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Standards and regimentations of biosafety and biosecurity in medical biology laboratories in Togo, 2021

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Legal instruments are necessary for the regulation of programs such as the biosafety and biosecurity (BSS) system in a country, yet little information is available in this sector in Togo. The study conducted aimed to take an analytical look at the normative and regulatory environment of biosafety and biosecurity in medical biology laboratories in Togo. A documentary review was carried out on the web, in the Official Journal, and on governmental sites between January and June 2021. A total of 76 documents were initially identified and then 14 were included in the synthesis. Of the 14 texts regulating the biosafety and biosecurity sector worldwide, 10 have been ratified or are being used in Togo. In total, 05 laws and 02 decrees are in force in the area of BSS in Togo on June 30, 2021. Our study has also allowed us to highlight several activities to be regulated. The approach adopted has revealed a current deficit in terms of regulations in the area of biohazard management in Togo in a multisectoral framework. It is necessary to strengthen the existing regulatory texts by taking into account the areas required internationally.

Key words: Biosafety, biosecurity, regulation, standards, medical biology laboratory.

INTRODUCTION

Faced with major public health regulatory challenges, both biosafety and biosecurity (BSS) call the scientific community's attention to fundamental questions about laboratory practices (Berns, 2014; Gao, 2019; Vogel et al., 2015). Biosafety is the set of containment principles, technologies, and practices implemented to prevent

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inadvertent exposure to or release of biological agents or toxins (ISO 15190, 2020). Biosecurity is the set of principles, technologies, and practices implemented for the protection, control, and accountability of biological materials and/or equipment, skills, and data related to their handling (ISO 15190, 2020). The expansion of biological hazards and threats is facilitated by non-compliance with approved containment protocols, shortcomings in laboratory storage of infectious pathogens, and the absence of other adequate BSS measures (Berns, 2014; Gao, 2018; Linkous et al., 2021). Laboratories at the forefront of technological advances in the search for human health solutions are useful for more than just responding to health emergencies. They also express concern about the risks of acquired infections to laboratory personnel (Beeckman and Rüdelsheim, 2020). There is also the possibility that dangerous microorganisms or toxins under investigation will escape from the laboratory and cause harm to public health and the environment, as was the case with highly pathogenic H5N1 avian flu and bioterrorism (Gao, 2018; Vogel et al., 2015). The limits of established laboratory measures and the risk of pathogen proliferation thus raise the question of regulation and its effectiveness. Most countries now rely on both the establishment of high-level microbiological safety research centres and the development of a range of laws, regulations, and standards to improve BSS capacity (Beeckman and Rüdelsheim, 2020; Gao, 2018, 2019; Huigang et al., 2021). Despite growing awareness, recent studies show that developing countries are struggling to build or anchor their BSS assurance policies in a global context of expanding diagnostic capacity (Chung et al., 2019; Heckert et al., 2011; Maehira and Spencer, 2019; OMS, 2018). These efforts are therefore insufficient in low-resource countries, as highlighted by the recent International Health Regulations (IHR) joint assessment report in 2018. For example, in Togo, a low-income country, in addition to the country assessments carried out in some laboratories, the IHR assessment noted weaknesses in the monitoring of key aspects of the biosafety and biosecurity system (OMS, 2018). Recommendations were made on compliance with international instruments and the effectiveness of BSS measures (Gao, 2019; OMS, 2018; Wurtz et al., 2014). In view of this situation, it was appropriate to examine the national legal framework for the implementation of BSS in Togo. The objective of this study was to analyze the normative and regulatory environment of Biosafety and Biosecurity in medical biology laboratories in Togo.

MATERIALS AND METHODS

Type and period of study

The study was descriptive in nature. Data was collected from January to June of 2021.

Inclusion criteria

The study targeted decrees, conventions, standards, laws, policies, and good practice guides. The latest versions of international instruments: standards, conventions, decrees, regulations, frameworks, and laws were consulted and requirements in terms of necessary regulations were identified. At the national level, the relevant legal instruments that have been ratified by Togo until 30 June 2021 were consulted. Similarly, a review of the main BSS management documents in Togo in terms of frameworks, laws, decrees, was carried out. Documents supplementing revised or country-specific regulatory texts and documents dealing exclusively with the animal and environmental sector were excluded.

Data sources

A document review on the Internet was used to explore the different texts. The websites of the National Assembly, the Government and the Ministry in charge of Health were visited. The archives of the Ministry of Health, the central library and the Official Journal of the Togolese Republic were also explored.

Research strategy

The search was done in duplicate and took into account Boolean operators (AND, OR, NOT) and keywords such as: biosecurity, biosafety and biosecurity, biological security, biosafety standards, biosecurity standards were used.

Data analysis

Data were imported into Zotero for further processing. Following the extraction of data, a comparison was made and a flow chart was produced. An analytical approach was used (Gouvernement du Canada, 2020; WHO, 2020a) to highlight the strengths, weaknesses, opportunities, and threats of each legal instrument. We highlighted several activities to be regulated that were conveniently grouped into areas of high impact on BSS worldwide. Country-level gaps in terms of BSS regulation were identified.

RESULTS

Flow chart

Figure 1 illustrates the selection process of international BSS normative and regulatory documents. Of 76 documents consulted, 14 were included in the synthesis.

