Sea to the open Atlantic coast of Europe. Retrieved from: <https://www.researchgate.net>
- Presidencia del Consejo de Ministros [Prime Minister Office] (2002). DS N° 108-2002 Reglamento de la Ley de prevención de riesgos derivados del uso de la biotecnología

[DS N° 108-2002 Manual of the Law for the prevention of risks derived from the use of biotechnology]. Retrieved from <https://www.gob.pe/minam>

Presidente de la República del Perú [Peruvian Presidency]. (2005). Texto único de procedimientos administrativos de la Marina de Guerra del Perú [Manual of administrative procedures of the Peruvian Navy.]. Retrieved from: <https://www.dicapi.mil.pe>

Petrera, M. & Montoya, M. (1993). Impacto económico de la epidemia del cólera: Perú 1991 [Economic impact of the cholera epidemic: Peru 1991]. Retrieved from: www.bvsde.paho.org

Presidente de la República del Perú [Peruvian Presidency]. (2009). Decreto Supremo N°-012-2009-MINAM, Política Nacional del Ambiente [National Environmental Policy]. Retrieved from: www.minam.gob.pe

Rooney, M.; Bartram, K.; Cramer, E.; Mantha, S.; Nichols, G.; Suraj, R. & Todd, E. (2004). A Review of Outbreaks of Waterborne Disease Associated with Ships: Evidence for Risk Management. Retrieved from: <https://www.ncbi.nlm.nih.gov>

Secretariat of Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety. Retrieved from: <https://www.cbd.int>

Schepin O. & Yermakov W. (1991). International quarantine. Retrieved from <https://catalogue.nla.gov.au>

Spaulding, S. & Elwell, L. (2007). Increase in Nuisance Blooms and Geographic Expansion of the Freshwater Diatom *Didymosphenia geminata*. Retrieved from: <https://www.researchgate.net>

Sociedad Nacional de Pesquería [Fisheries National Society] (2019). Industria pesquera: Contribución a la economía peruana [Fishing industry: Contribution to the Peruvian economy]. Retrieved from: <https://www.snp.org.pe>

Shiganova, T., Mirzoyan, Z.; Studenikina. E.; Volovik, S.; Siokou-Frangou, I.; Zervoudaki, S.; Christou, E.; Skirta, A. & Dumont, H. (2001). Population development of the invader *Mnemiopsis leidyi*, in the Black Sea and in other sea of the Mediterranean basin. Retrieved from: <https://www.researchgate.net>

Taylor, M., MacKenzie, L., Dodgshun, T., Hopkins, G., de Zwart, E., Hunt, C. (2007). Trans-Pacific shipboard trials on planktonic communities as indicators of open ocean ballast water exchange. Retrieved from: <https://www.researchgate.net>

- U.S. Department of Health and Human Services (2009). Biosafety in Microbiological and biomedical laboratories. Retrieved from: <https://www.cdc.gov>
- United Nations Development Program (n.d.). Looking to the future. Retrieved from: <https://www.undp.org>
- United Nations Development Program (2019). Small invasive polizons: Protect marine biodiversity while fighting invasive aquatic species. Retrieved from: <https://www.undp.org>
- United Nations (1992). Convention on Biological Diversity. Retrieved from: <https://www.cbd.int>
- Vinogradov, M.; Shushkina, E.; Musayeva, E., & Sorokin, P. (1989) A newly acclimated species in the Black Sea: the ctenophore *Mnemiopsis leidyi* (Ctenophora: Lobata). Retrieved from: <http://www.aquaticinvasions.ru>
- World Forum FAO / WHO (2002). Experience of the cholera epidemic in Peru 1991. Retrieved from <http://www.fao.org>
- World Health Organization (2005). International Health Regulations. Retrieved from: <https://www.who.int>
- World Health Organization (2016). Vector surveillance and control at ports, airports, and ground crossings. Retrieved from: <https://www.who.int>
- World Health Organization (2019). Ebola virus disease. Retrieved from: <https://www.who.int>
- World Health Organization (2014). Statement on the 3rd meeting of the IHR Emergency Committee regarding the 2014 Ebola outbreak in West Africa. Retrieved from: <https://www.who.int>
- World Customs Organization (2015). Coordinated border management Compendium. Retrieved from: <http://www.wcoomd.org>
- World Trade Organization (2017). Trade Facilitation Agreement. Retrieved from: <https://www.wto.org>

