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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
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
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                                                          | Use of living modified organisms                                                                         |
| Convention on Biological Diversity (CBD)                                                   | Biosafety provisions                                                                                     |
| Cartagena Protocol                                                                         | Management of genetic resources                                                                          |
| Nagoya-Kuala Lumpur Protocol                                                               | National cross-sectoral biosafety/biosecurity framework; biosecurity; transport of infectious substances; qualification/registration of *in vitro* diagnostic devices/reagents |
| International Health Regulations, WHO 2005                                                 | Requirements, bio-banking                                                                                 |
| ISO 20387: 2018. - General requirements for bio-banks                                       | Biomedical waste management; handling of human/tissue/residue samples; bio-containment                     |
| ISO 15190: 2020                                                                           | Containment and facilities; Protection of employees’ rights; environmental impact, general health and safety (fire, electrical risk, etc.) |
| ISO 35001: 2019                                                                           | 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 |
| ISO 15189: 2012                                                                           | 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 Handbook 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 |
| WHO Guidelines on Regulatory Implementation, Biosafety Requirements and Biosafety in Biomedical Laboratories a stepwise approach: 2020 | Transport of samples; decontamination of waste; decontamination of materials to be removed from the laboratory |
| Biosafety in microbiological and biomedical laboratories                                   | Waste management; transport of biological samples                                                          |
| CDC Guidelines for safe working practices in human and animal medical diagnostic laboratories |                                                                                                           |

Source: Authors
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 |
|---------------|-----------------------------------------------------------------------|-----------------------------------------------|
| **Laws (n=5)**| Law No. 88-14 of 3 November 1988 on the Environment Code               | Waste management in general                    |
|               | National Biosafety Framework, Togo, 2004                               | Regulation, living modified organisms          |
|               | Law n° 2009-007 on the Public Health Code, Togolese Republic          | Waste management                               |
|               | 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 |
|               | Law n° 2009-001-06/01/2009 Biosafety                                   | Regulation of living modified organisms        |
| **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                           |
|               | 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 |
| Weaknesses    | Biomedical laboratory specificity not taken into account              |
|               | Other biological agents not taken into account                        |
|               | Biomedical laboratory specificity not taken into account              |
|               | Biomedical laboratory specificity not taken into account              |
|               | Other biological agents not taken into account                        |
|               | Strategic Environmental Management Plan                                |
|               | Review, New technologies One Health approach                          |
|               | Resource Shortages, Pandemic Emergencies, Non-extension Language Barrier |
| Opportunities | Environmental and animal health not taken into account                |
|               | Other networks, New technologies One Health approach                  |
|               | Resource shortages, Pandemic outbreaks, Non-extension                 |
| Threats       | 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 to 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 biobanks must also be taken into account. Several suspected or confirmed biological samples are increasingly kept in biobanks 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.

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