International regulatory texts on biosafety and biosecurity

A total of 14 texts regulate the BSS sector worldwide, 10 of which have been ratified or are in use in Togo. Table 1 summarises the regulatory texts in force at the international level. Other accreditation standards

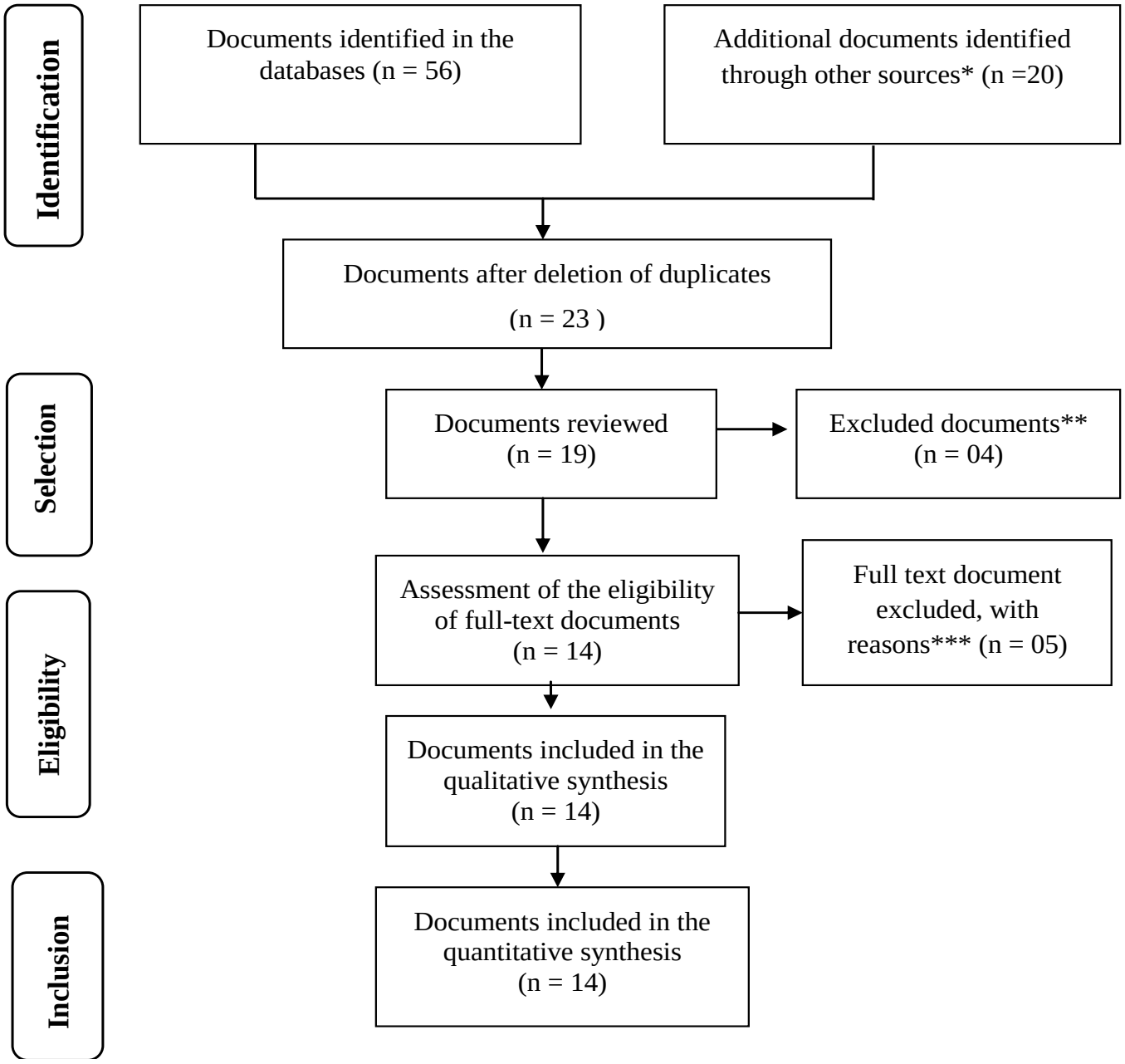

Figure 1. Flow chart illustrating the selection process of international BSS normative and regulatory documents. Of 76 documents consulted, 14 were included in the synthesis. Here, « documents » means: Standards, Regulations, Conventions, Laws, Protocols. *, ** and *** signify Government and UN agencies, Documents supplementing revised or country-specific regulations, Dealing exclusively with the animal and environmental sector respectively.
Source: Authors

ISO15189: 2012 and ISO/IEC 17025: 2017 relating to quality management devote a chapter to the management of laboratory premises and environment. The former was adopted by Togo in 2015. Of the 14 documents listed in Table 1, 09 take into account the specificity of medical biology laboratories, including three standards not adopted by Togo.

Areas of national biosafety and biosecurity regulation recommended by the international instruments listed

Table 2 shows the areas recommended for national regulation by each standard, regulation, protocol, convention or guide listed. The main areas of national

Table 1. Regulatory texts related to biosafety and biosecurity at the international level, 2021.