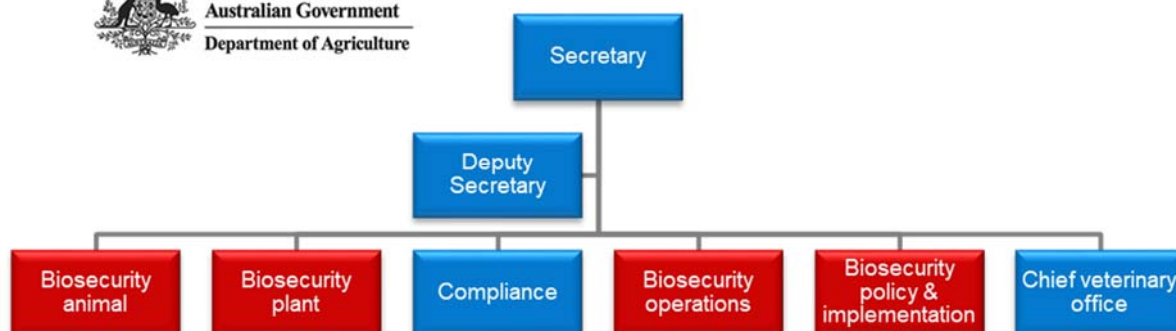
Appendices

Appendix 1: Rainbow trout case

One critical case related to invasive species is the arrival of rainbow trout. The first introduction of this non-native fish in Peru was made with 50,000 fertilized eggs from the United States that were taken to a hatchery in La Oroya, a region of Junín in 1925 (IMARPE, 1979). The impact that this introduction caused was predation of a native fish (genus *Astroblepus*) in the Río Abiseo National Park, region of San Martín and moving them to other areas (Ortega et al., 2007). The same occurs in Titicaca Lake. Rainbow trout consumes all the fish named *Orestias* and *Trichomycterus* genera, invertebrates, and frogs (Cánepa et al., 1998). While in Mala and Cañete rivers, region of Lima, it includes amphibians (*Bufo* and *Telmatobius* genera) in its diet and native fish (*Basilichthys* *archaeus*) (Palomino, 1984).

The arrival of rainbow trout would have brought the introduction of the parasite “*Ichthyophthirius multifiliis*,” which caused several epidemic events among the native fish of Titicaca Lake, causing the death of some 18 million *Orestias* in 1981 (Wurtsbaugh & Alfaro, 1988).

Appendix 2: Australian Biosecurity Organization



Biosecurity and human health zones

The *Biosecurity Act 2015* allows the Director of Biosecurity to establish biosecurity zones within Australia to monitor, control and respond to pests and diseases.

Monitoring zones

When a pest or disease that poses an unacceptable level of biosecurity risk enters, emerges or establishes (or is likely to) in Australia, monitoring zones can be established. Biosecurity officers have the power to monitor, control and respond to biosecurity risks within the boundaries of the zone. They typically conduct activities like setting traps and installing monitoring equipment within the zone.

Permanent biosecurity monitoring zones apply 400m beyond the boundary of:

- first points of entry for aircraft, vessels and goods
- international mail centres
- biosecurity activity zones
- other places as prescribed in [Biosecurity Regulation 2016](#) such as the [Torres Strait](#).

Temporary biosecurity monitoring zones can be declared to ensure a risk has not spread. When this occurs the department works with state and territory bodies responsible for biosecurity management in establishing the zone and responding to the threat.