Category	Title	Scope in relation to biosafety/biosecurity	Ratified/Adopted, Togo
Conventions (n=4)	Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxic weapons and on their destruction[a]	Biological and toxic weapons	Yes
	Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	Waste management, transport	Yes
	Bamako Convention	Transboundary control, transport of waste in Africa	Yes
	Convention on Biological Diversity (CBD)	Framing the use of living modified organisms	Yes
Protocols (n=2)	Cartagena Protocol	Provisions on biosafety in relation to living modified organisms	Yes
	Nagoya Protocol - Kuala Lumpur	Traditional knowledge associated with genetic resources/benefits arising from their use	Yes
Regulations (n=1)	International Health Regulations, WHO 2005[a]	Public health emergencies of international concern of infectious/chemical/toxic/nuclear origin	Yes
Standards (n=3)	ISO 20387: 2018. Biotechnology - Bio-banking[a]	General requirements, bio-banks	No
	ISO 15190: 2020[a]	Biological risk management	No
	ISO 35001: 2019[a]	Biological risk management	No
Manuals/Guides (n=4)	WHO Handbook, 2020[a]	Biological risk management	Yes
	WHO Regulatory Implementation Guidelines, Biosafety Requirements and Biosafety in Biomedical Laboratories, a phased approach: 2020[a]	Regulation, biosafety and biosecurity implementation framework	Yes
	Biosafety in microbiological and biomedical laboratories[a]	Good practices in biosafety and biosecurity	Yes
	CDC Guidelines for safe working practices in human and animal medical diagnostic laboratories[a]	Biosafety culture	No

[a]These documents take into account the specificity of medical laboratories at the international level. Other accreditation standards ISO15189: 2012 and ISO/IEC 17025: 2017 relating to quality management devote a chapter to the management of laboratory premises and environment. The former was adopted by Togo in 2015.
Source: Authors

biosafety and biosecurity regulation recommended by the international instruments listed have been grouped into 07 and their contents represented in Table 3.

Regulatory texts relating to biosafety and biosecurity listed in Togo

Table 4 summarizes the different regulatory texts related to BSS in Togo as of June 30, 2021. A total of 05 laws and 02 decrees are in force in Togo.

DISCUSSION

International normative and regulatory instruments on biosafety and biosecurity in medical biology laboratories

From the process of selecting normative and regulatory documents on BSS at the international level, 76 documents were initially listed, and then 14 were included in the summary. Our study showed that of the 14 international instruments listed, 10 had been ratified or were used by Togo, with 09 texts taking into account the specificity of medical biology laboratories. The ISO 15190 (2020) and ISO 35001 (2019) standards, which should help in the proper implementation of the BSS, have not been officially adopted, even though Togo's internal documentation on the

Table 2. List of areas of national biosafety and biosecurity regulation recommended by the international instruments listed.

Standards and regulations	Recommended areas for national regulation
Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxic Weapons and on their Destruction	Development, manufacture, acquisition, transfer, retention, storage and use of biological weapons and toxins. Threshold quantity of biological agents and toxins to be ordered
Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	Waste management, transport
Bamako Convention on the Ban of the Import into Africa of Hazardous Wastes and on the Control of Transboundary Movements and Management of Hazardous Wastes Produced	Transboundary control, transport of waste
Rotterdam Convention on Chemicals	Chemicals and pesticides management, consent procedure
Convention on Biological Diversity (CBD)	Use of living modified organisms
Cartagena Protocol	Biosafety provisions
Nagoya-Kuala Lumpur Protocol	Management of genetic resources
International Health Regulations, WHO 2005	National cross-sectoral biosafety/biosecurity framework; biosecurity; transport of infectious substances; qualification/registration of *in vitro* diagnostic *devices/reagents*
ISO 20387: 2018. - General requirements for bio-banks	Requirements, bio-banking
ISO 15190: 2020	Biomedical waste management ; handling of human/tissue/residue samples; bio-containment
ISO 35001: 2019	Containment and facilities; Protection of employees' rights; environmental impact, general health and safety (fire, electrical risk, etc.)
ISO 15189: 2012	Retention period of the laboratory archives; duration of storage of samples in the serum bank; handling of human samples/tissues/residues; storage, disposal, management of biomedical waste
WHO Handbook 2020	Eligibility and reliability of staff; medical surveillance; decontamination and management of biomedical waste; bio-containment: requirements for handling human samples, tissues or residues; arrangement, use of personal protective equipment
WHO Guidelines on Regulatory Implementation, Biosafety Requirements and Biosafety in Biomedical Laboratories a stepwise approach: 2020	Transport and transfer of samples, import, export, quantities, other controls; national cross-sector biosafety and biosecurity framework; records management, retention period of archives; inventory of pathogens and toxins, sample shelf life, bio-bank management; information management/security, shelf life of laboratory archives, potential dual use; bioethics ; compliance with international agreements
Biosafety in microbiological and biomedical laboratories	Transport of samples; decontamination of waste; decontamination of materials to be removed from the laboratory
CDC Guidelines for safe working practices in human and animal medical diagnostic laboratories	Waste management; transport of biological samples

Source: Authors

subject refers to them. Nevertheless, the ISO 15189 (ISO 15189, 2012) adopted in Togo in 2015, provides some guidance on the management

Table 3. Areas of biosafety and biosecurity regulations in the biomedical laboratory at the international level.

Title of the regulatory area	Content
National cross-sectoral biosafety and biosecurity framework	Biohazard management, compliance with international agreements
Biomedical waste management	Production, control of transport on territory/cross-border, storage, decontamination, disposal, traceability
Management of bioresources (modified living organisms, viruses, bacteria, fungi, prions, toxins...), chemicals and biological weapons	Transport of samples/infectious substances, transfer of samples, import, manufacture export, threshold quantities, other controls, use of living modified organisms, toxins, management of genetic resources, biosafety provisions, chemical and pesticide management, consent procedure, handling of samples, shelf life of samples, pathogen and toxin inventory, traceability
Information management and security, shelf life of laboratory archives, potential dual use	Retention period of laboratory records, specific requirements for competence, impartiality and consistent operation of bio-banks, eligibility and reliability of staff
Containment, facilities, personnel protection: requirements for handling human specimens, tissues or residues	Bio-containment, standard laboratory layout, environmental impact, general health and safety, provision and use of personal protective equipment, protection of workers' rights, medical surveillance
Qualification, registration of in vitro diagnostic devices and reagents for biomedical laboratories	Qualification/registration of in vitro diagnostic devices and reagents for biomedical laboratories
Bioethics	Bioethics

Source: Authors

of laboratory premises and environment.

On an international level

Over the past decade, although there has been little scientific publication on BSS legislation, the normative framework is being updated in the light of technological advances (Huigang et al., 2021; Maljean-Dubois, 2021; Qiu and Hu, 2021). Networks of countries have been established to contribute to the safe use of living modified organisms (LMOs). Other biological agents and toxins are rarely mentioned in regulatory texts. In order to support African countries in the implementation of the Cartagena Protocol (Secrétariat de la Convention sur la diversité biologique, 2000), the African Union has initiated a model law on biosafety in Africa. In relation to waste management, the Secretariat of the Basel Convention and the World Health Organization (WHO) have developed a decision support manual with the objective of identifying appropriate biomedical waste management practices through the development of assessment tools applicable in sub-Saharan Africa. It recommends to the States the implementation of a strong legislation in this area (OMS, s. d.a). Several other conventions guarantee the protection of the community, such as the one on diversity signed on June 5, 1992 (Nations Unies, s. d.). In 2005, the WHO (OMS, s. d.b) revised the IHR to address public health emergencies of international concern. The COVID-19 pandemic demonstrated the importance of reforming health systems to reduce the spread of infectious diseases early (Loh et al., 2020). Thus, every laboratory must have a BSS manual and the WHO manual (WHO, 2020b) details good practice in this area. In the same vein, Canada has developed a new version of the BSS analytical approach strategy tool in 2019 (Gouvernement du Canada, 2020). This evolving toolkit provides practical guidance to help other countries around the world independently establish or strengthen their biomonitoring policies and frameworks.

At the regional level

In Africa, countries such as Togo are adopting more of a preventive approach and there is a similarity in the regulatory efforts of the BSS. The Bamako convention on the ban of the import into Africa and the control of transboundary movements of hazardous wastes has been ratified by several countries (Secrétariat de la Convention sur la diversité biologique, 2000). In Mali, waste management in general has been regulated since 2000 through Law N°00-081 and then Decree N° 01-394 P RM, of September 6, 2001 (République du Mali, 2001).

In Benin, in addition to Decree No. 2002-484 making any producer of waste responsible for its disposal and making it a condition for the opening of health centres, Law No. 2021-01 was passed

Table 4. Strengths, weaknesses, opportunities and threats of biosafety and biosecurity regulatory texts identified in Togo, 2021.

Category	Title	Scope in relation to biosafety and biosecurity			
		Forces	**Weaknesses**	**Opportunities**	**Threats**
Laws (n=5)	Law No. 88-14 of 3 November 1988 on the Environment Code	Waste management in general	Biomedical laboratory specificity not taken into account	Strategic Environmental Management Plan	Resource Shortages, Pandemic Emergencies, Non-extension Language Barrier
	National Biosafety Framework, Togo, 2004	Regulation, living modified organisms	Other biological agents not taken into account	Review, New technologies One Health approach	
	Law n° 2009-007 on the Public Health Code, Togolese Republic	Waste management	Biomedical laboratory specificity not taken into account		
	Law N°2008-005 of 30 May 2008 on the framework law on the environment	Waste management in general/ Binding/ Mandatory/ Presence of compliance promotion provisions/ Environmental policing provided	Biomedical laboratory specificity not taken into account, Traceability/ Non-operational implementing legislation		
	Law n° 2009-001-06/01/2009 Biosafety	Regulation of living modified organisms	Other biological agents not taken into account		
Orders (n=2)	Order n° 113/98/CAB of 22/10/1998 Creation of the National Network of Laboratories for the rapid confirmation of epidemics	Transport of samples	Environmental and animal health not taken into account	Other networks, New technologies One Health approach	Resource shortages, Pandemic outbreaks, Non-extension
	Order n°1876/2015/MSPS/ CAB/SG/DPLET/DL of 28/09/2015 adopting the ISO 15189 standard as a quality management standard for medical laboratories in Togo	Quality standards with requirements on laboratory premises and environment	Binding implementing legislation not yet in place, compliance deadlines not specified Cross-sectoral nature not taken into account		

Source: Authors

(République du Bénin, 2021) on biosafety in compliance with the Cartagena Protocol. In Senegal, Decree No. 2008-1007 regulates the management of biomedical waste (République du Sénégal, 2008). The Senegalese approach could be a model for several reasons. It applies to all structures involved in the biomedical waste management chain. In addition to being binding, clauses on the obligation to pre-treat waste within 48 h and the obligation of traceability have greater weight than general waste laws common in several other West African sub-regional countries. In Burkina Faso, legislative and regulatory texts have been adopted in the area of health to ensure hygiene, quality of care in hospitals (Burkina Faso, 2005), and sustainable management of biomedical waste for the safety of users and staff (Burkina Faso, 2008).