Activity zones

Biosecurity activity zones can be established in Australian territory where a high biosecurity risk associated with people, goods and conveyances moving in and out of the area exists. An example is the [Post entry quarantine facility at Mickleham](#) where plants and animals are monitored for exotic diseases and illness after arriving from overseas. Like monitoring zones, activity zones are established in consultation with state and territory bodies responsible for biosecurity management.

Response zones

When a biosecurity officer has reasonable grounds for suspecting that a pest or disease is present on goods, or in a premises, and that they pose an unacceptable risk to Australia's biosecurity, a biosecurity response zone may be established.

State and territory governments have the primary responsibility for responses within their boundaries, although the Biosecurity Act does allow for the Department of Agriculture and Water Resources to engage in response activities.

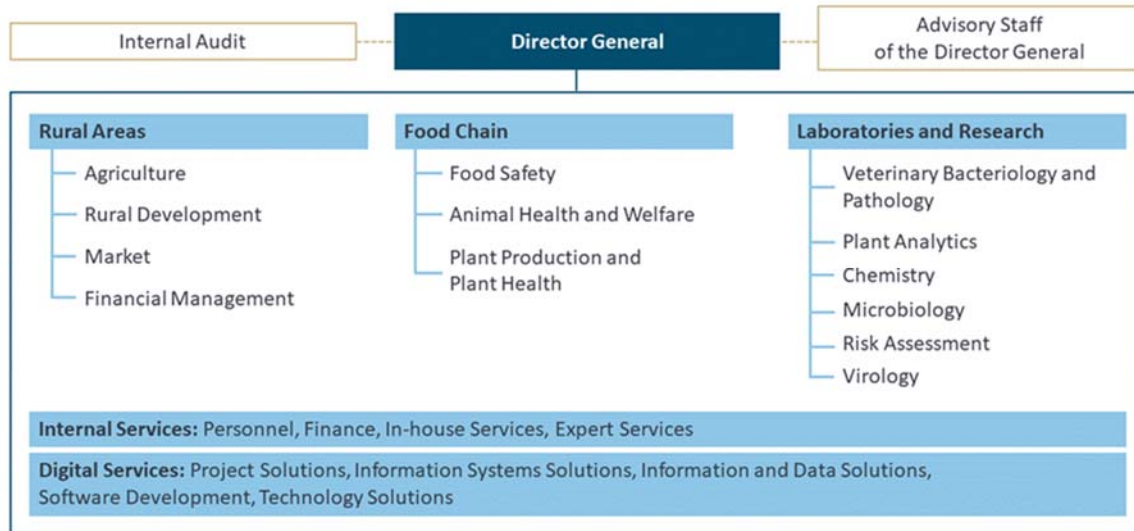
Human health response zones

The Director of Human Biosecurity may establish a human health response zone if it is necessary for purposes of preventing, or reducing the risk of, a [listed human disease](#) emerging, establishing or spreading in Australia or its territories.

The Department of Health has policy and operational carriage of this power, however biosecurity officers have the power to ask questions and/or require written information to be provided by individuals within a human biosecurity response zone.

Source: <http://www.agriculture.gov.au>

Appendix 3: Finish Biosecurity Organization



The Finnish Food Authority is headed by its Director General.

The Finnish Food Authority contains three departments and two operating entities:

- The Rural Areas Division acts as the paying agency of Finland and is responsible for the distribution of the funds provided by the subsidy systems and the mainland Finland rural development programme and for managing and monitoring that the funds are used in the appropriate manner.
- The Food Chain Division is responsible for monitoring the safety and quality of food-related production items used in agriculture and forestry – seeds, animal feeds, fertiliser products, plant propagation materials, forest reproductive material and plant protection products – as well as the health and wellbeing of animals and plants.
- The Laboratory and Research Division is responsible for animal and plant disease diagnostics; laboratory studies related to food, feeds, fertilisers, plant protection products and plants; and the laboratory analysis of supervision and monitoring samples as well as the related reference laboratory activities and risk assessment procedures. The division also conducts scientific research and maintains the necessary national research infrastructure in the fields that it operates in.
- The Internal Services is responsible for all HR and financial matters, the user services in offices as well as document management and data protection, legal services and procurement activities.
- The Digital Services is responsible for the centralised steering and coordination of all information management-related matters, the production of the development and maintenance work for the Finnish Food Authority's information systems, as well as all ICT-related procurements and data security. In addition, the unit is responsible for the IT services produced for the Finnish Food Authority's external customers.

The internal audit unit and headquarters operate directly under the Director General.

Source: <https://www.ruokavirasto.fi>

Appendix 4: New Zealand Biosecurity Organization

Ministry for Primary Industries
Manatū Ahu Matua



Our strategy

Our vision is that 'New Zealand will be the world's most sustainable provider of high-value food and primary products.' Our strategy tells the story of what we need to achieve to ensure the success of the primary sector for the benefit of all New Zealanders.

The 4 outcomes we're working towards



Prosperity

High-value food and primary sectors build prosperity for more New Zealanders.

- Our priorities under prosperity are to focus our expertise and resources to support innovation, to partner with the food and primary sectors for their success, and to help New Zealand producers increase the value of their goods.



Sustainability

Future generations will benefit from improved environmental performance by our primary industries.

- Our priorities under sustainability are to support farmers and growers to adopt more sustainable land use practices, to rejuvenate the forestry sector to improve environmental outcomes, and to advance fisheries practices for a healthier marine environment.



Protection

Our products are safe and New Zealand is protected from biological risk.

- Our priorities under protection are to protect New Zealand from harmful pests and diseases, demonstrate New Zealand's food safety system is world class, and to partner to preserve New Zealand's native plant and animal life.



Visible Leadership

We enable the food and primary sectors to thrive.

- Our priorities under visible leadership are to have a diverse and capable workforce, to take a visible leadership role wherever we work, and to grow our partnership with iwi and Māori.

Source: <https://www.mpi.govt.nz>

Appendix 5: U.K. Biosecurity organization

Minister responsible – Security Minister

Governance structure

Governance for much of the activity described in this strategy falls within departments' existing portfolios and governance mechanisms. This strategy brings together that activity to ensure that a cross-Government approach to biological security is maintained, while avoiding duplicating existing mechanisms and activities.

Many of the commitments can only be delivered if Government departments work together, in many cases across sectors that have not previously systematically engaged with one another. These commitments (as well as any new work or identified gaps that emerge when work on biological risks is being co-ordinated) will be owned by a cross-Government director-level governance board, made up of representatives from the following departments:

- Home Office
- DHSC (including PHE representation)
- Defra (including APHA representation)
- Agri-Food and Biosciences Institute (AFBI)
- MOD (including Dstl representation)
- FCO (including the Science and Innovation Network)
- BEIS

- DFID
- GO Science
- Cabinet Office
- HSE
- OLS
- Department for International Trade
- the Devolved Administrations

This governance board will report to the Threats, Hazards, Resilience and Contingencies Subcommittee of the National Security Council, through the Security Minister, to ensure that a forum at the highest level of Government holds departments to account. The Government Chief Scientific Adviser will maintain an oversight of developments under the strategy.



Department for Environment Food & Rural Affairs

Departmental roles and responsibilities

The **Civil Contingencies Secretariat (CCS)** is part of the National Security Secretariat within the Cabinet Office. CCS co-ordinates civil emergency planning and response, including ensuring that Government is ready to respond to, and recover from, a variety of challenges and is able to provide effective and co-ordinated crisis management. CCS also ensures that effective arrangements exist for short and longer term risk assessment at national and local levels and that appropriate capabilities and plans are in place internationally, nationally and locally to deal with the full range of significant risks.