Synthesis

The various international instruments for the prevention of global threats (Bakanidze et al., 2010) described in this study have been designed to address the multitude of BSS challenges. However, the provisions for assessment control and resource allocation are bottlenecks in the implementation of this

of many underdeveloped countries and even in Europe (Denault and Gardner, 2021). In the US, biodefense has been strengthened since the September 11, 2001 attack thanks threat reduction programs and global health security (Linkous et al., 2021). In China, it is only recently, on 15 April 2021, in the midst of the COVID-19 pandemic, that the first fundamental, comprehensive and systematic law came into effect in the national governance of BSS to minimize biological threats (Huigang et al., 2021). Thus, following this analysis at the international level, it is appropriate to highlight the areas of legislation covered by these instruments before looking at the regulations in force in Togo.

Areas to be covered by country texts under international biosafety and biosecurity instruments

Our study has highlighted several activities that could be regulated in the context of BSS. These activities have been conveniently grouped into seven areas of high impact on BSS worldwide. Although very few studies on this aspect have been conducted in the last decade, our results are consistent with the recommendations on regulation in this area in the Canadian Analytical Approach Guide (Gouvernement du Canada, 2020), the WHO guidelines on regulation (WHO, 2020b), and the BSS regulation study by Beeckman and Rüdelsheim in 2020 (Beeckman and Rüdelsheim, 2020). It is therefore necessary to analyze the inclusion of these key areas of BSS regulation in Togo's legal and regulatory texts.

Togo's instruments relating to biosafety and biosecurity in medical laboratories

In our study, out of 7 instruments relating to the BSS listed, 2 were specific to medical biology laboratories. The decree on the creation of the national network of laboratories for the rapid confirmation of epidemics (République du Togo, 1998) and the one on the adoption of the ISO 15189 standard (République du Togo, 2015) as a quality management standard in Togo are far from being binding and mandatory. A comparison of the content of the texts on BSS in Togo and the seven areas of regulation listed has made it possible to highlight the gaps in terms of inadequacies in the regulation of BSS in Togo.

Multi-sectoral regulatory framework of BSS

From the literature consulted, it appears that the backbone of regulation is a national cross-sectoral BSS framework. This framework will need to be brought in line with international standards and legislated on risk-based approaches for all licensing, monitoring and enforcement of BSS requirements (Gouvernement du Canada, 2020; WHO, 2020c). The country BSS framework should, according to Huigang et al. (2021), the country BSS framework should, according to Huigang et al, be a governing mechanism controlling the entire risk management process, which is crucial for global public health governance. Similarly, Qiu and Hu (2021) analyzing BSS legislation in China, noted that co-governance in BSS control is more than a necessity (Qiu and Hu, 2021). Togo has had a national biosafety framework in place since 2004 that deals primarily with LMO aspects (République du Togo, 2004). Not only are administrative controls on other bioresources not taken into account, this document is no longer operational in a globalization context. Its organizational structure is also no longer in line with current WHO regulations (Gouvernement du Canada, 2020; WHO, 2020a). The 2005 national biosafety framework of Mali, for example, has the same structure as that of Togo.

Biomedical waste management regulations

In terms of biomedical waste management, almost all the instruments analyzed place it in first position (Gouvernement du Canada, 2020; WHO, 2020c). Its regulation should take into account the production of waste, the control of transport on the territory, transboundary transport, storage, decontamination, disposal, and traceability. In relation to the legislation on the control of the waste management chain in Togo, several actions have been taken. Togo has put in place a national plan for the management of health care waste, revised in the 2016-2020 strategic plan (République du Togo, 2016) in addition to the Health Code (République du Togo, 2009). This code includes provisions on waste management in its sub-section 4 similar to that of Burkina Faso (Burkina Faso, 2005). In addition, Law N°2008-005 of May 30, 2008 (République du Togo, 2008) on the environment has the merit of being binding and compulsory; provisions for promoting compliance and an environmental police force have been included. However, the specificities of biomedical laboratories and the traceability aspect are not taken into account.

Regulation of bioresource management and bioweapons

For bioresource management, legislation should include activities involving all pathogens and toxins and bioweapons. Also, to be considered for infectious materials are the rules for transport, transfer, import, manufacture, export as well as the threshold quantities and control of the use of LMOs. In the same area of regulation, there are other equally important aspects to

consider. These include the management of genetic resources; provisions on risk prevention; the handling of human samples, tissues or residues; the length of time samples are kept in serum banks; the inventory of pathogens and toxins and their traceability (Gouvernement du Canada, 2020; ISO 15190, 2020; WHO, 2020c). In this very critical area where international bodies leave the choice to states to legislate in their environment, the aspects taken into account in the Public Health Code in force in Togo are not likely to guarantee the necessary controls on the panoply of present and future biological resources.

Information security regulations, retention period of laboratory archives, potential for dual use

The security of information, the retention period of the laboratory's archives, and the potential for dual use must be controlled (Moritz et al., 2020). The conditions of admissibility, reliability, and moral probity of the staff must be taken into account. Specific requirements for the competence, impartiality, and coherent operation of bio-banks must also be taken into account. Several suspected or confirmed biological samples are increasingly kept in bio-banks in Togo, especially concerning manipulated viruses such as LASSA, H5N1, and Covid-19. Malicious exploitation of knowledge, skills, and technology remains a concern and needs to be regulated (Berger, 2021; Evans et al., 2020; MacIntyre et al., 2020; Messaoudi et al., 2020). As regards the regulation of information, including dual use in the context of BSS, no regulatory text was identified in Togo during this study.