The **Department for Business, Energy and Industrial Strategy (BEIS)** ensures that the economy grows strongly in all parts of the country, based on a robust industrial strategy and secure energy supplies that are reliable, affordable and clean. It encourages investment and innovation that fully utilise the UK science, engineering and technology base.

- The **Office for Life Sciences (OLS)**, a joint team between BEIS and the DHSC, champions research, innovation and the use of technology to transform health services. It leads on Government policy for the UK's health and biological sciences industries (biopharmaceutical, medical technologies and digital health).
- BEIS (along with Defra) has responsibility for developing funding and regulatory strategies for both the agri-food industry and the wider bioeconomy.

- BEIS has responsibility for science and innovation policy and research funding, including through UK Research and Innovation. BEIS oversees the allocation of funding to these partners, who in turn provide support to universities and to key institutes that underpin the biosecurity strategy. BEIS also works with the research base as it develops policies for research integrity to ensure the highest standards of ethical research.

The **Department for Environment, Food and Rural Affairs (Defra)** has responsibility for safeguarding the natural environment against animal and plant diseases, flooding and other hazards, supporting the world-leading food and farming industry in England, and sustaining its thriving rural economy. For deliberate animal and plant disease threats Defra is responsible for co-ordinating the national recovery effort.

The **Department of Health and Social Care** leads the health and care system in England to help people to live better for longer. It ensures that people have compassionate services that protect and promote health and give safe, effective and efficient care. This includes work under all four pillars of the Biological Security Strategy, to understand the public health threats we face, prevent these where possible, rapidly detect any that occur, and respond effectively to disease outbreaks.

The **Department for International Development (DFID)** leads the UK's work to end extreme poverty – tackling the global challenges of our time, including poverty and disease, mass migration, insecurity and conflict. DFID contributes to the biological security of the UK and UK interests through its work to help developing countries strengthen their healthcare systems and address disease outbreaks – leading to a healthier, more stable world.

The **Foreign and Commonwealth Office (FCO)** has responsibility for safeguarding the UK's national security by countering terrorism and weapons proliferation in co-operation with allies and partners, and for strengthening the rules-based international order. In line with the National Counter Proliferation Strategy, it aims – including through the Counter Proliferation and Arms Control Centre, the Crisis Management Department (CMD), and Consular Work – to:

- maintain the international legal prohibition on biological weapons;
- encourage all states to adhere to international norms and treaties on the development and use of biological and toxin weapons; and
- make it as hard as possible for states or terrorists to acquire or develop capabilities by reducing the proliferation of information and materials.

The **Health and Safety Executive (HSE)** is the national regulator for workplace and workforce health and safety, including microbiology and biotechnology issues. Its purpose is to:

- promote standards of safety that are proportionate to the risks from high consequence micro-organisms, and reassure the public that appropriate controls are in place; and
- keep pace with change and anticipate, and tackle, new safety challenges, to enable the science and technology to develop.

The **Home Office** has responsibility for the UK's homeland security. The Home Office contains the Office for Security and Counter Terrorism, which protects the public by working across Government and with international partners to reduce the risk of terrorism against the UK or UK interests overseas through the counter terrorism strategy, CONTEST. This includes work to protect against the highest impact terrorist risks – including those involving a biological weapon.

The **Ministry of Defence (MOD)** has responsibility for defending the UK and its interests overseas from deliberate threats. MOD contributes to all four pillars of the UK Biological Security Strategy, with support from the Defence Science and Technology Laboratory (Dstl). This includes expertise and capabilities for disease and pathogen detection, analysis and attribution; provision of intelligence assessments to support cross-Government risk assessments of potential biological agent use by adversaries; strengthening international efforts to counter the risk of hostile use of biological agents; providing capability to make safe both biological weapons and associated infrastructure; and the ability to deploy resources in extremis as part of Government's response to disease outbreaks or biological agent use.