Bio-containment regulations, installation, personnel protection

In the area of bio-containment, facilities and personnel protection, the regulation should include the required conditions for handling human samples, tissues or residues. Also, to be taken into account are standard laboratory space plans, environmental impact, general health and safety, availability and use of personal protective equipment, protection of employees' rights and medical surveillance (Gouvernement du Canada, 2020; OIT and OMS, 2020; WHO, 2020a). In Togo, the legal framework is characterized by an absence of specific legislation in this area. Nevertheless, according to the Health Code in force, the protection and promotion of the health of the population as well as the provision of care and services are the responsibility of the State (République du Togo, 2009). However, this code does not effectively or explicitly guarantee the protection of laboratory staff. Under the terms of Article 67 of this code, an economic measure is provided for health personnel in the prevention and control of epidemics and in vaccination against certain transmissible diseases. Also, this code specifies that the opening and operation of a medical biology laboratory are subject to prior authorization by the Minister in charge of Health. However, the opening conditions set out in section 2 of the code do not explicitly include the obligations of the BSS. Other aspects of regulation, notably containment, standard installations and laboratory levels, are not covered by this code, SW.

Regulation of the qualification and registration of *in vitro* diagnostic devices and reagents in biomedical laboratories

It is equally important to put in place legislation governing the qualification and registration of *in vitro* diagnostic devices and reagents in biomedical laboratories. This registration is done at the Ministry of Health in Togo (République du Togo, 2009) and contributes to biosecurity, thus protecting medical staff from the use of harmful and counterfeit reagents.

Bioethics regulation

Bioethics needs a regulatory framework that helps the community to regulate and comply with BSS standards. It helps promote compliance and more generally fosters a culture of innovation while protecting the health and safety of the population (Messaoudi et al., 2020; Stoeklé et al., 2020; World Medical Association, 2013). In Togo, the legal framework is supported by institutional bodies set up by decree and order.

A Bioethics Committee, “Comité de Bioéthique pour la Recherche en Santé (CBRS)” (République du Togo, s. d.), has been created for this purpose. This committee, which has a charter as its rules of procedure, is an autonomous multidisciplinary structure responsible for giving opinions on clinical and biomedical or epidemiological research projects.

Conclusion

In the context of the improvements of the regulations in Togo in terms of biosafety and biosecurity in medical biology laboratories, the study carried out aimed to identify gaps in internationally accepted legislations. This analysis at the country level showed that some actions have been taken into account in the existing texts, but not enough to guarantee a better protection of humans and the environment against biological risks. The existing legal instruments are not all operational or are rather oriented by predilection towards living modified organisms, one element among the multitude of

biological agents. This study shows that there is a current deficit in terms of regulations aimed at guaranteeing the protection of laboratory staff, but above all, at potentiating efforts to set up a biosafety and biosecurity system in Togo in a multisectoral framework. This situation thus requires, in the light of the country's national security and safety strategy and in the face of the Covid-19 pandemic, a paradigm shift by proposing a legal framework aimed at ensuring the protection of medical and paramedical staff, the community and the environment.. This will raise the issue of human resources capable of identifying, assessing, mitigating and communicating risks and safety solutions, including dual use of biological materials. It is necessary to strengthen the existing regulatory texts taking into account the areas identified in this study and then to analyze the human environment for the implementation of biosafety and biosecurity in Togo.

Recommendations

In order to improve and strengthen the legislative construction, we propose that concerned bodies should:
1. Develop a national biosafety and biosecurity framework in Togo in a multisectoral context;
2. Develop and adopt the application texts of the various laws and international standards and implement them;
3. Set up an effective mechanism to disseminate the texts;
4. Mobilise more human and financial resources to support the implementation of the legal framework for biosafety and biosecurity in Togo.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interest.

REFERENCES

Bakanidze L, Imnadze P,Perkins D (2010). Biosafety and biosecurity as essential pillars of international health security and cross-cutting elements of biological nonproliferation. BMC Public Health 10(1):1-8. https://doi.org/10.1186/1471-2458-10-S1-S12.

Beeckman D,Rüdelsheim P (2020). Biosafety and Biosecurity in Containment : A Regulatory Overview. Frontiers in Bioengineering and Biotechnology 8:650. https://doi.org/10.3389/fbioe.2020.00650.

Berger KM (2021). Technological Advances that Test the Dual-Use Research of Concern Model. In: R. N. Burnette (Éd.), Applied Biosecurity: Global Health, Biodefense, and Developing Technologies (pp. 133-160). Springer International Publishing. https://doi.org/10.1007/978-3-030-69464-7_8.

Berns KI (2014). Grand Challenges for Biosafety and Biosecurity. Frontiers in Bioengineering and Biotechnology 2(35):1-3. https://doi.org/10.3389/fbioe.2014.00035.

Burkina Faso (2005). Loi N° 022-2005/AN portant code de l'hygiène publique au Burkina Faso. http://extwprlegs1.fao.org/docs/pdf/bkf53270.pdf.

Burkina Faso (2008). Décret N°2008-009/PRES/PM/MS/MECV du 10 janvier 2008 portant organisation de la gestion des déchets biomédicaux et assimilés. https://www.ecolex.org/fr/details/legislation/decret-n-2008-009prespmmsmecv-du-10-janvier-2008-portant-organisation-de-la-gestion-des-dechets-biomedicaux-et-assimiles-lex-faoc078707/.

Chung CL, Bellis KS, Pullman A, O'Connor A, Shultz A (2019). Building Biosafety Capacity in Our Nation's Laboratories. Health Security 17(5):353-363. https://doi.org/10.1089/hs.2019.0056.

Denault D, Gardner H (2021). OSHA Bloodborne Pathogen Standards. In StatPearls. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK570561/.

Evans DR, Griffith MP, Sundermann AJ, Shutt KA, Saul MI, Mustapha MM, Marsh JW, Cooper VS, Harrison LH, Van Tyne D (2020). Systematic detection of horizontal gene transfer across genera among multidrug-resistant bacteria in a single hospital. ELife 9:e53886. https://doi.org/10.7554/eLife.53886.

Gao GF (2018). From « A »IV to « Z »IKV: Attacks from Emerging and Re-emerging Pathogens. Cell 172(6):1157-1159. https://doi.org/10.1016/j.cell.2018.02.025.

Gao GF (2019). For a better world: Biosafety strategies to protect global health. Biosafety and Health 1(1):1-3. https://doi.org/10.1016/j.bsheal.2019.03.001.

Gouvernement du Canada (2020). Approche analytique: Cadre de surveillance de biosécurité et de biosûreté [Éducation et sensibilisation]. An analytical approach: biosafety and biosecurity oversight framework [e-learning course]. Government of Canada; 2020 (https://www.canada.ca/en/public-health/ services/laboratory-biosafety-biosecurity/analytical-approach.html, accessed 20 April 2020 [subscription required]). https://www.canada.ca/fr/sante-publique/services/biosecurite-biosurete-laboratoire/approche-analytique.html.

Gronvall GK, Rozo M (2015). Addressing the Gap in International Norms for Biosafety. Trends in Microbiology 23(12):743-744. https://doi.org/10.1016/j.tim.2015.10.002.

Heckert RA, Reed JC, Gmuender FK, Ellis M, Tonui W (2011). International Biosafety and Biosecurity Challenges: Suggestions for Developing Sustainable Capacity in Low-resource Countries. Applied Biosafety 16(4):223-230. https://doi.org/10.1177/153567601101600404.

Huigang L, Cui H, Xiaoli Z, Zhiming Y (2021). Significance of and outlook for the Biosecurity Law of the People's Republic of China. Journal of Biosafety and Biosecurity 3(1):46-50. https://doi.org/10.1016/j.jobb.2021.06.004.

ISO 15189 (2012). Laboratoires de biologie médicale Exigences concernant la qualité et la compétence.

ISO 15190 (2020). Medical laboratories—Requirements for safety. Accessed 22 December 2020, https://www.iso.org/cms/render/live/fr/sites/isoorg/contents/data/standard/07/21/72191.html.

ISO 35001 (2019). Biorisk management for laboratories and other related organization.

Linkous B, Burnette RN, Dittrich S (2021). Biodefense Promotes Biosecurity Through Threat Reduction Programs and Global Health Security. In R. N. Burnette (Éd.), Applied Biosecurity: Global Health, Biodefense, and Developing Technologies (pp. 51-71). Springer International Publishing. https://doi.org/10.1007/978-3-030-69464-7_4.

Loh TP, Horvath AR, Wang CB, Koch D, Lippi G, Mancini N, Ferrari M, Hawkins R, Sethi S, Adeli K (2020). Laboratory practices to mitigate biohazard risks during the COVID-19 outbreak: An IFCC global survey. Clinical Chemistry and Laboratory Medicine (CCLM) 58(9):1433-1440. https://doi.org/10.1515/cclm-2020-0711.

MacIntyre CR, Adam DC, Turner R, Chughtai AA, Engells T (2020). Public awareness, acceptability and risk perception about infectious diseases dual-use research of concern: A cross-sectional survey. BMJ Open 10(1):e029134. https://doi.org/10.1136/bmjopen-2019-029134.

Maehira Y, Spencer RC (2019). Harmonization of Biosafety and Biosecurity Standards for High-Containment Facilities in Low- and Middle-Income Countries: An approach from the perspective of occupational safety and health. Frontiers in Public Health 7:249.