Source: <https://www.gov.uk>

Appendix 6: National Environmental Policy

General Objective:

To improve people's quality of life, guaranteeing the existence of healthy, viable and functional ecosystems in the long term; and the sustainable development of the country, through the prevention, protection and recovery of the environment and its components, the conservation and sustainable use of natural resources, in a responsible and consistent manner with respect for the fundamental rights of the person.

Specific Objective:

- Conservation and sustainable use of natural resources, in relation with:
 - Biodiversity.
 - LMOs and GMOs.
 - Biosecurity (misuse of the word should be biosafety).
 - To promote the rational and responsible use of natural resources.
 - Energy and mining.
 - Forests.
 - Marine ecosystems.
 - Basins, freshwater and soil.
 - Mitigation and adaptation to climate change.
- Integral management of environmental quality.
- Consolidation of the environmental governance
- International environmental commitments and opportunities.

Appendix 7: CONAM legal framework

Law N° 28245, Framework Law of the National System of Environmental Management assigns CONAM the responsibility of the planning, promoting, coordinating, regulating, sanctioning and supervising actions aimed at environmental protection.

This Law promotes environmental research as well as integrate and strengthen relations with the competent entities of the public and private sector.

Take some actions with the objective of giving scientific and technical support to the different organizations involved; give opinions on the draft legislation with environmental implications; as well as promoting the development and use of cleaner technologies, methods, practices and production, and marketing processes.

Law N° 28611, General Environmental Law regulates the National Environmental Authority functions, establishes provisions of transectoral scope on the management of the environment and its components, without prejudice to the specific roles carried out by the sectoral, regional authorities and competent premises.

Likewise, it indicates that the State promotes the adoption of national technical norms, without generating unnecessary or unjustified obstacles to free trade, in accordance with current norms and international treaties ratified by the Peruvian State.

Article 102 indicates that the species conservation policy implies the need to establish minimum conditions for their survival, population recovery and care, and assessments for the entry and dispersion of invasive or exotic species.

Appendix 8: National Biosecurity Policy.

The National Environmental Policy indicates the policy guidelines for biosecurity in section 3, which are:

Establish mechanisms to regulate, under scientific parameters, any activity that involves the use of living modified organisms (LMOs) and genetically modified organisms (GMOs), as well as the safe and responsible use of modern biotechnology and its derived products.

An adequate level of protection of human health, the environment, biological diversity, and its sustainable use must be guaranteed, in the area of generation, research, production, transfer, handling, transport, storage, conservation, exchange, marketing, use confined and released to the environment, from GMOs and their derivative products.

Identify the applications of modern biotechnology and evaluate its relevance and opportunity in solving specific problems in national production processes or in the generation of services, in a safe, competitive, and sustainable way.

Promote the responsible use of modern biotechnology without damaging productive processes that are already competitive and sustainable, and whose goods and products are appropriate and appropriate.

Build and develop a regulatory system based on the application of transparent and scientific risk analysis; capable of guaranteeing the safety and traceability of the goods and / or services obtained through the application of modern biotechnology, responding to the demands of consumers, to our condition as a mega-diverse country and to the context of continuous technological developments.

Establish scientific, environmental, socio-economic and political criteria for a biosecurity system and responsible use of biotechnology, with levels of security compatible with the national / foreign trade policy and promotion of local and national innovation.

Generate, use, and disseminate quality information on biosecurity, to contribute to responsible decision-making between suppliers and users and for the construction of a properly informed public opinion.

Generate and strengthen the scientific and technological management and infrastructure capacities of the institutions whose scope of action is the regulation of modern biotechnology, necessary for the implementation of national and international biosecurity legal frameworks.

The development of the NBP was carried out by the Ministry of Environment, INIEA, Vive-Ministry of Fisheries, and DIGESA. The maritime sector was not taken into consideration generating gaps between these sectors. Procedures related to ballast water, biofouling and sewage is only concern of the MA for now.