https://doi.org/10.3389/fpubh.2019.00249.
Maljean-Dubois S (2021). Droit international et biosécurité. In Le droit international de la biodiversité (p. 356-413). Brill Nijhoff. https://doi.org/10.1163/9789004462885_006.
Messaoudi Z, Soltani N, Arrighi N (2020). Bioéthique—L'existence des contraintes légales et réglementaires des biobanques. Médecine/sciences 36(3):279-282. https://doi.org/10.1051/medsci/2020042.
Moritz RL, Berger KM, Owen BR, Gillum DR (2020). Promoting biosecurity by professionalizing biosecurity. Science 367(6480):856-858. https://doi.org/10.1126/science.aba0376.
Nations Unies. (s.d.). La Convention sur la diversité biologique. https://www.un.org/fr/observances/biological-diversity-day/convention. Accessed 5 June 2021
OIT, OMS (2020). Sécurité et santé au travail durant les crises sanitaires : Un manuel pour la protection des personnels de santé et des équipes d'intervention d'urgence. World Health Organization. https://apps.who.int/iris/handle/10665/333779. Licence: CC BY-NC-SA 3.0 IGO.
OMS (2018). Evaluation externe conjointe des principales capacités RSI de la République togolaise (p. 64). Rapport de mission.
OMS (s. d.a). Préparation des plans nationaux de gestion des déchets de soins médicaux en Afrique subsaharienne. WHO; World Health Organisation. Consulté 5 juin 2021, à l'adresse https://www.who.int/water_sanitation_health/medicalwaste/guidmanual/fr/.
OMS (s.d.b). Entrée en vigueur du Règlement sanitaire international. WHO; World Health Organisation. Consulté 5 juin 2021, à l'adresse https://www.who.int/mediacentre/news/releases/2007/pr31/fr/.
République du Togo (1998). Arrêté n° 113/98/CAB du 22/10/1998 Création du Réseau National des Laboratoires pour la confirmation rapide des épidémies.
République du Mali (2001). Décret 01-394 P RM, Gestion des déchets solides, https://www.semanticscholar.org/paper/De%CC%81cret-01-394-P-RM%2C-Gestion-des-de%CC%81chets-solides/e78da6004f6ef4c682748f1592d00ff23118e34d.
République du Sénégal (2008). Décret n° 2008-1007 du 18 août 2008 portant réglementation de la Gestion des déchets biomédicaux. Consulté 21 juin 2021, à l'adresse http://www.jo.gouv.sn/spip.php?rubrique493.
République du Bénin. (2021). Loi N° 2021-01 du 03 février 2021 sur la biosécurité en République du Bénin—LEGIS : Base de données des textes de loi en République du Bénin. Consulté 21 juin 2021, à l'adresse https://legis.cdij.bj/index.php/loi-n-2021-01-du-03-f-vrier-2021-sur-la-bios-curit-en-r-publique-du-b-nin.
République du Togo (2004). Cadre national de biosécurité. https://bch.cbd.int/en/pdf/documents/biosafetyLaw/BCH-LAW-TG-43407/2.
République du Togo (2008). Loi N°2008-005 du 30 mai 2008 portant loi-cadre sur l'environnement. http://www.environnement.gouv.tg/sites/default/files/documents/loi-cadre_sur_lenvironnement.pdf.
République du Togo (2009). Loi-Portant-Code-de-la-Santé-Publique-de-la-République-Togolaise- Consulté 5 juin 2021, à l'adresse https://www.prb.org/wp-content/uploads/2018/04/Loi-Portant-Code-de-la-Sante%CC%81-Publique-de-la-Re%CC%81publique-Togolaise-2009.pdf.
République du Togo (2015). Arrêté n°1876/2015/MSPS/CAB/SG/DPLET/DL du 28/09/2015 portant adoption de la norme ISO 15189 comme norme de management de la qualité dans les laboratoires de biologie médicale au Togo.
République du Togo (2016). Plan Stratégique de gestion des déchets médicaux 2016-2020. Consulté 5 juin 2021, à l'adresse https://www.afro.who.int/fr/publications/plan-strategique-de-gestion-des-dechets-medicaux-2016-2020.
République du Togo (s. d.). Comité de Bioéthique pour la Recherche en Santé (CBRS). Consulté 5 juin 2021, à l'adresse www.healthresearchweb.org/fr/togo/ethics_1132.
Secrétariat de la Convention sur la diversité biologique (2000). Protocole de Cartagena sur la prévention des risques biotechnologiques relatif à la Convention sur la diversité biologique : Texte et annexes. Montréal: Secrétariat de la Convention sur la diversité biologique.
Stoeklé HC, Hervé C, Vogt G (2020). La bioéthique en tant que science : Réflexion épistémologique et méthodologique. Ethics, Medicine and Public Health 13:100473. https://doi.org/10.1016/j.jemep.2020.100473.
Qiu S, Hu M (2021). Legislative Moves on Biosecurity in China. Biotechnology Law Report 40(1):27-34. https://doi.org/10.1089/blr.2020.29217.mh.
Vogel KM, Ozin AJ, Suk JE (2015). Biosecurity and Dual-Use Research: Gaining Function – But at What Cost? Frontiers in Public Health 3(13):1-2. https://doi.org/10.3389/fpubh.2015.00013.
World Health Organization (WHO) (2020a). Guidance on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories – a stepwise approach. Geneva: World Health Organization; License: CC BY-NC-SA 3.0 IGO.
World Health Organization (WHO) (2020b). Laboratory biosafety manual. World Health Organization. https://apps.who.int/iris/handle/10665/337956.
World Health Organization (WHO) (2020c). Laboratory biosafety manual, 4th edition: Biosafety programme management. Consulté 19 juin 2021, à l'adresse https://www.who.int/publications-detail-redirect/9789240011434.
World Medical Association (2013). World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA, 310(20):2191. https://doi.org/10.1001/jama.2013.281053.
Wurtz N, Grobusch MP, Raoult D (2014). Negative impact of laws regarding biosecurity and bioterrorism on real diseases. Clinical Microbiology and Infection: The Official Publication of the European Society of Clinical Microbiology and Infectious Diseases 20(6):507-515. https://doi.org/10.1111/1469-0691.12709.